CARDIO METABOLIC

Bisoprolol & Aspirin

5/75 mg and 10/75 mg, 5/100 mg and 10/100 mg

Capsule

ATHENA PHARMACEUTIQUES

Fixed combination of two reference agents improving compliance and adherence to the treatment in the secondary prevention of cardiovascular disease (CVD).

Key features

- Patented barrier layer protecting aspirin against moisture and innovative galenic formulation preventing chemical in vivo interaction between the two active ingredients in the gastrointestinal tract.

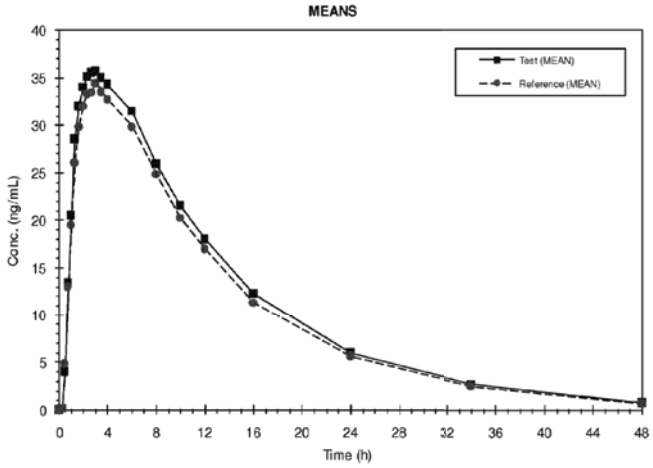
Competitive advantages

- Fixed-combination therapy improves adherence by 44%[1]

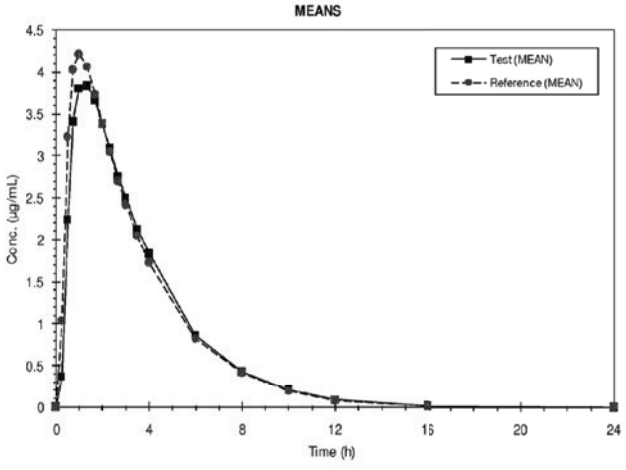
Regulatory status

- INN: Bisoprolol, Aspirin
- ATC: C07FX04
- Reference compound: EMCOR (Merck, UK) & HJERTEMAGNYL (Nycomed, Denmark)
- Zone IVb Stability data: available
- eCTD dossier available

Pharmacokinetic Profile of Means:
Bisoprolol:



Pharmacokinetic Profile of Means:
Salicylic Acid:



Bisoprolol & Aspirin
5/75 mg and 10/75 mg, 5/100 mg and 10/100 mg

Capsule

CARDIO METABOLIC

Market highlights

- Cardiovascular diseases (CVDs) are the leading causes of morbidity, mortality, and disability in both high-income and low- and middle-income countries[2]
- An estimated 17.9 million people died from CVD in 2019 (32% of all global deaths)[3]
- 85% of all CVD deaths are due to heart attacks and stroke[3]
- WHO and the Combination Pharmacotherapy and Public Health Research Working Group[4, 5] have recognized the potential value of applying the fixed-dose combination therapy for secondary prevention of CVD

Information at a glance

- Commercial Batch size (million doses): 0.25 – 1.0 & 2.0
- Dossier Batch size (million doses): 0.1 (registration) – 0.2 (bioequivalence)
- Shelf-life: 60 months
- Storage conditions: Room temperature below 25°C
- Pack info: 30 size 1 caps Aclar/aluminium PVC (child resistant)
- Capsule weight: 5/75 mg & 10/75 mg : 326 mg – 5/100 mg and 10/100 mg : 355 mg

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ATHENA PHARMACEUTIQUES

Key numbers

- **17.9 million people died from CVD in 2019**
- **CVD represents 32% of all global deaths**
- **85% of all CVD deaths are due to heart attacks and stroke**

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Domperidone 10 mg
Orodispersible Tablet

ATHENA PHARMACEUTIQUES

Orodispersible facilitates oral intake and improves patients' compliance

Key features

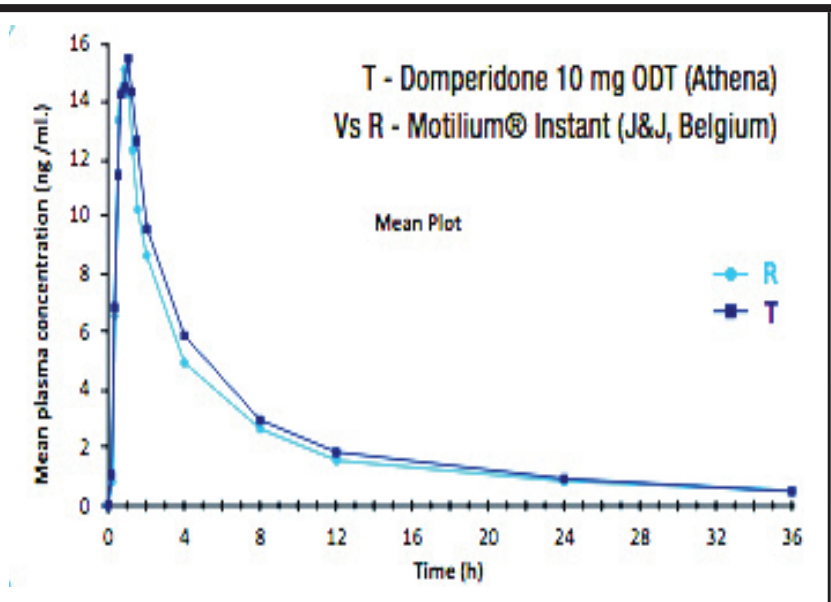
- Firstline treatment of nausea and vomiting acting with lower potential to induce dystonic, extrapyramidal symptoms or galactorrhoea.
- Orodispersible tablet formulation facilitating water-free intake by oral route in patients suffering from nausea and vomiting or who have difficulties in swallowing.

Competitive advantages

- Selective D2/D3 dopamine antagonist.
- Combine prokinetic and anti-emetic activities on gastrointestinal tract making it an ideal agent for treating gastroparesis (postprandial fullness, nausea, vomiting and stomach fullness). Does not cross the blood-brain barrier minimizing CNS adverse events.

Regulatory status

- INN: Domperidone
- ATC Code: A03FA03
- CAS registry number 57808-66-9
- Reference compound: MOTILIUM®, Janssen.
- BioEq. study
  - Patient population: 36 male & female healthy volunteers.
  - Methodology: Randomized two-way crossover.
  - Reference product: MOTILIUM® instant 10 mg, J&J Belgium.
- Zone IV stability data available.
- CTD dossier available.
- Marketed in Europe & Emerging markets.



Domperidone 10 mg
Oro-Dispersible Tablet

ANTI-EMETIC / ONCOLOGY

Information at a glance

- Commercial batch size (million doses): 0.5
- Dossier Batch size (million doses): 0.5
- Shelf-life: 3 years
- Storage conditions: Room temperature between 20 and 25°C
- Pack info: Aluminium 10-tabs blister & pack
- Tablet weight: 250 mg
- Flavour: Trusil peppermint

Market highlights

- The global nausea and vomiting treatment market size is projected to reach $7,214 million by 2026 from $4,947 in 2020 at a CAGR of 6.5% from 2021 to 2026[1].
- The global chemotherapy-induced nausea and vomiting market is valued $1,663 million in 2015 to reach $2,659 million by 2022 at a CAGR of 7,1% from 2016-2022. According to the US National Cancer Institute chemotherapy-induced nausea and vomiting occurs in up to 80% of patients[2, 3].

Competitors' landscape

- Neuroleptic derivatives (PRIMPERAN®/metoclopramide, VOGALENE®/metopimazine, PHENERGAN®/promethazine, etc.), 5-HT3 receptor antagonists, neurokinin NK1 antagonists.

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2. Global Chemotherapy-induced Nausea & Vomiting Market; Allied Market Research
3. US National Cancer Institute, Physician Data Query (PDQ) Summary

ATHENA PHARMACEUTIQUES

Key numbers

- **2026 Global Nausea & Vomiting market > $7.2 billion**
- **Chemotherapy-induced nausea & vomiting occurs in up to 80% of patients**
- **2022 Chemotherapy-induced nausea & vomiting market > $2.6 billion**

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Donepezil 5 & 10 mg

OroDispersible Tablet

ATHENA PHARMACEUTIQUES

Orodispersible facilitates oral intake and improves patients' compliance

Key features

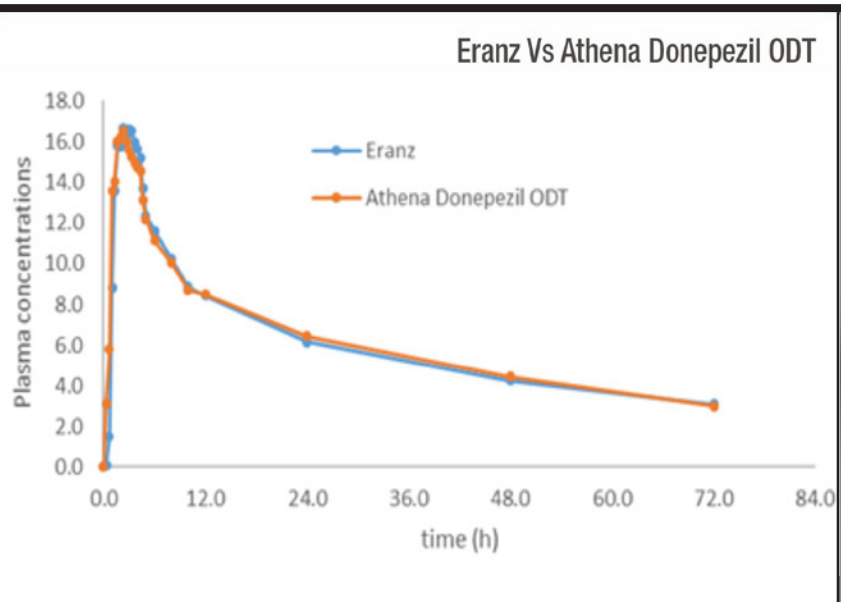
- Significant improvement in cognitive and global functions, activity of daily living and in patients suffering from light, moderate or severe Alzheimer's disease after 12-24 weeks of treatment vs. placebo[1, 2, 3, 4, 5, 6, 7, 8, 9].
- Clinical improvements in non-cognitive behaviours and in caregiver stress.
- Reduction of the two core symptoms of dementia, i.e. agitation and delusions[10, 11, 12].
- Commonly used in Lewy Body dementia and reduce visual hallucinations[13].

Competitive advantages

- Lesser behaviour deterioration vs. Galantamine[14].
- Superior Global Responder Rate vs. Galantamine[14].
- Lower risk of treatment withdrawals for any reason or because of an adverse event for Donepezil vs. Rivastigmine or Galantamine[14].

Regulatory status

- INN: Donepezil
- ATC Code: N06DA02, CAS Registry Number: 120014-06-4
- Reference compound: ARICEPT®, Pfizer.
- BioEq. study
  - Patient population: 40 male & female healthy volunteers.
  - Methodology: Randomized, 3-way cross over study.
  - Reference product: ERANZ®, Wyeth.
- Zone IV stability data available.
- CTD dossier available.



Donepezil 5 & 10 mg
OroDispersible Tablet

CNS

Information at a glance

- Commercial batch size / strength (million doses): 5 mg:0.5 | 10 mg: 0.25
- Dossier Batch size / strength (million doses): 5 mg:0.5 | 10 mg: 0.25
- Shelf-life: 2 years
- Storage conditions: Room temperature between 20 and 25°C
- Pack info / strength: Aluminium10-tabs blister and pack
- Tablet weight / strength: 5 mg: 140 mg | 10 mg: 280 mg
- Flavour: Orange

Market highlights

- According to the WHO, Alzheimer Disease afflicts at least 50 million people throughout the world.
- Alzheimer's Therapeutic Market is expected to reach $12.4 billion by 2026 (4.6% CAGR 2018-26)[15].

Competitors' landscape

- Cholinesterase inhibitors (REMINYL®/galantamine, EXELON®/rivastigmine and COGNEX®/tacrine), NMDA receptor antagonists (NAMENDA®/N-Methyl-D-Aspartate; EBIXA®/Memantine)

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ATHENA PHARMACEUTIQUES

Key numbers

- **50 million peoples suffering from Alzheimer worldwide**
- **Alzheimer market expected to reach $12.4 billion by 2026**
- **CAGR 2018-26: +4.6%**

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Demeclocycline 150 mg

Capsule

ATHENA PHARMACEUTIQUES

Firstline therapy in the management of chronic hyponatremia due to SIADH

Key features

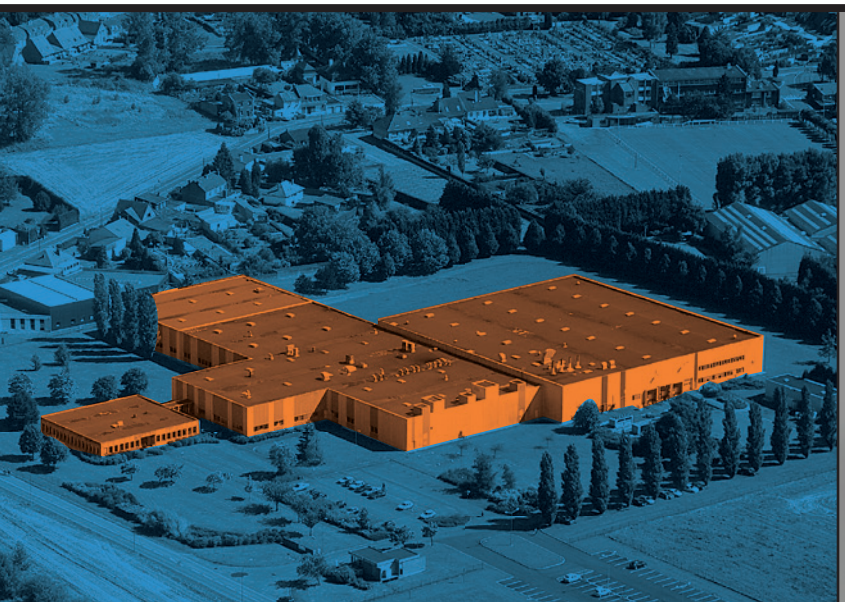
- Semisynthetic tetracyclin used as an antibiotic in the treatment of Lyme disease and widely prescribed as therapy of hyponatremia due to the Syndrome of Inappropriate Secretion of Antidiuretic Hormone (SIADH)

Competitive advantages

- Reference compound in the management of SIADH

Regulatory status

- INN: Demeclocycline
- ATC: D06AA01
- CAS registry number: 127-33-3
- Zone II stability available
- Zone IVb stability to be started in 2021.
- eCTD dossier available



Demeclocycline 150 mg

Capsule

ORPHAN / HYPONATREMIA SIADH

Information at a glance

- Dossier Batch size (million doses): 0.3
- Shelf-life: 36 months
- Storage conditions: Room temperature between 20 and 25°C
- Pack info: White polyethylene bottle (150 mL); white temper evident polyethylene cap.
- Tablet weight: 400 mg

Market highlights

- Hyponatremia treatment market is driven by increase in geriatric population. According to U.S Department of Health & Human Product estimates, the U.S will have about 72.1 million geriatric population by 2030.
- Prevalence of SIADH is estimated to be 2500-3000 cases per 100,000 individuals[1].

Competitors' landscape

- Vasopressin-receptor antagonists (Tolvaptan/SAMSCA®; Conivaptan/VAPRISOL®), Intravenous fluid therapy[2].

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ATHENA PHARMACEUTIQUES

Key numbers

- **Prevalence of SIADH: 2500-3000 cases per 100,000 individuals.**

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Esomeprazole 20 & 40 mg

Enteric coated pellets in capsules

ATHENA PHARMACEUTIQUES

Superior acid control compared to other Proton Pump Inhibitors

Key features

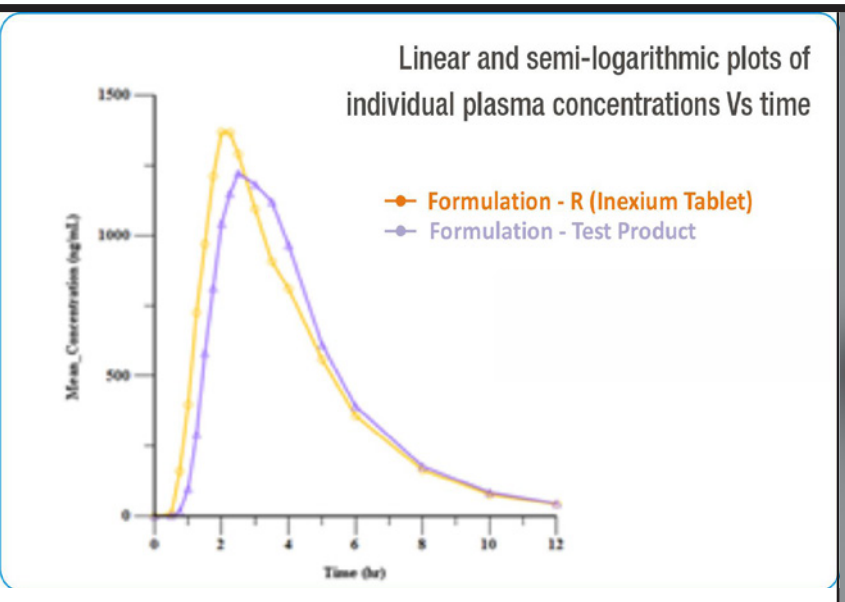
- Enteric coated pellets formulation ensures a stable and improved pharmaceutical composition guaranteeing esomeprazole integrity until it reaches the proximal part of the small intestine, hence facilitating its absorption.

Competitive advantages

- First single stereospecific S-isomer of omeprazole less prone to first-pass metabolism[1].
- Higher bioavailability than omeprazole[2].
- Superior acid control compared with all other Proton Pump Inhibitors (omeprazole, pantoprazole, lansoprazole & rabeprazole)[3, 4, 5, 6, 7].

Regulatory status

- INN: Esomeprazole
- ATC Code: A02BC05
- CAS Registry Number: 161796-78-7
- Reference compound: INEXIUM®, AstraZeneca.
- BioEq. study
  - Patient population: 54 fasting adult healthy volunteers.
  - Methodology: Randomized, single-dose, Tw treatments, two sequences, two period crossover.
  - Reference product: INEXIUM® 20 & 40 mg, AstraZeneca, France.
- Zone II & IV stability data available.
- eCTD dossier available.



Esomeprazole 20 & 40 mg

Enteric coated pellets in capsules

GASTROENTEROLOGY

Information at a glance

- Commercial batch size / strength (million doses): 20 mg: 3 | 40 mg: 1.5
- Dossier Batch size / strength (million doses): 20 mg: 1 | 40 mg: 0.5
- Shelf-life: 2 years
- Storage & Transport conditions: Room temperature between 20 & 25°C
- Pack info / strength: Alu-Alu. 7-caps blister pack
- Tablet weight / strength: 20 mg: 87.51 mg | 40 mg: 175.02 mg
- Capsule size: 20 mg: 4 | 40 mg: 3

Market highlights

- The Gastroesophageal Reflux Disease (GERD) therapeutic market is expected to reach $4,34 billion by 2025[8].
- Every year in the US more than 80 million of patients suffer from GERD, of which 75% on a monthly basis.
- Global Peptic Ulcer therapeutic market size was $4.3 billion in 2019 and is projected to reach $5.1 billion by 2027 growing at a CAGR of 2.4% from 2020-2027[9].

Competitors' landscape

- Antacids (GAVISCON®, MAALOX®, PHOSPHALUGEL®), H2 receptor blockers (TAGAMET®/cimetidine, AZANTAC®/ranitidine), Proton Pump Inhibitors (PRILOSEC®/omeprazole, INIPOMP®/pantoprazole, LANZOR®/lansoprazole, PARIET®/rabeprazole).

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8. Gastroesophageal Reflux Disease Therapeutics Market Size Report by Grand View research (2016)
9. Peptic Ulcer Drug Market report by Fortune Business Insights (2020)

ATHENA PHARMACEUTIQUES

Key numbers

- **More than 80 million of patients suffer from GERD in the USA**
- **Global Peptic ulcer market expected to reach $5.13 billion by 2027**
- **CAGR 2020-27: 2.4%**

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Etifoxine 50 mg
Capsules

ATHENA PHARMACEUTIQUES

Non-benzodiazepine anxiolytic medication with minimal abuse and misuse potential vs. benzodiazepine drugs.

Key features

- Non-benzodiazepine anxiolytic medication indicated in the management of trauma and stress-related disorders associated with anxiety, a highly prevalent disorder[1, 2, 3] with a significant impact of the day-to-day function, quality of life of patients and potentially progressing to a more serious disorder[4].

Competitive advantages

- Anxiolytic effect equivalent to lorazepam, a higher responder rate, and a lower rate of rebound anxiety at treatment discontinuation (one week) in patients receiving etifoxine[5].

Regulatory status

- INN: Etifoxine
- ATC: N05BX03
- CAS registry number: 56776-32-0
- Reference compound: STRESAM®, Biocodex
- BioEq. Study referenced EIN-P3-750
  - Patient population: 40 fasting healthy volunteers.
  - Methodology: Monocentric randomized blinded single dose 2-periods, 2-sequences crossover
- Zone IVb Stability data: starting in Q2 2021.
- eCTD dossier.

Figure 1: Linear Profile of the Mean for Etifoxine, EIN-P3-750

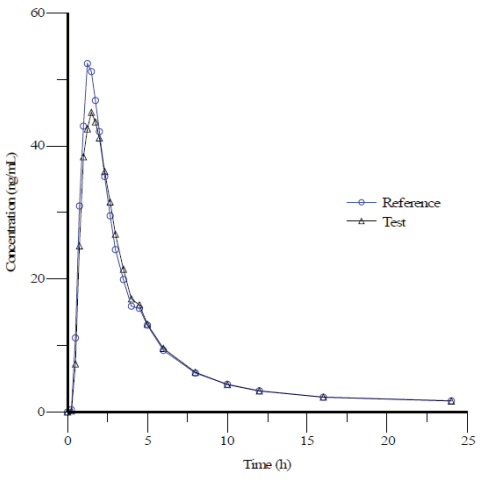
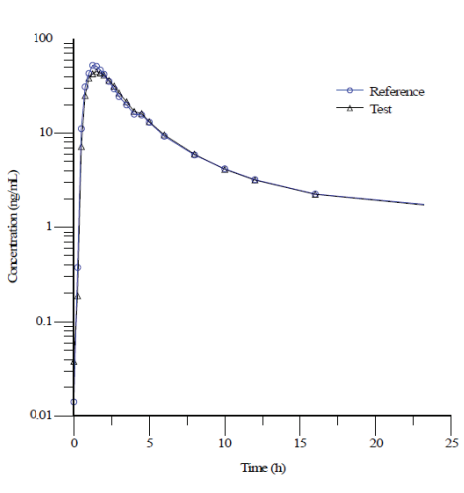


Figure 2: Logarithmic Profile of the Mean for Etifoxine, EIN-P3-750



Etifoxine 50 mg

Capsules

CNS

Information at a glance

- Commercial Batch size (million doses): 1.0
- Dossier Batch size (million doses): 1.0
- Shelf-life: 3 years
- Storage conditions: Do not store above 25°C.
- Pack info: PVC (250 µm)/PVDC (90g/m²) Alu. (25 µm) blister pack of 15 capsules (box of 60 capsules)
- Capsule weight: 263 mg

Market highlights

- Adjustment disorder has been reported to be almost three times as common as major depression (13.7% vs. 5.1%) in acutely ill medical in-patients[6]
- The Global anxiety disorder and depression treatment market is forecasted to reach $18.9 Bi by 2026 (CAGR of 2.4%)[7]
- Anxiety disorder treatment market is expected to reach $16.7 M at a CAGR of 5.4% by 2025[8].

Competitors' landscape

- Anxiolytic benzodiazepines (XANAX®/alprazolam, VALIUM®/diazepam, TEMESTA®/lorazepam, LEXOMIL®/bromazepam), buspirone, and ATARAX®/hydroxyzine.

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ATHENA PHARMACEUTIQUES

Key numbers

- **Anxiety disorder treatment market expected to reach $16,7 M by 2025**

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Fenofibrate 160 mg

Tablet

ATHENA PHARMACEUTIQUES

Fenofibrate micronized formulation for a once-a-day administration

Key features

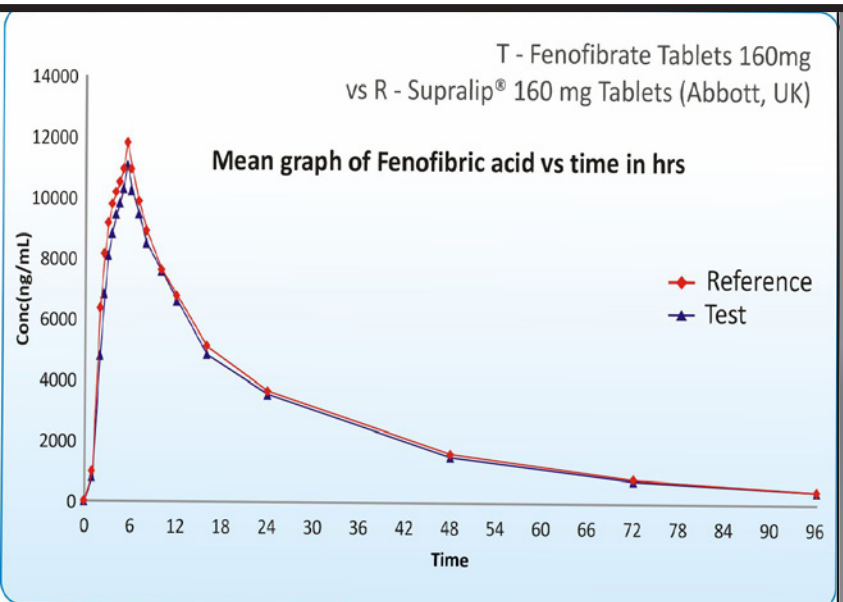
- Tablet form, which avoids the use of raw materials of animal origins such as gelatine.
- Fenofibrate micronized formulation results in a greater solubility and improved bioavailability allowing for a once-a-day administration and a daily dosage reduction.
- Micronized formulation results improving patient's compliance, daily dose reduction whilst ensuring an optimal drug efficacy.

Competitive advantages

- Fenofibrate is a third generation fibric acid practically insoluble in water, making it challenging to consistently achieve therapeutic levels[1,2]. Micronization technology improves the dissolution rate-limited gastrointestinal absorption.

Regulatory status

- INN: Fenofibrate
- ATC Code: C10AB05
- CAS registry number: 49562-28-9
- Reference compound: SUPRALIP®, Abbott.
- BioEq. study
  - Patient population: 28 male & female healthy volunteers.
  - Methodology: Randomized single dose crossover fed study.
  - Reference product: SUPRALIP® 160 mg tablet, Abbott UK.
- Zone IV stability data available.
- CTD dossier available.



Fenofibrate 160 mg

Tablet

CARDIO METABOLIC

Information at a glance

- Commercial batch size (million doses): 0.6
- Dossier Batch size (million doses): 0.2
- Shelf-life: 3 years
- Storage conditions:
- Pack info: packed in clear transparent plain on both side, packed PVC-PVDC alu. blister
- Tablet weight / strength: 160 mg: 500 mg
- Flavour: None

Market highlights

- Hyperlipidaemia is the most predominant risk factor associated with the high mortality rate in patients suffering from coronary artery disease[3].
- Lipid lowering drugs market was valued $20.6 billion by 2019 and is expected to grow at a CAGR of 2.6% over the period 2020-2027[4].

Competitors' landscape

- Fibrates (LIPUR®/gemfibrozil, ATROMID®/clofibrate), ezetimibe (ZETIA®), HMG-CoA Reductase inhibitors (LESCOL®/fluvastatin, PRAVACHOL®/pravastatin, ZOCOR®/simvastatin, LIPITOR®/atorvastatin, CRESTOR®/rosuvastatin), bile acid sequestrants (QUESTRAN®/cholestyramine).

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ATHENA PHARMACEUTIQUES

Key numbers

- **Lipid-lowering drug market: $20.6 billion in 2019**
- **CAGR 2020-2027: 2.6%**

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Fenofibrate 160 , 200 & 267 mg

Capsule

CARDIO METABOLIC

ATHENA PHARMACEUTIQUES

Fenofibrate micronized formulation for a once-a-day administration

Key features

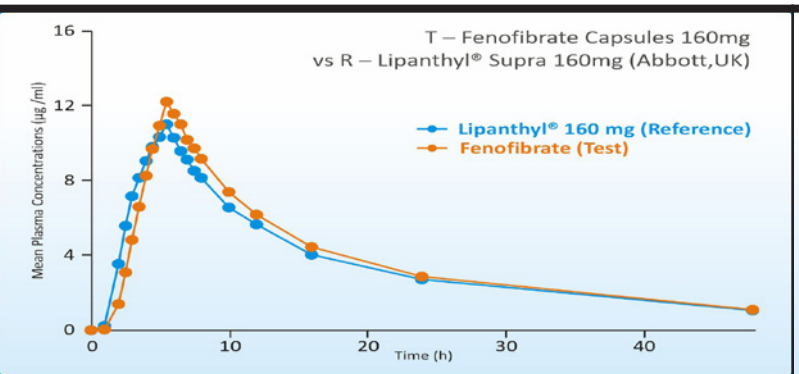
- Micronized formulation results improving patient's compliance, daily dose reduction whilst ensuring an optimal drug efficacy.

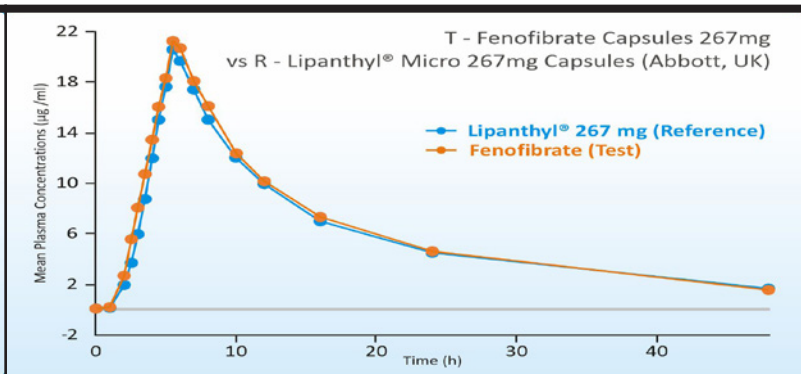
Competitive advantages

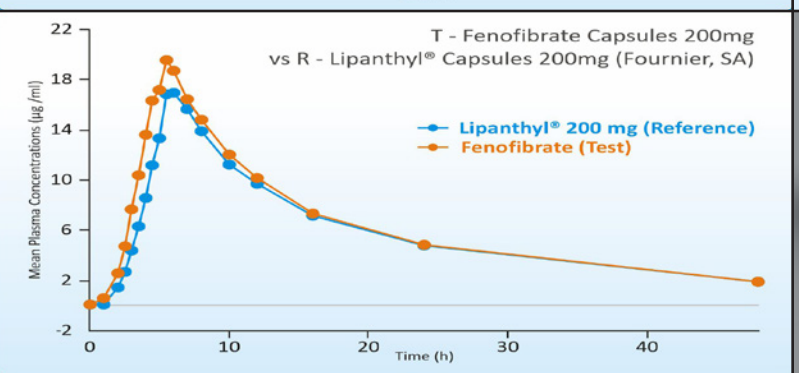
- Fenofibrate is a third generation fibric acid practically insoluble in water, making it challenging to consistently achieve therapeutic levels[1,2]. Micronization technology dramatically improves the dissolution rate-limited gastrointestinal absorption.

Regulatory status

- INN: Fenofibrate
- ATC Code: C10AB05
- CAS registry number: 49562-28-9
- Reference compound: LIPANTHYL® Capsule, Abbott.
- BioEq. study
  - Patient population: 25 (160 mg), 20 (200 mg) & 25 (267 mg) male & female healthy volunteers.
  - Methodology: Randomized, 2-way crossover, fed study.
  - Reference product: LIPANTHYL® 160 mg supra, LIPANTHYL® 200 mg capsule & LIPANTHYL® 267 mg micro-capsule, Abbott UK & France (200 mg).
- Zone IV stability data available.
- CTD dossier available.







Fenofibrate 160, 200 & 267 mg

Capsule

CARDIO METABOLIC

Information at a glance

- Commercial batch size (million doses): 160 mg: 1 225 | 200 mg: 0.975 | 267 mg: 0.725
- Dossier Batch size (million doses): 160 mg: 0.625 | 200 mg: 0.375 | 267 mg: 0.125
- Shelf-life: 160 mg: 2 years | 200 & 267 mg: 3 years
- Storage conditions: Store at 25 °C; excursions permitted to 15-30 °C - Protect from moisture
- Pack info: clear transparent PVC-Alu. blister
- Tablet weight / strength: 160 mg: 240 mg | 200 mg: 300 mg | 267 mg: 400 mg

Market highlights

- Hyperlipidaemia is the most predominant risk factor associated with the high mortality rate in patients suffering from coronary artery disease[3].
- Lipid lowering drugs market was valued $20.6 billion by 2019 and is expected to grow at a CAGR of 2.6% over the period 2020-2027[4].

Competitors' landscape

- Fibrates (LIPUR®/gemfibrozil, ATROMID®/clofibrate), ezetimibe (ZETIA®), HMG-CoA Reductase inhibitors (LESCOL®/fluvastatin, PRAVACHOL®/pravastatin, ZOCOR®/simvastatin, LIPITOR®/atorvastatin, CRESTOR®/rosuvastatin), bile acid sequestrants (QUESTRAN®/cholestyramine).

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ATHENA PHARMACEUTIQUES

Key numbers

- **Lipid-lowering drug market: $20.6 billion in 2019**
- **CAGR 2020-2027: 2.6%**

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Ibuprofen 200 & 400 mg

Orodispersible tablet

ATHENA PHARMACEUTIQUES

Orodispersible facilitates oral intake and improves patients' compliance

Key features

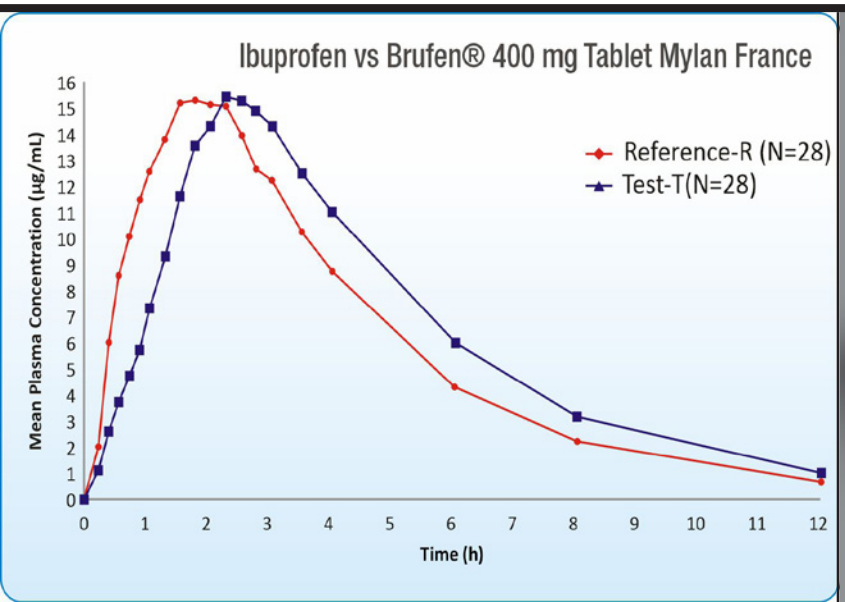
- ODT Athena's technology is a perfect fit for bedridden patients or patients with difficulties in swallowing or chewing conventional solid dosage forms, without need for water at the time of administration.

Competitive advantages

- Rated as the safest non-steroidal anti-inflammatory Drug by spontaneous adverse drug reaction reporting in the UK[1, 2].
- Prominent analgesic & antipyretic activities particularly useful in the management of pain related to dysmenorrhea, headache, postoperative dental pain and rheumatoid arthritis[3].
- Ibuprofen among the most prescribed pain-relieving drugs [4].

Regulatory status

- INN: Ibuprofen
- ATC Code: M01AE
- CAS Registry Number: 115687-27-1
- Reference compound: BRUFEN®, Mylan.
- Biostudy
  - Patient population: 30 male and female healthy volunteers.
  - Methodology: Randomized, single-dose, 2-way crossover (test without water vs. reference with water).
  - Reference product: BRUFEN® 400 mg Mylan, France.
- Zone IV stability data available.
- eCTD dossier available.



Ibuprofen 200 & 400 mg

Orodispersible tablet

PAIN / ANTI-INFLAMMATORY

Information at a glance

- Commercial batch size (million doses): 200 mg: 0.5 | 400 mg: 0.25
- Dossier Batch size (million doses): 200 mg: 0.25 | 400 mg: 0.125
- Shelf-life: 3 years
- Storage conditions: Light resistant containers at 15-30°C
- Pack info: PVC-PVDC / Alu blister, 1 carton x 10 blister x 10 tabs
- Tablet weight / strength: 200 mg: 600 mg | 400 mg: 1 200 mg
- Flavour: Orange

Market highlights

- NSAIDs market size is expected to move from $15.6 billion in 2019 to $24.4 billion by 2027 exhibiting a CAGR of 5.8% during the forecast period[4].
- Arthritis segment hold 38.0% NSAIDs market share in 2019 and is likely to lead throughout the forthcoming years[4].
- Ibuprofen market valued at $294.4 million in 2020 and expected to reach $448.0 million by 2026 growing at a CAGR of 6.1% during the forecasted period[5].

Competitors' landscape

- NSAIDs (NAPROSYN®/naproxen, CATAFLAM®/diclofenac, ORUDIS®/ketoprofen, MOBIC®/meloxicam, TORADOL®/ketorolac, FELDENE®/piroxicam) and COX-2 selective NSAIDs (CELEBREX®/celecoxib, VIOXX®/rofecoxib, BEXTRA®/valdecoxib).

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ATHENA PHARMACEUTIQUES

Key numbers

- **NSAIDs market expected to reach $24.4 billion by2026**
- **NSAIDs market led by arthritis segment with a market share of 38%**
- **Global ibuprofen market expected to reach $448 million by 2026 growing at a CAGR of 6.1% during the forecasted period**

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Levocetirizine 5 mg

Orodispersible tablet

ATHENA PHARMACEUTIQUES

Orodispersible facilitates oral intake and improves patients' compliance

Key features

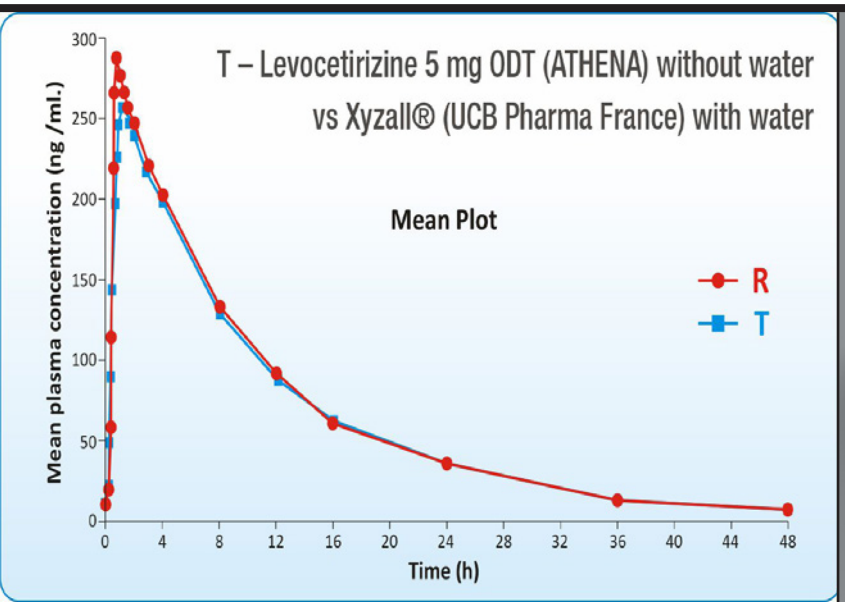
- Second-generation piperazine derivative with potent H1-selective antihistaminic activity.
- Improved oral bioavailability and onset of action vs. conventional oral slide form by avoiding hepatic first-pass effect.
- Nasal decongestant effect, in contrast to older conventional anti-histaminic agents[1, 2].

Competitive advantages

- Levocetirizine efficacy superior to loratadine, desloratadine and fexofenadine[3, 4, 5, 6, 7, 8].
- 43% saving on the social cost of persistent allergic rhinitis[9].
- Minimal impairment of memory and psychomotor functioning nor mood changes after acute and sub chronic administration of levocetirizine[10].

Regulatory status

- INN: Levocetirizine
- ATC Code: R06AE09
- CAS registry number: 0130018-77-8
- Reference compound: XYZALL®, UCB Pharma.
- BioEq. study
  - Patient population:23 male and female healthy volunteers.
  - Methodology: Randomized, single-dose 2-way crossover study (test without water vs. Reference with water).
  - Reference product: XYZALL®, UCB Pharma France.
- Zone IV stability data available.
- CTD dossier available.



Levocetirizine 5 mg

Orodispersible tablet

ALLERGY

Information at a glance

- Commercial batch size (million doses): 0.5
- Dossier Batch size (million doses):0.125
- Shelf-life:3 years
- Storage conditions: Room temperature between 20-25°C
- Pack info: Alu-Alu 10-tabs blister
- Tablet weight / strength: 250 mg
- Flavour: Blackcurrant

Market highlights

- Allergic rhinitis affects around 10 to 30% of the population every year[11].
- The global antihistamine market is projected to reach $277 million by 2026 at a CAGR of 5.6% from 2021 to 2026[12].
- Second-generation antihistamines segment is the largest market[13].

Competitors' landscape

- First-generation (non-selective) antihistaminic drugs (BENADRIL®/diphenhydramine, RYVENT®/carbinoxamine), second-generation (selective) antihistaminic drugs (ZYRTEC®/cetirizine, CLARITIN®/loratadine, AERIUS®/ebastine, TELDANE®/terfenadine) and third-generation antihistaminic drugs (CLARINEX®/desloratadine, ALLEGRA®/fexofenadine).

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ATHENA PHARMACEUTIQUES

Key numbers

- **Allergic rhinitis affects 10% to 30% of the population every year**
- **Global anti-histaminic market: $277 million by 2026**
- **CAGR 2021-26: 5.6%**

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Meloxicam 7.5 mg & 15 mg

Orodispersible tablet

ATHENA PHARMACEUTIQUES

Orodispersible facilitates oral intake and improves patients' compliance

Key features

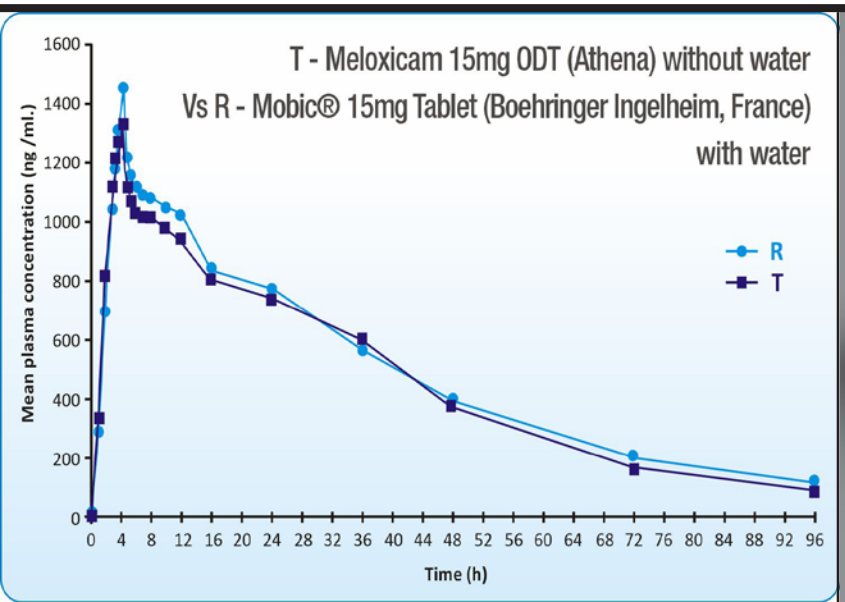
- Meloxicam appears to have better gastrointestinal tolerance than non-selective Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) thanks to its preferential inhibition of COX-2 vs. COX-1. The Orodispersible tablets enhance patient compliance, administration without water and accuracy of dosage.

Competitive advantages

- Meloxicam, compared to diclofenac[1] piroxicam[2] or naproxen[3, 4], caused less gastrointestinal related adverse events (respectively 13% vs. 19%; p=0.001;10.3% vs. 15.4%; p=0.001 and 0.36 events per patient vs. 0.52; p=0.002).
- Once-a-day administration.

Regulatory status

- NN: meloxicam
- ATC Code: M01AC06
- CAS registry number: 71125-38-7
- Reference compound: MOBIC®, Boehringer Ingelheim.
- BioEq. study
  - Patient population: 24 male & female healthy volunteers.
  - Methodology: Randomized 2-way crossover (Test w/o water, reference with water).
  - Reference product: MOBIC® 15 mg Boehringer Ingelheim, France.
- Zone IV stability data available.
- CTD dossier available.



Meloxicam 7.5 mg & 15 mg

Orodispersible tablet

PAIN / ANTI-INFLAMMATORY

Information at a glance

- Commercial batch size (million doses): 7.5 mg: 0.5 | 15 mg: 0.5
- Dossier Batch size (million doses): 7.5 mg: 0.225 | 15 mg: 0.225
- Shelf-life: 3 years
- Storage conditions: store at 25°C
- Pack info: Alu-Alu paper backed peel off blister / Alu-Alu. pack of 10-tabs blister
- Tablet weight / strength: 7.5 mg: 180 mg | 15 mg: 360 mg
- Flavour: Orange

Market highlights

- NSAIDs market size is expected to move from $15.6 billion in 2019 to $24.4 billion by 2027 exhibiting a CAGR of 5.8% during the forecast period[5].
- Arthritis segment hold 38.0% NSAIDs market share in 2019 and is likely to lead throughout the forthcoming years[5].

Competitors' landscape

- NSAIDs (NAPROSYN®/naproxen, CATAFLAM®/diclofenac, ORUDIS®/ketoprofen, MOBIC®/meloxicam, TORADOL®/ketorolac, FELDENE®/piroxicam) and COX-2 selective NSAIDs (CELEBREX®/celecoxib, VIOXX®/rofecoxib, BEXTRA®/valdecoxib).

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ATHENA PHARMACEUTIQUES

Key numbers

- **NSAIDs market expected to reach $24.4 billion by 2026**
- **NSAIDs market led by arthritis segment with a market share of 38%**

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Mesalamine 500 / 1000 & 2000 mg

Sustained-Release Sachet

GASTROENTEROLOGY

ATHENA PHARMACEUTIQUES

High dosage improves patient's compliance and treatment acceptability

Key features

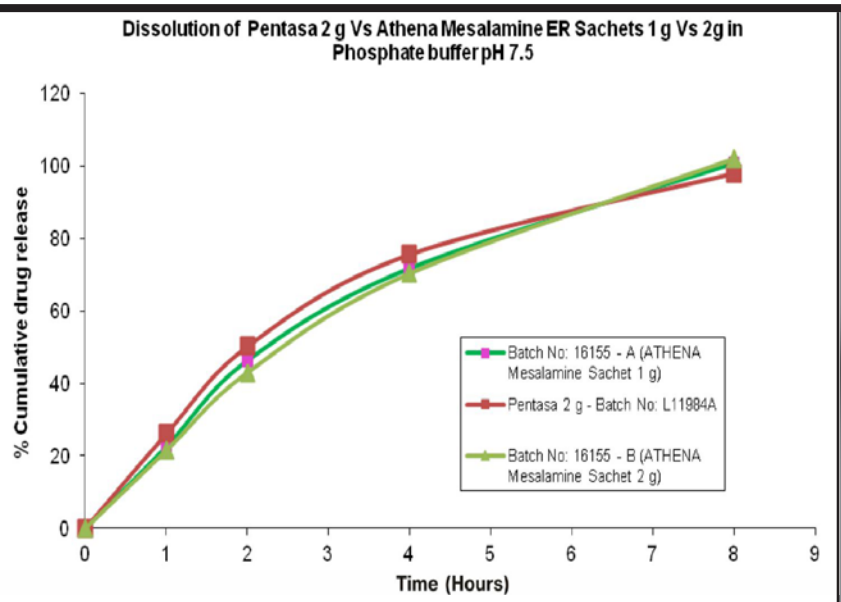
- Athena's Mesalamine (or Mesalazine) sachet formulation offers the same release as conventional Mesalamine tablet preparations with the advantage of fewer oral doses and ease of swallowing[1] and therefore leading to an improved patient's compliance and acceptability of the treatment.

Competitive advantages

- Excellent First-line therapy for a step-up approach in the management of mild to moderate active ulcerative colitis (UC) and for the maintenance of remission. Mesalamine induces UC remission in 20-30% and UC improvement or remission in 40-70%[2, 3].
- Mesalamine sachet formulations are more acceptable than tablets for patients and are a better option for long-term treatment[4, 5].

Regulatory status

- INN: Mesalamine
- ATC Code: A07EC02
- CAS registry number: 89-57-6
- Reference compound: PENTASA®, Ferring.
- Comparative dissolution study
  - Athena Mesalamine sachet, 1 000 & 2 000 mg vs. reference product (PENTASA® 2 000 mg).
  - Study conditions: Dissolution conducted in a phosphate solution buffered at pH 7.5.
- Zone IV stability data available.
- CTD dossier available.
- All strengths already marketed.
- Patent process (PCT/IN2015/000143) filled in EU & China (under review).



Mesalamine 500, 1000/2000 mg

Sustained-Release Sachet

GASTROENTEROLOGY

Information at a glance

- Commercial batch size (million doses) / strength: 500 mg: 0.36 | 1 000 mg: 0.18 | 2 000 mg: 0.09
- Dossier Batch size (million doses) / strength: 1 000 mg: 0.18 | 2 000 mg: 0.09
- Shelf-life: 2 years
- Storage conditions: Room temperature between 20-25°C
- Pack info: Paper coated aluminium sachet
- Sachet weight / strength: 500 mg: 833.4 mg | 1 000 mg: 1 666.7 mg | 2 000 mg: 3 333.3 mg

Market highlights

- In the US, about 1 million of people are affected with UC [6].
- Annual incidence is 10.4-12 cases / 100,000 people [6].
- The global Ulcerative Colitis market accounted for $6.8 billion in 2018 and is expected to reach $10.3 billion by 2027 (CAGR of 4.6%)[7].
- Mesalamine market size is $134.6 million and expected to reach $181.6 million by 2026 (CAGR of 4.1%)[8].

Competitors' landscape

- Topical (rectal) mesalamine, sulfasalazine (SALAZOPYRINE®), biologics agents, such as infliximab (REMICADE®). 6-mercaptopurine (PURINETHOL®) or IMURAN®/azathioprine in maintenance treatment.

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ATHENA PHARMACEUTIQUES

Key numbers

- **10.4-12 case/100,000 people each year**
- **Global UC market by 2027: $10.7 billion**
- **Global Mesalsamine market by 2027: $182 million**

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Metformin 750 mg

Sustained-release Tablet

ATHENA PHARMACEUTIQUES

Improves patient's adherence and tolerability to treatment with a simpler dosing regimen, leading to a greater glycaemic control.

Key features

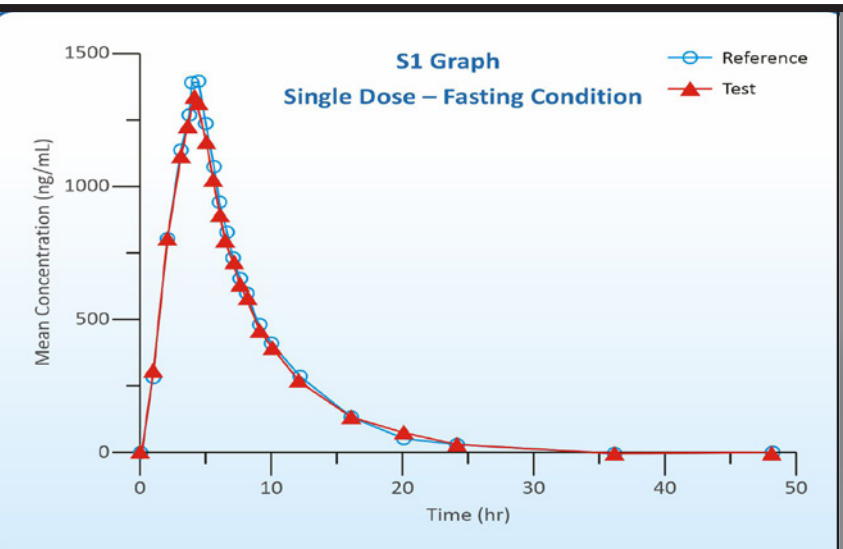
- Sustained-release formulation for type 2 diabetic patients, improving Gastrointestinal tolerability whilst allowing for a once-daily dosing[1, 2].

Competitive advantages

- Outstanding ability to decrease plasma glucose levels in type 2 diabetic patients[3].
- Firstline treatment of type 2 diabetes[3].
- Treatment of choice in pregnant women with type 2 diabetes[4].
- Superior efficacy than conventional agents (chlorpropamide, glibenclamide, insulin) in type 2 diabetic patients for any diabetes-related endpoint, diabetic-related death and for all-cause mortality. Associated with less weight gain and fewer hypoglycaemic attacks[5].

Regulatory status

- INN: Metformin
- ATC Code: A10BA02
- CAS registry number: 657-24-9
- Reference compound: GLUCOPHAGE®, Merck Serono.
- BioEq. Studies
  - Study 1: 54 male & female healthy fasting volunteers, single dose.
  - Study 2: 42 male & female healthy fed volunteers, single dose.
  - Study 3: 36 male & female healthy fed volunteers, multiple dose.
  - Reference product: GLUCOPHAGE®, Merck Serono, UK.
- Zone IV stability data available.
- CTD dossier available.
- All strengths already marketed.
- Patent process (PCT/IN2015/000143) filled in EU & China (under review).



Metformin 750 mg

Sustained-release Tablet

CARDIOMETABOLIC

Information at a glance

- Commercial batch size (million doses): 0.5
- Dossier Batch size (million doses): 0.125
- Shelf-life: 3 years
- Storage conditions: Room temperature between 20-25°C
- Pack info: Clear PVC-PVDC Alu 14-tabs blister
- Tablet weight / strength: 1 250 mg

Market highlights

- 6.3% of the world's population is affected by type 2 diabetes (462 million) & over 1 million deaths per year can be attributed to diabetes alone, making it the 9th leading cause of mortality worldwide[6].
- Metformin global market is valued at $178 million in 2019, expected to reach $260 million by 2024, leaded by metformin extended release formulations[7].
- Global Type 2 Diabetes market is set to almost double from $31 billion in 2015 to $59 billion by 2025 (CAGR of 6.5%)[8].

Competitors' landscape

- Sulfonylureas (glyburide/GLYNASE®, glipizide/GLUCOTROL®, glimepiride/AMARYL®), Meglitinides (repaglinide/PRANDIN®, nateglinide/STARLIX®), Thiazolidinediones (rosiglitazone/AVANDIA®, pioglitazone/ACTOS®), DPP-4 inhibitors (sitagliptin/JANUVIA®, saxagliptin/ONGLYZA®, linagliptin/TRADJENTA®), injectable GLP-1 receptors agonists (exenatide/BYETTA®, liraglutide/VICTOZA®, semaglutide/OZEMPIC®) and SGLT-2 inhibitors (canagliflozin/INVOKANA®, dapagliflozin/FARXIGA®, empagliflozin/JARDIANCE®).

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ATHENA PHARMACEUTIQUES

Key numbers

- **462 million of individuals affected by type 2 diabetes**
- **Global type 2 diabetes market expected to reach $59 billion by 2025**
- **Metformin global market expected to reach $260 million by 2024**

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Metronidazole 250 & 500 mg

Film coated tablet

ANTI-INFECTIVES

ATHENA PHARMACEUTIQUES

First line anti-anaerobic antibiotic

Key features

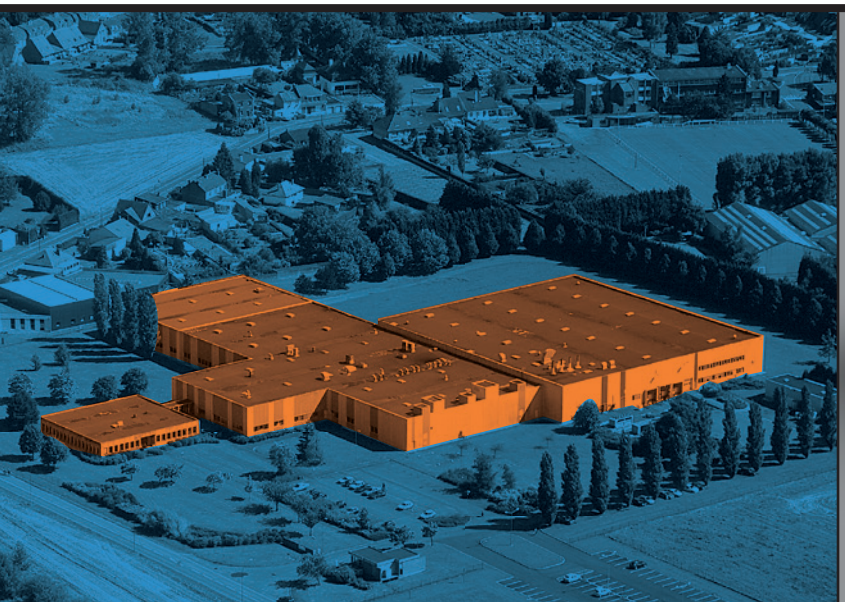
- Nitroimidazole antimicrobial antibiotic effective in the management of protozoal infestation and a powerful and-anaerobic compound. On the World Health Organization's List of Essential Medicines[1].

Competitive advantages

- Antiprotozoal properties:
  Treatment of Giardiasis, the most common intestinal parasite as the etiological agent of diarrhea around the world;
  Treatment of Trichomoniasis, a protozoan parasite responsible for one of the most sexually transmitted disease;
  Amoebiasis (amebic colitis or liver abscess) and Bacterial Vaginosis
- Antimicrobial properties:
  Eradication of Clostridium Difficile, a major cause of nosocomial infections;
  In combination with other antibiotics, highly efficacious against anaerobic bacteria

Regulatory status

- INN: metronidazole
- ATC: P01AB01
- CAS registry number: 443-48-1
- Zone IVb stability data available
- eCTD dossier available



Metronidazole 250 & 500 mg

Film coated tablet

ANTI-INFECTIVES

Information at a glance

- Dossier Batch size (million doses): 250 mg: 1 | 500 mg: 0.5
- Shelf-life: 36 months
- Storage conditions: Protect from light
- Pack info: Clear thermoformed PVC 250 µm / aluminum 25 µm blister
- Tablet weight: 250 mg: 352.8 mg | 500 mg: 705.6 mg

Market highlights

- The global Metronidazole market was valued at $114.5 million in 2019 and is expected to reach $110.5 million by the end of 2026, growing at a CAGR of -0.5% during the forecast period[2].

Competitors' landscape

- FUROXONE®, DEPENDAL-M®/furazolidone, LOTRIMIN®/clotrimazole, CATENULIN®/paromomycin, CLINACIN®, DALACIN®, CLEOCIN®clindamycin, NIZONIDE®/nitazoxanide, VERMOX®/mebendazole, ALBENZA®, ZENTEL®/albendazole, VANCOCIN®/clindamycin, NORMIX®/rifaximin.

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2. Global Metronidazole Market Research Report, MarketWatch, 2021

ATHENA PHARMACEUTIQUES

Key numbers

- **Metronidazole Global market size $115 million (2019)**

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N-Acetyl Cysteine 200 mg

Stick powder with/without water

ATHENA PHARMACEUTIQUES

Reference mucolytic agent with antioxidant properties in a convenient, water-free, stick formulation.

Key features

- N-Acetyl-Cysteine (NAC) is on the World Health Organization's List of Essential Medicines[1].
- On top of its mucolytic properties, NAC exert a direct antioxidant action[2].
- The stick powder formulation improves adherence and compliance to the treatment and avoid dosing-mistakes.

Competitive advantages

- Mucolytic agent with antioxidant and anti-inflammatory properties effective in the management of patients with bronchiectasis or Chronic Obstructive Pulmonary Diseases (COPD)[3, 4].

Regulatory status

- INN: N-acetyl cysteine
- ATC: R05CB01
- CAS registry number: 616-91-1
- Zone II stability available
- Zone IVb stability to be started in 2021.
- eCTD dossier

N-Acetyl Cysteine 200 mg

Stick powder with/without water 

OTC

Information at a glance

- Dossier Batch size (million doses): 0.5
- Shelf-life: 24 months
- Storage conditions: Store below 25°C
- Pack info: sticks of 22 x 80 mm containing 2.00 g of granules.
- stick weight: 2.00 g
- Flavour: Orange

Market highlights

- NAC Global market (medicine and nutritional supplements) is valued at $ 0.5 million in 2018 and will reach $ 2.34 Billion by the end of 2025, growing at a CAGR of 21.5% during 2019-2025[5].
- COPD market set to hit $14.1 Billion by 2025 (CAGR 3.7%)[6].

Competitors' landscape

- Carbocysteine (MUCOLEX®, General Pharmaceuticals LTd), Erdosteine (ESTECLIN®, Edmon Pharma), Fudosteine (CLEANAL®, Mitsubishi Tanabe Pharma, Dornase alfa (PULMOZYME®, Genentech)

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4. Archivosd de Bronconeumologia Volume 54, Issue 2, February 2018
5. Global Acetylcysteine Market Insights, Forecast to 2025, 360 Market Updates, 2020
6. PharmaPoint: Chronic Obstructive Pulmonary Disease – Global Drug Forecast and Market Analysis to 2025

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Key numbers

- **NAC global market: $2.34 Billion by 2025**
- **COPD market: $14.1 Billion by 2025**

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Ondansetron 4 & 8 mg

Orodispersible tablet

ATHENA PHARMACEUTIQUES

Orodispersible ease drug intake in patients suffering from chemotherapy-induced nausea & vomiting

Key features

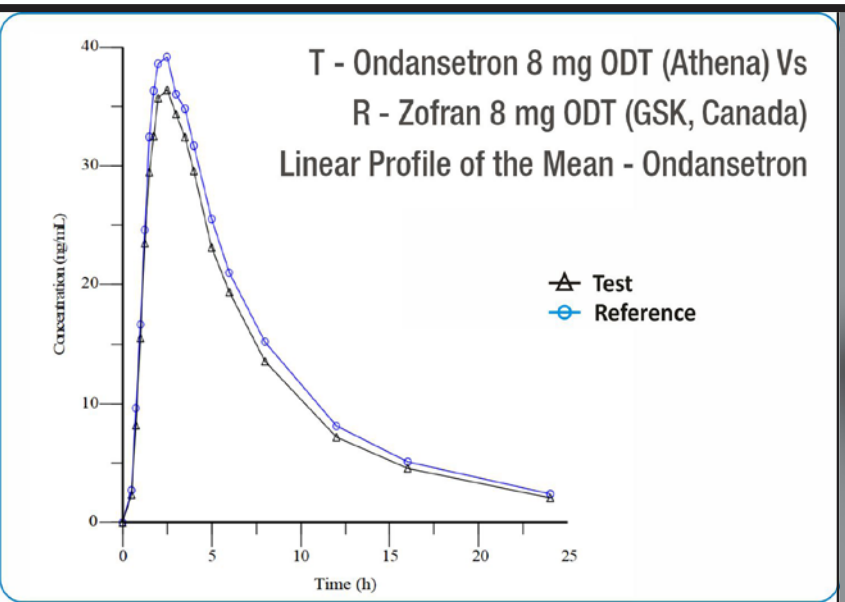
- Thanks to Athena's orodispersible technology, not requiring water, a rapid drug intervention therapy with ondansetron can be achieved (melting < 30 sec.), in patients suffering from chemotherapy-induced nausea and vomiting who are unable/reluctant to swallow.

Competitive advantages

- Ondansetron, a serotonin 5-HT3 receptor antagonist is effective in the control of nausea and vomiting in patients treated by highly emetogenic chemotherapy and after radiotherapy. Furthermore, ondansetron shows clinical benefits in the management of patients receiving highly emetogenic chemotherapy who have poorly responded to conventional antiemetics, or who suffer from intolerable side effects. Ondansetron is also indicated for the prevention and treatment of postoperative nausea and vomiting[1]. In paediatrics (4-18y) ondansetron is effective and well tolerated in the treatment of post-chemotherapy induced nausea and vomiting[2].
- Ondansetron is on the WHO List of Essential Medicines[3].

Regulatory status

- INN: Ondansetron
- ATC Code: A04AA01
- CAS registry number: 99614-02-5
- Reference compound: ZOFRAN®, GSK.
- BioEq. study
  - Patient population: 24 male and female fasting healthy volunteers.
  - Methodology: Randomized, 2-way crossover, single dose (Test and reference without water).`
  - Reference product: ZOFRAN® Orodispersible Tablet 8 mg, GSK, UK.
- Zone IV stability data available.
- CTD dossier available.



Ondansetron 4 & 8 mg

Orodispersible tablet

ANTI-EMETIC / ONCOLOGY

Information at a glance

- Commercial batch size (million doses) / strength: 4 mg: 0.225 | 8 mg: 0.225
- Batch size (million doses) / strength: 4 mg: 0.225 | 8 mg: 0.225
- Shelf-life: 3 years
- Storage conditions:
- Pack info: Pack in Alu. Alu 10-tabs blister
- Tablet weight / strength: 4 mg: 200 mg | 8 mg: 400 mg
- Flavour: Strawberry

Market highlights

- The global chemotherapy-induced nausea and vomiting market is valued at $2.0 billion in 2017 and estimated to reach $3.6 billion by 2026 (CAGR of 6.5%)[4].
- Highly-emetogenic cytotoxic chemotherapy drugs cause nausea and vomiting in 30 to 90% of patients[5].
- Within 5 days of chemotherapy administration vomiting occurs in 23.8% and nausea in 42%[6].
- Within 3 days of radiotherapy nausea and/or vomiting occurs in 28%[7].

Competitors' landscape

- Serotonin 5-HT3 receptor antagonists (granisetron/KYTRIL®, dolasetron/ANZEMET®, palosetron/ALOXI®), neurokinin-1 (NK1) receptor antagonist (aprepitant/EMEND®). In a lesser extent, dopamine D2 receptor antagonist antiemetics (PRIMPERAN®/metoclopramide, VOGALENE®/metopimazine).

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Key numbers

- **Global CINV market: $2 billion by 2026**
- **CAGR 2017-26: 6.5%**

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Prednisolone sodium phosphate 5 & 10 mg

Soluble tablet

PAIN / ANTI-INFLAMMATORY

ATHENA PHARMACEUTIQUES

Soluble tablet improves patient adherence and provides flexibility for treatment

Key features

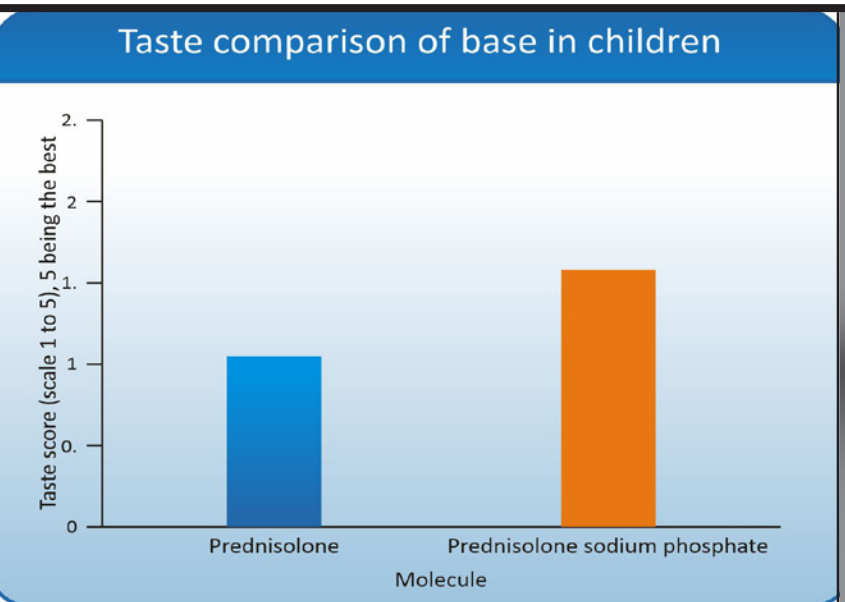
- Massive improvement in patient's treatment adherence (especially in children) over liquid preparation based on solid tablet forms which requires hazardous manipulations (crushing, scoring, or adding excipients) that may affect stability, cause inaccurate dosing and be hazardous for the ersatz compounder[1].

Competitive advantages

- Prednisolone is highly effective and significantly more effective that Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) in rheumatoid arthritis and may be used intermittently[2].
- Prednisolone is the active metabolite of prednisone and prednisone's efficacy is related to the patient's hepatic function capacity to convert prednisone to prednisolone[3].
- Prednisolone is on the World Health Organization's List of Essential Medicine[4].
- Sodium phosphate prednisolone should be preferred over prednisolone base as it is less bitter in order to improve children's acceptance[5, 6].

Regulatory status

- INN: Prednisolone
- ATC Code: S02BA03
- CAS registry number: 20-24-8
- Reference compound: SOLUPRED®, Sanofi.
- Bioequivalence waiver applied.
- Zone II stability data (doesn't pass Zone IV).
- CTD dossier available.



Prednisolone sodium phosphate 5 & 10 mg

Soluble tablet

PAIN / ANTI-INFLAMMATORY

Information at a glance

- Commercial batch size (million doses) / strength: 5 mg: 0.5 | 10 mg: 0.5
- Dossier Batch size (million doses) / strength: 5 mg: 0.11 | 10 mg: 0.11
- Shelf-life: 3 years
- Storage conditions: Store below 25°C
- Pack info: Alu-Alu 10-tabs blister
- Tablet weight / strength: 5 mg: 145 mg | 10 mg: 290 mg
- Tablet dissolution time: 1'30 to 2'
- Flavour: Strawberry

Market highlights

- The global corticosteroid therapy market is expected to grow from $4.2 billion in 2019 to $4.9 billion by 2023 at a CAGR of 4.2% over the forecasted period[7].
- Global prednisolone market size was $2.5 billion in 2019 and will expand at a CAGR of 7.1% from 2020 to 2025[8].

Competitors' landscape

- CORTEF®/Hydrocortisone, DECADRON®/dexamethasone, DELTASONE®/prednisone, CORTONE®/cortisone, KENALOG®/triamcinolone, CELESTONE®/betamethasone, MEDROL®/methylprednisolone.

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6. Giblin E et al US pharmacist (2015)
7. Corticosteroids Therapy Global Market report The Business Research Company (2020)
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ATHENA PHARMACEUTIQUES

Key numbers

- **Global corticosteroid therapy market: $4.9 billion in 2023**
- **CAGR global corticosteroid market: 4.2%**
- **Global prednisolone market: $2.5 billion in 2019**

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Racecadotril 10 & 30 mg

sachet

ATHENA PHARMACEUTIQUES

Safe and effective product can be given to infants aged over 3 months

Key features

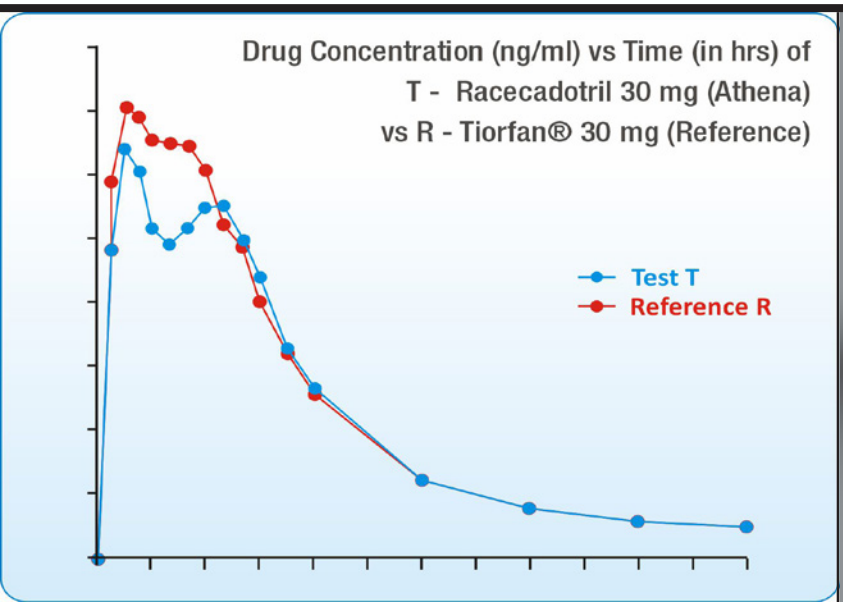
- Racecadotril is indicated for the symptomatic treatment of acute diarrhoea in infants aged over 3 months.

Competitive advantages

- Racecadotril is a guideline-recommended treatment to alleviate symptoms of acute diarrhoea[1, 2, 3]. Safety profile is similar to that of placebo. Racecadotril inhibits the degradation of enkephalins, which in turn have potent antisecretory activity but only little effect on motility in the gut in contrast to loperamide (IMODIUM®)[4, 5, 6].
- Resolution of symptoms with racecadotril when compared to loperamide is associated with less rebound constipation and less abdominal discomfort[7].
- Reduction of water and electrolytes losses in children suffering from acute diarrhoea[8, 9].
- Racecadotril is indicated for the complementary symptomatic treatment of acute diarrhoea in infants aged over 3 months[10, 11].

Regulatory status

- INN: Racecadotril
- ATC Code: A07XA04
- CAS registry number: 81110-73-8
- Reference compound: TIORFAN®, Bioprojet Pharma.
- BioEq. study
  - Patient population:48 male and female fasting healthy volunteers.
  - Methodology: Randomized single-dose 2-way crossover (Test and reference administered with water).
  - Reference product: TIORFAN®, Bioprojet Pharma, France.
- Zone II & IV stability data available.
- CTD dossier available.
- Patent filled in USA, EU, Brazil, Mexico, Russia, China & Korea Regarding the pharmaceutical composition & process for preparation of racecadotril (PCT/IN2018/050085).



Racecadotril 10 & 30 mg

sachet

GASTROENTEROLOGY

Information at a glance

- Commercial batch size (thousand doses) / strength: 10 mg: 330 | 30 mg: 110
- Dossier Batch size (thousand doses) / strength: 10 mg: 330 | 3 mg: 110
- Shelf-life: 3 years
- Storage conditions: Room temperature between 20-25°C
- Pack info: Heat sealed aluminium sachet. A soft tempered, silver coloured, one side shiny and other side opaque, printed alu. foil
- Sachet weight / strength: 10 mg: 1 000 mg | 30 mg: 3 000 mg

Market highlights

- Worldwide, 1.7 billion episodes of Acute Secretory Diarrhoea occur each year[12].
- Children's diarrhoea drug treatment account for the largest market share (63% in 2019)[12].
- Global antidiarrheal Drugs market is valued $4,3 billion reaching $5.8 billion by 2026 (CAGR: 4.5%)[13].

Competitors' landscape

- Loperamide (IMODIUM®), bismuth subsalicylates (mostly OTC).

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ATHENA PHARMACEUTIQUES

Key numbers

- **1.7 billion episodes of Acute Secretory Diarrhoea worldwide each year**
- **Global antidiarrheal Drugs market will reach $5.8 billion by 2026**

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Secnidazole 2 mg

sachet

ATHENA PHARMACEUTIQUES

First oral single-dose treatment for bacterial vaginosis

Key features

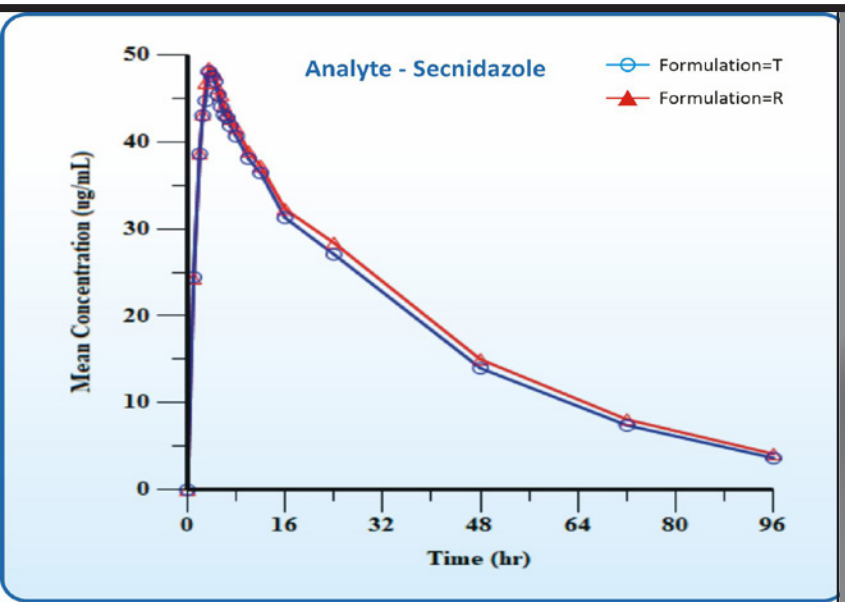
- Single-dose oral treatment of bacterial vaginosis vs. oral metronidazole twice a day for seven days, or tinidazole or clindamycin for two to seven days[1].
- No significant drug-drug interaction with oral contraceptives containing ethinyl oestradiol & norethindrone[2].
- Administration can occur without regard to the timing of meals.

Competitive advantages

- Next-generation 5-nitroimidazole prodrug granted priority review by the FDA with longer half-life (17h) allowing for a once-daily dosing.
- Secnidazole has similar activity against the range of microorganisms associated with bacterial vaginosis compared to metronidazole or tinidazole whilst sparing Lactobacilli, beneficial microorganisms[3].

Regulatory status

- INN: Secnidazole
- ATC Code: P01AB07
- CAS registry number: 3366-95-8
- Reference compound: SECNOL®, Iprad.
- BioEq. study
  - Patient population: 30 male & female healthy volunteers.
  - Methodology: Randomized 2-way crossover single dose study.
  - Reference product: SECNOL® 2 g sachet Iprad, France.
- Zone IV stability data available.
- CTD dossier available.



Secnidazole 2 mg

sachet

GYNAECOLOGY

Information at a glance

- Commercial batch size (thousand doses): 65
- Dossier Batch size (thousand doses): 65
- Shelf-life: 2 years
- Storage conditions: Room temperature between 20-25°C
- Pack info: Pellets is self-sealed polyethylene bag and finished pack in paper alu. coated sachet
- Sachet weight / strength: 4 228 mg

Market highlights

- 84% of women suffering from bacterial vaginosis have no symptoms (CDC).
- Prevalence of bacterial vaginosis is estimated to be 29,2% in women aged 14-49 (21.1M) (CDC).
- Global Bacterial Vaginosis Drug market is valued at $800 million in 2018 and will reach $1.03 billion by 2025 (CAGR 2019-25: 3.2%)[4].

Competitors' landscape

- FLAGYL®/Metronidazole, members of the 5-nitroimidazole class (FASIGYN®/tinidazole, XYNOR®/ornidazole), CLEOCIN®/clindamycin.

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4. Global Bacterial Vaginosis Drug Market 2020 360Market updates (2020)

ATHENA PHARMACEUTIQUES

Key numbers

- **Global Bacterial Vaginosis valued $1.06 billion by 2025**
- **CAGR of 1.1% between 2020-2025**

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Sildenafil 50 & 100 mg

Orodispersible tablet

ATHENA PHARMACEUTIQUES

Orodispersible facilitates oral intake and improves patients' compliance

Key features

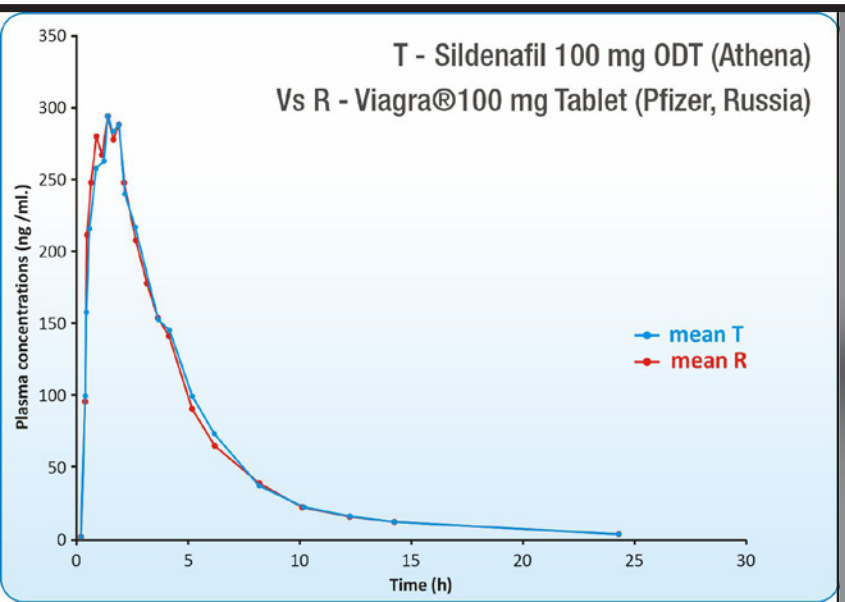
- Added patient convenience and acceptability of sildenafil dosage form, first-in-class & first-line treatment of erectile dysfunction does not require administration with water[1, 2].

Competitive advantages

- Fist-in-class selective PDE5-inhibitor. Highest number of studies and published scientific papers in this drug calls[1, 2].
- More than 25 of clinical experience confirm the risk/benefit profile of sildenafil and establish it as an effective first line option for erectile dysfunction[1, 2].
- Convenient and discrete method of intake with rapid onset of action[1, 2].

Regulatory status

- INN:Sildenafil
- ATC Code: G04BE03
- CAS registry number: 171599-83-0
- Reference compound: VIAGRA®, Pfizer.
- BioEq. study
  - Patient population: Male fasting healthy volunteers.
  - Methodology: Randomized, 2-way crossover single dose study.
  - Reference product: VIAGRA® 100 mg film-coated tablet, Pfizer, Russia.
- Zone IV stability data available.
- CTD dossier available.



Sildenafil 50 & 100 mg

Orodispersible tablet

GYNAECOLOGY

Information at a glance

- Commercial batch size (thousand doses): 50 mg: 250 | 100 mg: 250
- Dossier Batch size (thousand doses): 50 mg: 250 | 100 mg: 250
- Shelf-life: 2 years
- Storage conditions: Store below 30°C
- Pack info: Alu-Alu. blister strip of 2/4/6 tabs.
- Tablet weight / strength: 50 mg: 600 mg | 100 mg: 1 200 mg
- Flavour: Peppermint

Market highlights

- Global drug for erectile dysfunction market valued $4.8 billion in 2017 and expected to grow to $7.1 billion by 2024 at a CAGR of 5.7% over the forecasted period[3].
- Sildenafil global market is expected to reach $1.8 billion by 2025, growing at a CAGR of 5.8% during the forecast period 2020-25 due to a strong loyalty to the brand which lost patent in 2019[3, 4].

Competitors' landscape

- Phosphodiesterase 5 inhibitors family (CIALIS®/Tadalafil, LEVITRA®/vardenafil, MVIX®/mirodenafil, ZYDENA®/udenafil, and STENDRA®/avanafil), self-administered intracavernosal injectable prostaglandin E1 alprostadil (CAVERJECT®, EDEX®).

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ATHENA PHARMACEUTIQUES

Key numbers

- **Global erectile dysfunction drug market will reach $7.1 billion by 2024**
- **Global sildenafil market will reach $1.8 billion by 2025**
- **Global sildenafil market CAGR: 5.8% (2020-2025)**

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Spiramycin + Metronidazole 0.75 MUI/125 mg & 1.5 MUI/250 mg

Film coated tablet

ATHENA PHARMACEUTIQUES

Effective treatment of acute, chronic, or recurrent stomatological infections.

Key features

- Synergistic effects between spiramycin and metronidazole in the treatment of polymicrobial aerobic-anaerobic infections.

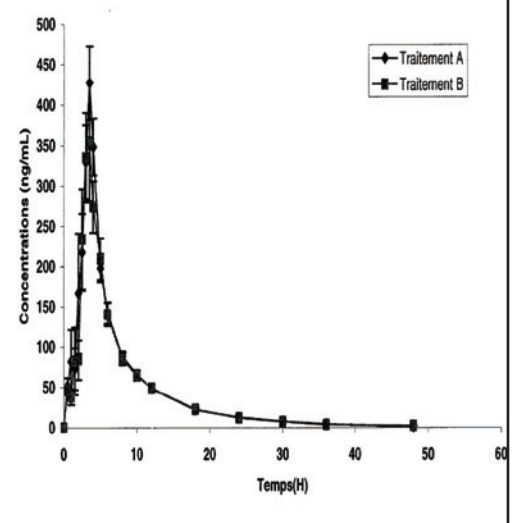
Competitive advantages

- Combination of spiramycin and metronidazole has a synergistic effect on the bucco-dental flora[1,2].

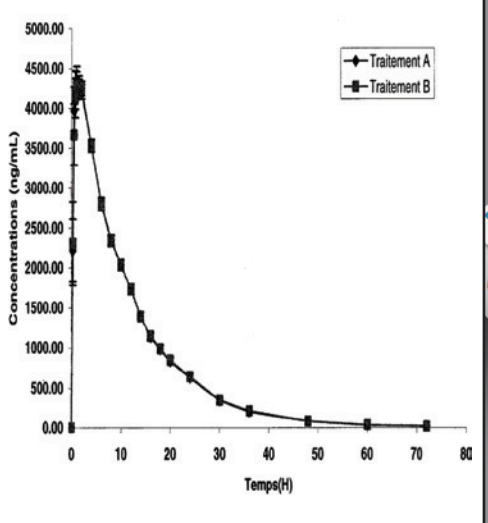
Regulatory status

- INN: Spiramycin and metronidazole
- ATC: J01RA04
- CAS registry number: 87705-26-8
- Reference compound: RODOGYL® 1.5 MUI/250 mg, Sanofi.
- BioEq. study
  - Patient population: male & female healthy volunteers.
  - Methodology: Randomized two-way crossover.
  - Reference product: RODOGYL®, Sanofi
- Zone II stability available
- Zone IVb stability to be started in 2021.
- eCTD dossier under upgradation.

Spiramycin



Metronidazole



Spiramycin + Metronidazole 0.75 MUI/125 mg & 1.5 MUI/250 mg

Film coated tablet

STOMATOLOGY

Information at a glance

- Dossier Batch size (million doses): 0.75 UI/125 mg: 0.4 | 1.5 MUI/250 mg: 0.4
- Shelf-life: 36 months
- Storage conditions: Room temperature between 20 and 25°C
- Pack info: PVC/Aluminum blister
- Tablet weight: 0.75 UI/125 mg: 411 mg | 1.5 MUI/250 mg: 822 mg

Market highlights

- The global dental infection control products market worldwide is poised to grow by $207 million during 2020-2025 (CAGR over 3%), weighting $1.1 Billion by 2025[3].

Competitors' landscape

- Amoxicillin, Amoxicillin + clavulamic acid, clindamycin, azithromycin, doxycycline, metronidazole, often co-prescribed with amoxicillin.

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ATHENA PHARMACEUTIQUES

Key numbers

- **Global dental infection: $1.1 Billion by 2025**

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Tramadol 37.5 mg + Paracetamol 325 mg

Orodispersible tablet

ATHENA PHARMACEUTIQUES

Orodispersible facilitates oral intake and improves patients' compliance

Key features

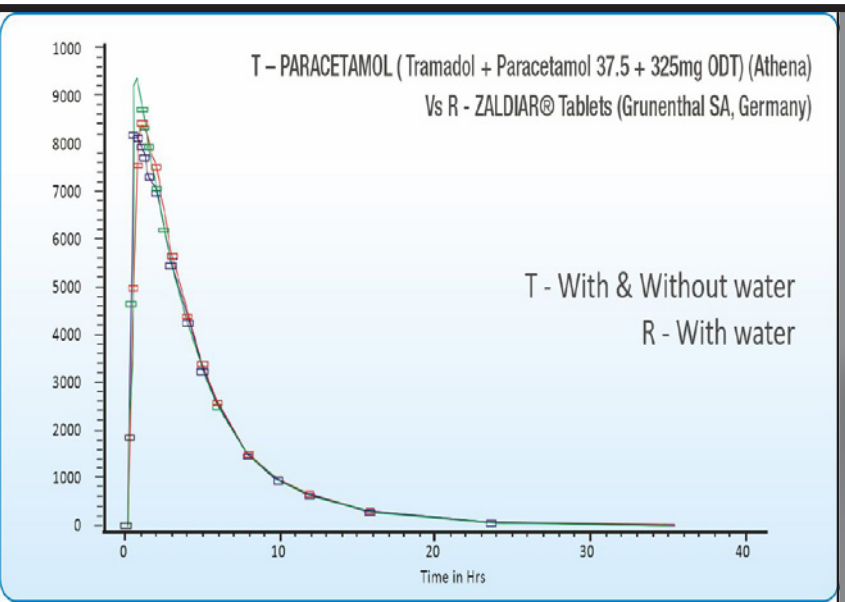
- Fixed-combination, offering a convenient method of intake maximizing analgesic efficacy whilst reducing daily tramadol and paracetamol doses, hence minimizing tramadol's potential for dependence and misuse and paracetamol hepatotoxicity.

Competitive advantages

- Fixed-combination of two well-known and established analgesics, devoid of the gastrointestinal, cardiovascular and renal adverse events associated with Non-Steroidal Anti-inflammatory Drugs (NSAIDs) responsible for 3.500-16.500 death per year in the USA[1, 2].
- Fixed-dose combination treatment reduces tramadol consumption by 24% vs. Tramadol monotherapy[3, 4]. Fixed-combination extensively evaluated than other combination products[5]. Only fixed-combination where both the dual mechanism of action and synergy between the two compounds have been demonstrated in both preclinical studies and in humans[6, 7, 8, 9].

Regulatory status

- INN: Tramadol & Paracetamol
- ATC Code: N02AJ13
- CAS registry number: 147630-10-2
- Reference compound: ZALDIAR®, Grunenthal.
- BioEq. study
  - Patient population: 37 fasting male and female healthy volunteers.
  - Methodology: single dose, 3-way crossover (test with & without water vs. reference with water).
  - Reference product: ZALDIAR® Tablets, Grunenthal SA, Germany.
- Zone IV stability data available.
- CTD dossier available.



Tramadol 37.5 mg + Paracetamol 325 mg

Orodispersible tablet

PAIN / ANTI-INFLAMMATORY

Information at a glance

- Commercial batch size (million doses): 0.5
- Dossier Batch size (million doses): 0.5
- Shelf-life: 3 years
- Pack info: Alu-Alu, Alu-PVC blister strip of 10 &6 tablets
- Tablet weight / strength: 1 200 mg
- Flavour: Peppermint

Market highlights

- The Global pain management market was valued at $71.4 billion in 2019 and is projected to reach $91.6 billion by 2027 registering a CAGR of 3.8% (2020-2027)[10].

Competitors' landscape

- NSAIDs (NAPROSYN®/naproxen, CATAFLAM®/diclofenac, ORUDIS®/ketoprofen, MOBIC®/meloxicam, TORADOL®/ketorolac, FELDENE®/piroxicam), anticonvulsants (TEGRETOL®/carbamazepine, TRILEPTAL®/oxcarbazepine, APTIOM®/eslicarbazepine, NEUROTIN®/gabapentin, LYRICA®/pregabalin), opioids (OXYCONTIN®/oxycodone, DUROGESIC®/fentanyl, DOLOPHINE®/methadone, DEMEROL®/meperidine, codeine, SUBUTEX®/buprenorphine) and nonnarcotic analgesics.

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8. Desmeules JA et al Br J Clin Pharmacol 41(1):7-12 (1996)
9. Filitz J et al Pain 136(3):262-270 (2008)
10. Pain Management Drugs Market 2019-2027, Allied Market Research (2020)

ATHENA PHARMACEUTIQUES

Key numbers

- **Global pain market: $71.4 billion in 2019 and $91.6 billion by 2027**
- **CAGR: 3.8% (2020-2027)**

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Tramadol 37.5 mg + Paracetamol 325 mg

Tablet

ATHENA PHARMACEUTIQUES

Fixed-combination analgesics broadening analgesic spectrum and synergistic analgesic efficacy

Key features

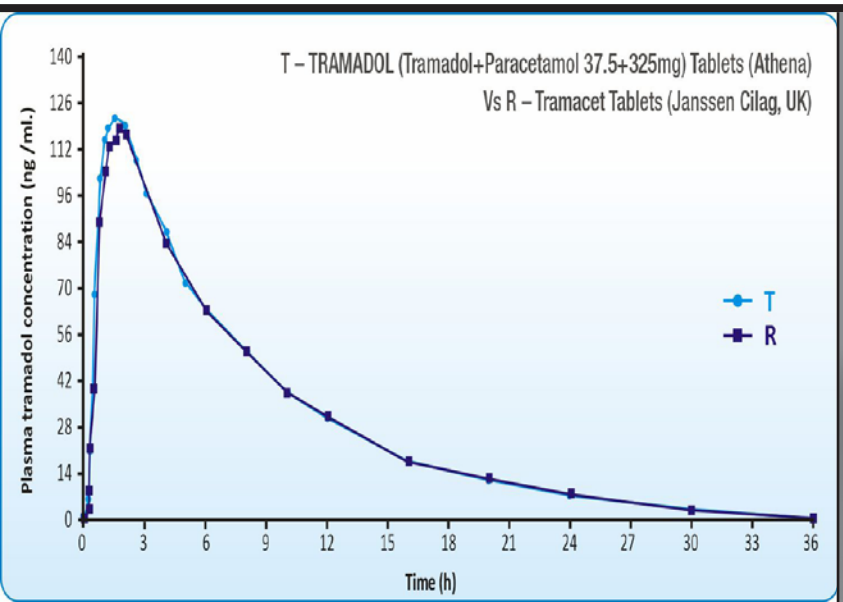
- Fixed-combination maximizing analgesic efficacy whilst reducing daily tramadol and paracetamol doses, hence minimizing tramadol's potential for dependence and misuse and paracetamol hepatotoxicity.

Competitive advantages

- Fixed-combination of two well-known and established analgesics, devoid of the gastrointestinal, cardiovascular and renal adverse events associated with Non-Steroidal Anti-inflammatory Drugs (NSAIDs) responsible for 3.500-16.500 death per year in the USA[1, 2].
- Fixed-dose combination treatment reduces tramadol consumption by 24% vs. Tramadol monotherapy[3, 4]. Fixed-combination extensively evaluated than other combination products[5]. Only fixed-combination where both the dual mechanism of action and synergy between the two compounds have been demonstrated in both preclinical studies and in humans[6, 7, 8, 9].

Regulatory status

- INN: Tramadol & Paracetamol
- ATC Code: N02AJ13
- CAS registry number: 147630-10-2
- Reference compound: TRAMACET®, Janssen.
- BioEq. study
  - Patient population: 36 male and female healthy volunteers.
  - Methodology: Single dose 2-way crossover.
  - Reference product: TRAMACET® tablets, Janssen Cilag, UK.
- Zone IV stability data available.
- CTD dossier available.



Tramadol 37.5 mg + Paracetamol 325 mg

Tablet

PAIN / ANTI-INFLAMMATORY

Information at a glance

- Commercial batch size (million doses): 0.5
- Dossier Batch size (million doses): 0.25
- Shelf-life: 3 years
- Storage conditions: Store below 30°C
- Pack info: PVC-PVDC 10-tabs Alu. blister strips
- Tablet weight / strength: 459 mg

Market highlights

- The Global pain management market was valued at $71.4 billion in 2019 and is projected to reach $91.6 billion by 2027 registering a CAGR of 3.8% (2020-2027)[10].

Competitors' landscape

- NSAIDs (NAPROSYN®/naproxen, CATAFLAM®/diclofenac, ORUDIS®/ketoprofen, MOBIC®/meloxicam, TORADOL®/ketorolac, FELDENE®/piroxicam), anticonvulsants (TEGRETOL®/carbamazepine, TRILEPTAL®/oxcarbazepine, APTIOM®/eslicarbazepine, NEUROTIN®/gabapentin, LYRICA®/pregabalin), opioids (OXYCONTIN®/oxycodone, DUROGESIC®/fentanyl, DOLOPHINE®/methadone, DEMEROL®/meperidine, codeine, SUBUTEX®/buprenorphine) and nonnarcotic analgesics.

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ATHENA PHARMACEUTIQUES

Key numbers

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- **CAGR: 3.8% (2020-2027)**

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Zolpidem 5 & 10 mg

Orodispersible tablet

ATHENA PHARMACEUTIQUES

Orodispersible facilitates oral intake and improves patients' compliance

Key features

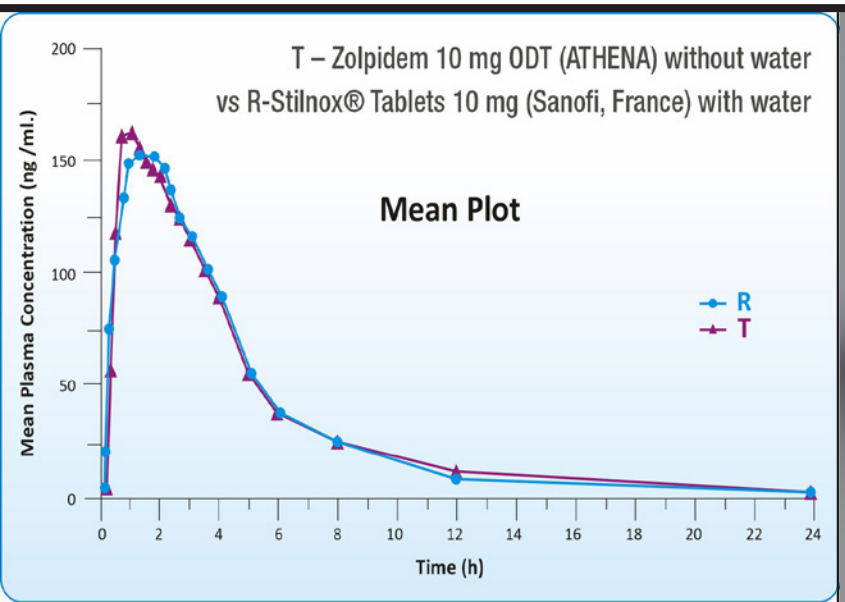
- ODT technology particularly suitable in insomnia patients who have difficulties swallowing tablets, or those who may not, or do not, always have access to water at bedtime[1,2].

Competitive advantages

- Zolpidem is particularly suitable for insomniac patient suffering with difficulties with sleep initiation.

Regulatory status

- INN: Zolpidem hemitartrate
- ATC Code: N05CF02
- CAS registry number: 99294-93-6
- Reference compound: STILNOX®, Sanofi.
- BioEq. study
  - Patient population: 38 male & female healthy volunteers.
  - Methodology: 2-way crossover single study (Test w/o water; Reference w/water).
  - Reference product: STILNOX®, Sanofi France.
- Zone IV stability.
- CTD dossier available.



Zolpidem 5 & 10 mg

Orodispersible tablet

CNS

Information at a glance

- Commercial batch size (million doses) / strength: 5 mg: 0.5 | 10 mg: 0.125
- Dossier Batch size (million doses) / strength: 5 & 10 mg: 1
- Shelf-life: 3 years
- Storage conditions: This medicinal product does not require any special storage conditions when packaged in Aluminium-Aluminium blisters.
- Pack info: Alu-Alu 10 tabs-blister; 10 blister strips / carton
- Tablet weight / strength: 5 mg: 150 mg | 10 mg: 300 mg
- Flavour: Black current

Market highlights

- Insomnia is one of the largest CNS disorders, affecting on average one adult out of 3[3, 4].
- Global insomnia market valued at $4.1 billion in 2016 and estimated to reach $5,5 billion by 2023 at a CAGR of 4.2% from 2017 to 2023[5].

Competitors' landscape

- Hypnotic & anxiolytic benzodiazepines (LEXOMIL®/bromazepam, VALIUM®/diazepam, XANAX®/alprazolam) IMOVANE®/zopiclone, LUNESTA®/eszopiclone, SONATA®/zaleplon, sedative anti-H1 (DRAMAMINE®/dimenhydrinate, BENADRYL®/diphenhydramine, DONORMYL®/doxylamine) sedative antidepressants (SINEQUAN®/doxepin, REMERON®/mirtazapine, DESYREL®/trazodone), melatonin receptor agonists (ROZEREM®/ramelteon, BELSOMRA®/survorexant) melatonin & other OTC derivatives.

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1. Staner L et al Expert Rev. Neurother. 12(2) (2012)
2. Inoue Y et al J Drug Res Dev (1) Vol 3.1 (2017)
3. CDC Newsroom (2016)
4. Roth T J Clin Sleep Med 3(Supp.5)3 S7-S10 (2007)
5. Prescription Sleep Aids and OTC Sleep Aids Allied Market Research (2017)

ATHENA PHARMACEUTIQUES

Key numbers

- **One adult out of 3 suffer from insomnia**
- **Global insomnia market valued at $5.5 billion by 2023**
- **CAGR 2017-2023: 4.2%**

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Zolpidem 5 & 10 mg

Sublingual tablet

ATHENA PHARMACEUTIQUES

Faster sleep onset initiation and lesss variability versus conventional tablet

Key features

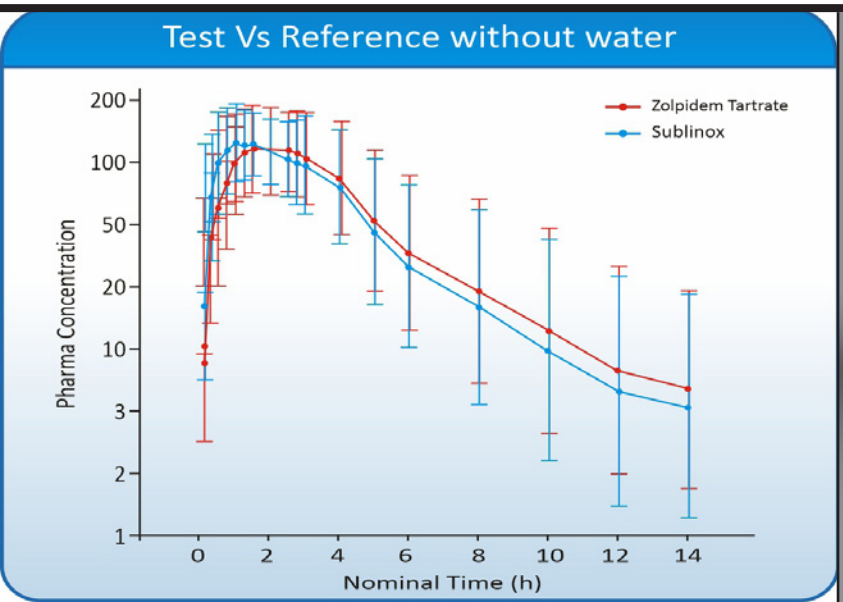
- Sublingual formulation allows a faster sleep onset, and lesser disturbance of sleep routine vs. pills which need water to be swallowed[1, 2].

Competitive advantages

- Faster and less variability sleep initiation in patients suffering from insomnia compared to conventional tablet formulations[1, 2].

Regulatory status

- INN: Zolpidem hemitartrate
- ATC Code: N05CF02
- CAS registry number: 99294-93-6
- Reference compound: SUBLINOX®, Valeant.
- BioEq. study
  - Patient population: 27 Healthy Volunteers.
  - Methodology: Randomized 2-way crossover study, single dose (test & reference without water).
  - Reference product: SUBLINOX® tablets, Valeant Canada.
- Zone IV stability data available.
- CTD dossier available.



Zolpidem 5 & 10 mg

Sublingual tablet

CNS

Information at a glance

- Commercial batch size (million doses) / strength: 5 mg: 1.0 | 10 mg: 0.5
- Dossier Batch size (million doses) / strength: 5 mg: 0.2 | 10 mg: 0.125
- Shelf-life: 36 months
- Storage conditions: Store in cool dry conditions in well-sealed receptacles
- Transport conditions: None
- Pack info: 5 & 10 mg - 10-tabs Alu-Alu blister, 10 blister strips packed/carton
- Tablet weight / strength: 5 mg: 150 mg | 10 mg: 300 mg
- Flavour: Blackcurrant

Market highlights

- Insomnia is one of the largest CNS disorders, affecting on average one adult out of 3[3, 4].
- Global insomnia market valued at $4.1 billion in 2016 and estimated to reach $5,5 billion by 2023 at a CAGR of 4.2% from 2017 to 2023[5].

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4. Roth T J Clin Sleep Med 3(Supp.5)3 S7-S10 (2007)
5. Prescription Sleep Aids and OTC Sleep Aids Allied Market Research (2017)

ATHENA PHARMACEUTIQUES

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