

COMPANY PORTFOLIO



Antibiotice,
an international company

- Manufacturer with tradition in finished dosage forms: sterile powders for injection, capsules, tablets, ointments, gels, creams, suppositories, pessaries
- Owns a complex **Hospital & Partners** portfolio of more than 30 products for hospital use – penicillins, penicillins in combination with beta-lactams inhibitors, cephalosporins and carbapenems; updated dossiers for beta-lactam products
- Leading worldwide manufacturer of **Nystatin API** and several finished dosage forms using Nystatin, vertically integrated
- Has developed a various portfolio of products intended to improve the **Quality of Life**: food supplements, dermato-cosmetics, products for women’s health; medicines for the health of cardiovascular, osteo-articular and digestive systems
- Plans upcoming launches of creams, ointments and pessaries with clinical trials, focused on dermatology and **Women’s Health**
- Internationally acknowledged approvals and certificates: US-FDA approval for Nystatin and sterile powders for injection, Certificate of Suitability to the European Pharmacopoeia (CoS) for Nystatin, Good Manufacturing Practice (GMP) certificate for all manufacturing sites, Good Laboratory Practice (GLP) for Bioanalytical Laboratories from Clinical Trials Center, integrated Management System
- Hosts on the site a Clinical Trial Center - a full-service Contract Research Organization (CRO), authorized by the National Agency for Medicines and Medical Devices of Romania (EU Member State), specialized in conducting phase I clinical trials and bioequivalence (BE) studies;
- 4 offices in Vietnam (Hanoi), Ukraine (Kiev), Serbia (Novi Sad), Republic of Moldavia (Chisinau);
- More than 60 products registered on different international markets



Leading Worldwide Manufacturer

NYSTATIN API

Active Pharmaceutical Ingredients



Leading Worldwide Manufacturer of Nystatin

Antifungal substance obtained by biosynthesis process using certain strains of *Streptomyces noursei* as the production micro-organism

- Certificate of Suitability from EDQM
- Food and Drug Administration Approval

Nystatin Atb

- Reference Standard confirmed by USP

Pharmaceutical forms in which Nystatin may be included:

- Oral suspensions/oral drops
- Creams/ointments
- Tablets
- Pessaries
- Capsules
- Topical powder

Humane use

Nystatin (non-micronised)

Quality: EP/USP current edition

Packing: cardboard boxes of 100 BOU Nystatin, with 2 polyethylene bags of 50 BOU each

Nystatin (micronised)

Quality: EP/USP current edition

Particle size: 90% <10 μm , 10% <15 μm

Packing: cardboard boxes of 50 BOU Nystatin, with 1 polyethylene bag of 50 BOU



Antibiotic **at**

PENICILLINS

CARBAPENEMS

CEPHALOSPORINS

Hospital and partners

GMP

FDA

The image is a dark blue advertisement for antibiotics. At the top center, the word "Antibiotic" is written in white, followed by a red logo consisting of a stylized lowercase "a" and "t". Below this, a glowing blue globe is centered, with two wireframe hands reaching towards it from the left and right. In the center of the globe, three white vials are arranged. To the left of the vials is the word "PENICILLINS" and to the right is "CARBAPENEMS". Below the vials is the word "CEPHALOSPORINS". At the bottom of the image, the text "Hospital and partners" is written in a large, white, sans-serif font. In the bottom left corner, there is a circular logo with "GMP" in the center and "GOOD MANUFACTURING PRACTICE" around the perimeter. In the bottom right corner, there is a circular logo with "FDA" in the center and "U.S. FOOD AND DRUG ADMINISTRATION" around the perimeter.

J – Antiinfectives for systemic use

No	Name of the product	Pharmaceutical form	Active substance	Packaging	File status
J01 – Antibacterials for systemic use					
1	AMOXICILLIN Atb® 250 mg	capsules	amoxicillin trihydrate	Box x 20 capsules Box x 1000 capsules	EU eCTD
2	AMOXICILLIN Atb® 500 mg	capsules	amoxicillin trihydrate	Box x 10 capsules Box x 1000 capsules	EU eCTD
3	AMOXIPLUS® 1000 mg/200 mg	powder for injection/ infusion	amoxicillin sodium + potassium clavulanate	Box x 1 vial Box x 25 vials Box x 50 vials Box x 100 vials	EU eCTD
4	AMPICILLIN Atb® 250 mg	powder for injection	ampicillin sodium	Box x 1 vial Box x 100 vials	EU eCTD
5	AMPICILLIN Atb® 500 mg	powder for injection	ampicillin sodium	Box x 1 vial Box x 50 vials Box x 100 vials	EU eCTD
6	AMPICILLIN Atb® 1000 mg	powder for injection	ampicillin sodium	Box x 1 vial Box x 10 vials Box x 50 vials Box x 100 vials	EU eCTD
7	AMPICILLIN Atb® 2000 mg	powder for injection	ampicillin sodium	Box x 1 vial Box x 10 vials Box x 50 vials Box x 100 vials	EU eCTD
8	AMPIPLUS® 1000 mg/500 mg	powder for injection/ infusion	ampicillin sodium + sulbactam sodium	Box x 1 vial Box x 25 vials Box x 50 vials	EU eCTD
9	BENZYLPENICILLIN POTASSIUM Atb® 1 000 000 IU	powder for injection	benzylpenicillin potassium	Box x 1 vial Box x 50 vials Box x 100 vials	*
10	BENZYLPENICILLIN SODIUM Atb® 400 000 IU	powder for injection	benzylpenicillin sodium	Box x 1 vial Box x 50 vials Box x 100 vials	*
11	BENZYLPENICILLIN SODIUM Atb® 1 000 000 IU	powder for injection	benzylpenicillin sodium	Box x 1 vial Box x 50 vials Box x 100 vials	*
12	CEFALEXINE Atb® 250 mg	capsules	cefalexin monohydrate	Box x 20 capsules Box x 1000 capsules	**
13	CEFALEXINE Atb® 500 mg	capsules	cefalexin monohydrate	Box x 10 capsules Box x 1000 capsules	**
14	CEFORAN® 500 mg	capsules	cefadroxil monohydrate	Box x 10 capsules Box x 1000 capsules	**
15	CEFORT® 250 mg	powder for injection/ infusion	ceftriaxone sodium	Box x 1 vial Box x 10 vials Box x 50 vials Box x 100 vials	**

* Dossier with limited production and/or regulatory support

** Dossier available for some territories

J – Antiinfectives for systemic use

No	Name of the product	Pharmaceutical form	Active substance	Packaging	File status
J01 – Antibacterials for systemic use					
16	CEFORT® 500 mg	powder for injection /infusion	ceftriaxone sodium	Box x 1 vial Box x 10 vials Box x 50 vials Box x 100 vials	**
17	CEFORT® 1 g	powder for injection /infusion	ceftriaxone sodium	Box x 1 vial Box x 10 vials Box x 50 vials	**
18	CEFORT® 2 g	powder for injection /infusion	ceftriaxone sodium	Box x 1 vial Box x 10 vials Box x 50 vials Box x 100 vials	**
19	CEFOTAXIME Atb® 1 g	powder for injection /infusion	cefotaxime sodium	Box x 1 vial Box x 10 vials	**
20	CEFTAMIL® 1 g	powder for injection /infusion	ceftazidime pentahydrate	Box x 1 vial Box x 10 vials Box x 50 vials	**
21	CEFTAMIL® 2 g	powder for injection /infusion	ceftazidime pentahydrate	Box x 1 vial Box x 10 vials Box x 50 vials	**
22	CEFUROXIME Atb® 750 mg	powder for suspension (im) /injection (iv)	cefuroxime sodium	Box x 1 vial Box x 10 vials Box x 100 vials	**
23	CEFUROXIME Atb® 1.5 g	powder for suspension (im) /injection (iv)	cefuroxime sodium	Box x 1 vial Box x 10 vials Box x 100 vials	**
24	COLISTIN Atb® 1 000 000 IU	powder for injection /infusion	colistimethate sodium	Box x 1 vial Box x 50 vials Box x 100 vials	in-licensing
25	EFICEF® 100 mg	capsules	cefixime	Box x 10 capsules Box x 1000 capsules	**
26	EFICEF® 200 mg	capsules	cefixime	Box x 10 capsules Box x 1000 capsules	EU eCTD
27	ERTAPENEM Atb® 1 g	powder for concentrate for solution for infusion	ertapenem sodium	Box x 10 vials	in-licensing
28	FLUCLOXACILLIN Atb® 500 mg	powder for injection /infusion	flucloxacillin sodium	Box x 1 vial Box x 10 vials	EU eCTD
29	FLUCLOXACILLIN Atb® 1000 mg	powder for injection /infusion	flucloxacillin sodium	Box x 1 vial Box x 10 vials	EU eCTD
30	IMIPENEM/CILASTATIN Atb® 500 mg/500 mg	powder for infusion	imipenem monohydrate + cilastatin sodium	Box x 1 vial Box x 5 vials Box x 10 vials	in-licensing
31	LEVOFLOXACIN Atb® 250 mg	film coated tablets	levofloxacin	Box x 10 tablets	EU eCTD

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** Dossier available for some territories

J – Antiinfectives for systemic use

No	Name of the product	Pharmaceutical form	Active substance	Packaging	File status
J01 – Antibacterials for systemic use					
32	LEVOFLOXACIN Atb® 500 mg	film coated tablets	levofloxacin	Box x 10 tablets	EU eCTD
33	MEROPENEM Atb® 500 mg	powder for injection /infusion	meropenem trihydrate	Box x 1 vial Box x 10 vials Box x 50 vials	in-licensing
34	MEROPENEM Atb® 1000 mg	powder for injection /infusion	meropenem trihydrate	Box x 1 vial Box x 10 vials Box x 50 vials	in-licensing
35	MOLDAMIN® 1200000 IU	powder for suspension for injection	benzathine benzylpenicillin	Box x 1 vial Box x 10 vials Box x 50 vials	**
36	NAFCILLIN 1 g	powder for injection	nafcillin sodium	Box x 10 vials	US eCTD
37	NAFCILLIN 2 g	powder for injection	nafcillin sodium	Box x 10 vials	US eCTD
38	OXACILLIN Atb® 500 mg	powder for injection /infusion	oxacillin sodium monohydrate	Box x 1 vial Box x 50 vials Box x 100 vials	*
39	OXACILLIN Atb® 1 g	powder for injection /infusion	oxacillin sodium monohydrate	Box x 1 vial Box x 50 vials Box x 100 vials	*
40	PERASIN® 2 g/0.25 g	powder for infusion	piperacillin sodium + tazobactam sodium	Box x 1 vial Box x 10 vials	EU eCTD
41	PERASIN® 4 g/0.5 g	powder for infusion	piperacillin sodium + tazobactam sodium	Box x 1 vial Box x 10 vials	EU eCTD
42	ROCLARIN® 500 mg	film coated tablets	clarithromycin	Box x 20 tablets	**
43	TIGECYCLINE Atb® 50 mg	powder for infusion	tigecycline	Box x 1 vial Box x 10 vials	in-licensing

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** Dossier available for some territories

Antibiotice **at**

DERMATOCOSMETICS

FOOD SUPPLEMENTS

WOMEN'S HEALTH



ANTIINFLAMMATORIES

CARDIOVASCULAR

Quality of life



A – Alimentary tract and metabolism

No	Name of the product	Pharmaceutical form	Active substance	Packaging	File status
A06 – Drugs for constipation					
1	GLYCEROL SUPPOSITORIES for adults	suppositories	glycerol	Box x 6 suppositories Box x 12 suppositories	**
2	GLYCEROL SUPPOSITORIES for children	suppositories	glycerol	Box x 6 suppositories Box x 12 suppositories	**
A07 – Antidiarrheals, intestinal antiinflammatory / antiinfective agents					
1	NYSTATIN Atb® 500 000 IU	film coated tablets	nystatin	Box x 20 tablets Box x 1500 tablets	**

B – Blood and blood forming organs

No	Name of the product	Pharmaceutical form	Active substance	Packaging	File status
B01 – Antithrombotic agents					
1	ROMPIRIN® E 100 mg	gastro-resistant film coated tablets	acetylsalicylic acid	Box x 20 tablets Box x 50 tablets Box x 1500 tablets	EU CTD Bibliographical Application

C - Cardiovascular System

No	Name of the product	Pharmaceutical form	Active substance	Packaging	File status
C03 – Diuretics					
1	INDAPAMIDE Atb® 1.5 mg	prolonged release tablets	indapamide	Box x 30 tablets	EU eCTD
C04 - Peripheral vasodilators					
1	NICERGOLINE Atb® 30 mg	film coated tablets	nicergoline	Box x 30 tablets	EU eCTD
C07 – Beta Blocking Agents					
1	BISOTENS® 5 mg	film coated tablets	bisoprolol fumarate	Box x 30 tablets	EU eCTD
2	BISOTENS® 10 mg	film coated tablets	bisoprolol fumarate	Box x 30 tablets	EU eCTD
3	GLADYCOR® 6.25 mg	tablets	carvedilol	Box x 30 tablets	EU eCTD
4	GLADYCOR® 12.5 mg	tablets	carvedilol	Box x 30 tablets	EU eCTD
5	GLADYCOR® 25 mg	tablets	carvedilol	Box x 30 tablets	EU eCTD
6	NOLET® 5 mg	tablets	nebivolol hydrochloride	Box x 30 tablets	EU eCTD

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** Dossier available for some territories

C - Cardiovascular System

No	Name of the product	Pharmaceutical form	Active substance	Packaging	File status
C08 - Calcium channel blockers					
1	ALMACOR® 5 mg	tablets	amlodipine besilate	Box x 30 tablets	**
2	ALMACOR® 10 mg	tablets	amlodipine besilate	Box x 30 tablets	**
C09 - Agents acting on the Renin-Angiotensin System					
1	CANDESARTAN Atb® 8 mg	tablets	candesartan cilexetil	Box x 30 tablets	EU eCTD
2	CANDESARTAN Atb® 16 mg	tablets	candesartan cilexetil	Box x 30 tablets	EU eCTD
3	LISINOPRIL Atb® 10 mg	tablets	lisinopril dihydrate	Box x 20 tablets Box x 30 tablets	EU eCTD
4	LISINOPRIL Atb® 20 mg	tablets	lisinopril dihydrate	Box x 10 tablets Box x 30 tablets	EU eCTD
5	LISINOPRIL Atb® 40 mg	tablets	lisinopril dihydrate	Box x 10 tablets Box x 30 tablets	EU eCTD
6	RAMIPRIL Atb® 2.5 mg	tablets	ramipril	Box x 30 tablets	EU eCTD
7	RAMIPRIL Atb® 5 mg	tablets	ramipril	Box x 30 tablets Box x 60 tablets Box x 90 tablets	EU eCTD
8	RAMIPRIL Atb® 10 mg	tablets	ramipril	Box x 30 tablets Box x 60 tablets Box x 90 tablets	EU eCTD
C10 - Lipid modifying agent					
1	ROSUVASTATIN Atb® 5 mg	film coated tablets	rosuvastatin calcium	Box x 30 tablets	EU eCTD
2	ROSUVASTATIN Atb® 10 mg	film coated tablets	rosuvastatin calcium	Box x 30 tablets	EU eCTD
3	ROSUVASTATIN Atb® 20 mg	film coated tablets	rosuvastatin calcium	Box x 30 tablets	EU eCTD
4	ROSUVASTATIN Atb® 40 mg	film coated tablets	rosuvastatin calcium	Box x 30 tablets	EU eCTD

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** Dossier available for some territories

D - Dermatologicals

No	Name of the product	Pharmaceutical form	Active substance	Packaging	File status
D01 – Antifungals for dermatological use					
1	CLOTRIMAZOLE Atb® 10 mg/g	cream	clotrimazole	Box x 1 tube x 15 g Box x 1 tube x 35 g	EU eCTD Under upgrade Q2 2021
D06 – Antibiotics and chemotherapeutics for dermatological use					
1	CICATROL® 10 mg/g	cutaneous paste	silver sulfadiazine	Box x 1 tube x20 g Box x 1 tube x 50 g Box x 1 tube x 100 g	**
D07 – Corticosteroids, dermatological preparations					
1	EKARZIN® 0.5 mg/g	cream	betamethasone dipropionate	Box x 1 tube x 15 g	*
2	CLO-EKARZIN® 0.50 mg/10 mg/g	cream	clotrimazole + betamethasone dipropionate	Box x 1 tube x 15 g	*
3	CLOBETASOL Atb® 0.50 mg/g	cream	clobetasol propionate	Box x 1 tube x 25 g	EU eCTD Under upgrade Q3 2022
4	CLOBETASOL Atb® 0.50 mg/g	ointment	clobetasol propionate	Box x 1 tube x 25 g	EU eCTD Under upgrade Q4 2021
5	FLUOCINOLONE N Atb® 0.25 mg/5 mg/g	ointment	fluocinolone acetonide + neomycin sulfate	Box x 1 tube x 18 g	*
6	MOMETASONE Atb® 1 mg/g	cream	mometasone furoate	Box x 1 tube x 15 g	EU eCTD Under upgrade Q1 2023
7	MOMETASONE Atb® 1 mg/g	ointment	mometasone furoate	Box x 1 tube x 15 g	*
8	NIDOFLOR®	cream	nystatin + neomycin sulfate + triamcinolone acetonide	Box x 1 tube x 15 g	*
9	SAL-EKARZIN® 0.50 mg/30 mg/g	ointment	betamethasone dipropionate + salicylic acid	Box x 1 tube x 15 g	*

G - Genito-urinary system and sex hormones

No	Name of the product	Pharmaceutical form	Active substance	Packaging	File status
G01 – Gynecological antiinfectives and antiseptics					
1	NYSTATIN Atb® 100 000 IU	pessaries	nystatin	Box x 7 pessaries Box x 14 pessaries	* Bibliographical Application
2	ZIFEX® DUO	pessaries	metronidazole + clotrimazole	Box x 7 pessaries Box x 14 pessaries	* Bibliographical Application EU eCTD Under upgrade Q3 2021
3	ZIFEX® COMPLEX	pessaries	nystatin + neomycin sulfate + metronidazole + hydrocortisone acetate	Box x 7 pessaries Box x 14 pessaries	* Bibliographical Application

* Dossier with limited production and/or regulatory support

** Dossier available for some territories

J – Antiinfectives for systemic use

No	Name of the product	Pharmaceutical form	Active substance	Packaging	File status
J04 – Antimycobacterials					
1	CYCLOSERINE Atb® 250mg	capsules	cycloserine	Box x 50 capsules Box x 100 capsules	in-licensing
2	ETHAMBUTOL Atb® 250mg	film coated tablets	ethambutol hydrochloride	Box x 20 tablets Box x 1500 tablets	**
3	ETHAMBUTOL Atb® 400mg	film coated tablets	ethambutol hydrochloride	Box x 20 tablets Box x 1500 tablets	**
4	ETHIONAMIDE Atb® 250 mg	film coated tablets	ethionamide	Box x 100 tablets	in-licensing
5	ISONIAZID Atb® 100 mg	tablets	isoniazid	Box x 20 tablets Box x 1500 tablets	**
6	ISONIAZID Atb® 300 mg	tablets	isoniazid	Box x 30 tablets Box x 1500 tablets	**
7	PYRAZINAMIDE Atb® 500 mg	tablets	pyrazinamide	Box x 20 tablets Box x 1500 tablets	**
8	SINERDOL® ISO	capsules	rifampicin + isoniazid	Box x 10 capsules Box x 1000 capsules	**
9	SINERDOL® 150 mg	capsules	rifampicin	Box x 20 capsules Box x 1000 capsules	**
10	SINERDOL® 300 mg	capsules	rifampicin	Box x 10 capsules Box x 1000 capsules	**

M – Musculo-skeletal system

No	Name of the product	Pharmaceutical form	Active substance	Packaging	File status
M01A – Antiinflammatory and antirheumatic products, non-steroids					
1	ACECLOFEN®	suppositories	paracetamol + diclofenac sodium	Box x 6 suppositories Box x 12 suppositories	EU eCTD Under upgrade Q2 2021
2	CLAFEN® 100 mg	suppositories	diclofenac sodium	Box x 6 suppositories Box x 12 suppositories	**
M02 – Topical products for joint and muscular pain					
1	CLAFEN® 10 mg/g	gel	diclofenac sodium	Box x 1 tube x 40 g Box x 1 tube x 100 g	
2	CLAFEN® 50 mg/g	gel	diclofenac sodium	Box x 1 tube x 25 g Box x 1 tube x 45 g Box x 1 tube x 100 g	

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** Dossier available for some territories

N – Nervous system

No	Name of the product	Pharmaceutical form	Active substance	Packaging	File status
N02 – Analgesics					
1	PARACETAMOL Atb® 125 mg	suppositories	paracetamol	Box x 6 suppositories Box x 12 suppositories	
2	PARACETAMOL Atb® 250 mg	suppositories	paracetamol	Box x 6 suppositories Box x 12 suppositories	
N07- Other nervous system drugs					
1	BETAHISTINE Atb® 8 mg	tablets	betahistine dihydrochloride	Box x 30 tablets	EU eCTD
2	BETAHISTINE Atb® 24 mg	tablets	betahistine dihydrochloride	Box x 30 tablets	EU eCTD

V03AB – Antidotes

No	Name of the product	Pharmaceutical form	Active substance	Packaging	File status
1	POTASSIUM IODIDE Atb® 65 mg	tablets	potassium iodide	Box x 30 tablets	**

Food supplements

No	Name of the product	Pharmaceutical form	Active substance	Packaging
1	EQUILIBRA®	capsules	magnesium + pyridoxine hydrochloride	Box x 60 capsules
2	FEZIVIT C®	capsules	ascorbic acid + iron + zinc lactate dihydrate	Box x 10 capsules Box x 30 capsules Box x 60 capsules
3	FLUXIV®	tablets	ascorbic acid + troxerutin + diosmine + hesperidine	Box x 60 tablets
4	IMUNOFIX®	tablets	Organic vitamin C (as Hibiscus sabdariffa flower extract standardized in at least 5% Vitamin C) Echinacea aerial part extract (Echinacea purpurea) standardized in at least 4% polyphenols Echinacea root extract (Echinacea angustifolia) standardized in at least 4% echinacosides Zinc dihydrate lactate	Box x 10 tablets Box x 30 tablets Box x 60 tablets
5	LEJER®	capsules	Senna leaf extract (Cassia senna) standardized in at least 20% sennosides Rhubarb root extract (Rheum palmatum) standardized in at least 5% rhein Ginger root extract (Zingiber officinale) standardized in at least 5% gingerols Organic vitamin C (as Hibiscus sabdariffa flower extract standardized in at least 5% vitamin C)	Box x 10 capsules Box x 30 capsules Box x 60 capsules

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** Dossier available for some territories

Food supplements

No	Name of the product	Pharmaceutical form	Active substance	Packaging
6	SILITHOR®	capsules	silybum + methionine + L-cysteine	Box x 60 capsules
7	SORISO®	tablets	rhodiola rosea ("golden root") + ocimum basilicum (basil)	Box x 60 tablets
8	SORISO Activ®	capsules	Polygonum cuspidatum root extract, standardized in at least 50% trans-resveratrol Ginkgo biloba leaf extract standardized in at least 24% flavonoid glycosides and 6% terpene lactones Vitamin B6 (pyridoxine hydrochloride)	Box x 10 capsules Box x 30 capsules Box x 60 capsules
9	SORISO Memo®	capsules	Guarana seeds extract (Paullinia cupana) standardized in at least 22% caffeine Niacine L-glutamine Taurine Tryptophan	Box x 10 capsules Box x 30 capsules Box x 60 capsules
11	SPRINTEN®	tablets	chondroitin sulfate sodium + ascorbic acid + zinc lactate dihydrate + glucosamine sulfate potassium chloride + hyaluronic acid (sodium salt)/sodium hyaluronate	Box x 60 tablets Box x 20 tablets

Cosmetic products

No	Name of the product	Pharmaceutical form	Active substance	Packaging
1	CUTADEN®	cream	zinc oxide + ichthammol + hamamelis virginiana extract	Box x 1 tube x 40 g
2	CUTADEN® Bebe	cream	zinc oxide + ichthammol + titanium dioxide + Vital ET™	Box x 1 tube x 40 g
3	FLUXIV®	cream	troxerutin + d-panthenol	Box x 1 tube x 40 g Box x 1 tube x 100 g
4	TINERO®	gel	nicotinamide	Box x 1 tube x 40 g Box x 1 tube x 100 g

DISCLAIMER: These products cannot be supplied into countries in which their use and/or commercialization may be in conflict with existing IP rights of a third party.

In any event, any use and/or commercialization in breach of the above will be made under your sole and/or the final buyer's responsibility (as the case may be) and you will keep us fully indemnified and harmless from any claims and consequences arising out of such commercialization, use and breach.

Pipeline

J – Antiinfectives for systemic use

No	Name of the product	Pharmaceutical form	Active substance	Packaging	File status
J01 – Antibacterials for systemic use					
1	AMPIPLUS® 3 g	powder for solution for injection/infusion	ampicilin sodium, sulbactam sodium	Box x 1 vial Box x 10 vials Box x 25 vials	Q4 2019
2	EFICEF® 400 mg	capsules	cefixime	Box x 10 capsules	Q3 2020
3	LINEZOLID Atb® 600 mg	film-coated tablets	linezolid	Box x 10 tablets	Q4 2021

A – Alimentary tract and metabolism

No	Name of the product	Pharmaceutical form	Active substance	Packaging	File status
A02 – Drugs for acid related disorders					
1	OMEPRAZOL Atb® 20 mg	gastro-resistant capsules	omeprazole	Box x 10 capsules	Q3 2019

D - Dermatologicals

No	Name of the product	Pharmaceutical form	Active substance	Packaging	File status
N01 – Anesthetics, local					
1	PRILOCAINE/LIDOCAINE 25 mg/25 mg/ g	cream	prilocaine, lidocaine hydrochloride	Box x 1 tube x 5 g Box x 1 tube x 30 g	Q4 2022
D06 – Dermatologicals, antibiotics for topical use					
2	NEOMICINE/ZINC BACITRACINE 5000 IU/250 IU/ g	ointment	neomycin sulfate + bacitracin zinc	Box x 1 tube x 20 g	Q3 2019 Bibliographical application

* Dossier with limited production and/or regulatory support

** Dossier available for some territories

G – Genito-urinary system and sex hormones

No	Name of the product	Pharmaceutical form	Active substance	Packaging	File status
N01 – Anesthetics, local					
1	ZIFEX TRIO	pessaries	metronidazole, nystatin, neomycin sulfate	Box x 7 pessaries Box x 14 pessaries	Q1 2021

M – Musculo-skeletal system

No	Name of the product	Pharmaceutical form	Active substance	Packaging	File status
M01 – Antiinflammatory and antirheumatic products					
1	NAPROXEN/ESOMEPRAZOLE 500 mg/20 mg	modified-release tablets	naproxen sodium, esomeprazole magnesium	Box x 10 tablets	Q1 2022
M02 – Topical products for joint and muscular pain					
2	DICLOFENAC DIETHYLAMINE 11.6 mg/g	gel	diclofenac diethylamine	Box x 1 tube x 40 g	Q4 2019

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** Dossier available for some territories

Antibiotice **at**

DERMATOCOSMETICS

ANTIINFECTIVES

GYNECOLOGICAL

Women's
Health



Clinical Trials Center

The Clinical Trials Center (CTC) is a full service Contract Research Organization (CRO), authorized by National Agency for Medicines and Medical Devices of Romanian (EU Member State), specialized in conducting phase I clinical trials and bioequivalence (BE) studies.

For more than 15 years, many generic companies successfully succeed to register their products all over the world, using our knowledge and the studies developed and conducted on our site.

CTC benefits of a fully integrated organizational structure in one site, comprised from:

- GCP inspected Clinical Unit - 32 beds;
- GLP authorized Analytical Unit - state-of-the-art laboratory equipment and technologies;
- GMP authorized IMP secondary packaging flow - certified flow for packaging and labeling of investigational medicinal products.

Client-oriented CRO

We offer facilities and services for conducting Phase I clinical trials and bioequivalence/bioavailability studies across a broad spectrum of therapeutic areas:

- we offer expert advice (scientific, regulatory) on biopharmaceutics data requirements and expectations of the regulatory agencies
 - we provide a multidisciplinary highly – skilled and dedicated team, adaptable for the needs and expectation of the clients providing innovative and high – quality services, with integrity and reliability
 - we provide Quality Guarantee through the Internal Quality Assurance and Control Units developing well-designed set of Standard Operating Procedures (SOPs) and ensuring that the conduct of clinical trials is according to ICH, Integrated Management System (ISO 9001, ISO 14001, OHSAS 18001), Good Clinical and Laboratory Practice guidelines and Helsinki Declaration



Medical writing and Study Management

- Clinical Project management
- Protocol development
- Investigators brochure development
- Subject information sheets and consent forms, including local language ICFs (prepared and reviewed by the relevant country)
 - Clinical study reports according to ICH E3 and eCTD format
 - Regulatory applications and submissions to EC & regulatory authorities
 - Archiving of study essential documents and all related data.
 - Safety reporting and other pharmacovigilance activities related to the clinical studies
 - GCP monitoring and auditing



Data Management & Biostatistics

- CRF design
- Database Design and Validation
- Medical Coding
- Data Entry
- Biostatistics
- PK; PK/PD analysis



Research and Development

offers various Analytical Services, Formulation Services and Pharmaceutical Services, such as:

- Characterization of the reference drug product
- Development and validation of in-house analytical methods
- Design of pharmaceutically equivalent drug products, in different pharmaceutical forms:
 - powders for solutions/suspensions for injection (beta-lactam penicillins in low volumes)
 - semi-solid products (gel, cream, ointment)
 - suppositories and pessaries conventional
 - modified release or gastro-resistant tablets
 - hard gelation capsules
- Pilot technology for research and development
- Monitoring drug product quality through stability studies
- Design of the manufacturing process

Regulatory expertise

- Differentiated regulatory strategies for EU, USA and other countries for drug product and active substances sustained by Regulatory Affairs experts
- Full regulatory support for eCTD, NeeS and paper submission
- Multilingual packaging and labeling
- Maintenance of regulatory approvals throughout their lifecycle

Pharmacovigilance Services



Contact data

Out & In - Licensing

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Active Ingredients Export

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Dosage Forms Export

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