

# PRODUCT LIST

2023





**GENERICS FDFs**

Available Dossiers

Dossiers Under Development

Dossiers Under Consideration



**GENERICS APIs**

Available Portfolio - Malta

Available Portfolio - Spain

Under Development



**CHLORHEXIDINE AND OTHER ANTISEPTICS**

APIs

FDFs

Pharmaceutical Grade

Cosmetic Grade

Biocide Grade












## AVAILABLE DOSSIERS

MOLECULE	PHARMACEUTICAL FORM & STRENGTH	REFERENCE PRODUCT	INDICATION	DOSSIER STATUS
Apixaban	Film-coated tablets 2,5 mg, 5 mg	Eliquis® BMS/Pfizer	Stroke and systemic embolism Deep vein and thrombosis Pulmonary embolism	Approved: US, EU, UK
Captopril	Tablets 12,5 mg, 25 mg, 50 mg, 100 mg	Captopril Mylan	Hypertension Heart failure	Approved: US
Daptomycin	Powder for solution for injection or infusion in glass vial 350 mg, 500 mg	Cubicin® Merck	Skin and soft-tissue infections Endocarditis	Approved: CA, EU, UK, KR, UA, AU, ZA
Mirtazapine	Tablets 7,5 mg*, 15 mg, 30 mg, 45 mg	Remeron® Organon	Major depression	Approved: EU*, US
Prucalopride Succinate	Film-coated tablets 1 mg, 2 mg	Motegrity® Shire Resolor® Takeda	Chronic constipation	Approved: EU, UK, US filing NCE: Dec'23
Rivaroxaban	Film-coated tablets 2,5 mg, 10 mg, 15 mg, 20 mg	Xarelto® Bayer	Stroke and systemic embolism Deep vein thrombosis Pulmonary embolism	Approved: EU, CIS Filed: IL
Sugammadex Sodium	Solution for injection 200 mg / 2 ml 500 mg / 5 ml	Bridion® MSD	Reversal of neuromuscular blockade in anesthesia	Approved: EU, UK, NZ Filed: IL, MX, SEA
Sunitinib Maleate	Capsules 12,5 mg, 25 mg, 37,5 mg, 50 mg	Sutent® Pfizer	Renal carcinoma Pancreatic and stromal tumors	Approved: EU, KSA Filed: MX, JO
Thalidomide	Capsules 50 mg	Thalidomid Celgene® Celgene	Multiple myeloma	Approved: EU, UK
Tobramycin	Nebulizer solution in plastic ampoule blow-fill-seal 300 mg / 5 ml	Tobi® Novartis	Cystic fibrosis	Approved: AU, EU, UK, BR, PA, GT, NZ, US, KSA



## DOSSIERS UNDER DEVELOPMENT

MOLECULE	PHARMACEUTICAL FORM	STRENGTH	REFERENCE PRODUCT	INDICATION	DOSSIER READINESS
Calcium gluconate	Intravenous vial	100 mg/ml	Calcium gluconate® Fresenius Kabi	Treatment of acute symptomatic hypocalcemia	DMF Q2 2025
CNS long acting injectable	Subcutaneous or intramuscular injection	TBD	NA	Schizophrenia	
Esmolol	Ready-to-use plastic bags	10 mg/ml 20 mg/ml	Brevibloc® in plastic container Baxter	Supraventricular tachycardia or non-compensatory sinus tachycardia, intraoperative and postoperative tachycardia and hypertension	Q1 2025
 Fluvoxamine CR	Capsules extended release	100 and 150 mg	Luvox CR® Jazz Pharmaceuticals	Obsessive compulsive disorder	Q1 2025
 Ivacaftor	Film coated tablets	150 mg	Kalydeco® Vertex	Cystic fibrosis	Q2 2025
 Lofexidine	Film coated tablets	0,18 mg	Lucemyra® US WorldMeds	Opioid withdrawal	Q4 2024
 Revefenacin	Solution for inhalation	175 mcg / 3 ml	Yupelri® Mylan	Chronic obstructive pulmonary disease (COPD)	Already submitted on NCE-1
 Ruxolitinib hemifumarate	Tablets	5 mg, 10 mg, 15 mg, 20 mg	Jakavi® (EU) Novartis Europharm / Incyte	Myelofibrosis Polycythemia vera Graft-versus-host disease (GvHD)	Q3 2024
 Varenicline L-tartrate	Tablets	0,5 mg, 1 mg	Chantix®, Champix® Pfizer	Smoking cessation	Already submitted (EU) Ready for submission (US)
 Voclosporin	Soft gel capsules	7,9 mg	Lupkynis® Aurinia Pharmaceuticals / Otsuka Pharmaceutical	Lupus Nephritis	Q1 2025 (NCE-1)



## DOSSIERS UNDER CONSIDERATION

MOLECULE	PHARMACEUTICAL FORM	STRENGTH	REFERENCE PRODUCT	INDICATION
Amiodarone	Ready-to-use bags	1,5 mg/ml 1,8 mg/ml	Nexterone® Baxter	Ventricular fibrillation Hemodynamically unstable ventricular tachycardia
Isavuconazonium sulfate	Intravenous powder (vial)	372 mg	Cresemba® Astellas	Invasive aspergillosis mucormycosis
Lurbinectedin	Intravenous powder (vial)	4 mg	Zepzelca® PharmaMar / Jazz Pharmaceutical	Metastatic small cell lung cancer
Potassium phosphate dibasic + Potassium phosphate monobasic	Intravenous vial	236 mg/ml + 224 mg/ml	Potassium phosphates®	Source of phosphorus to correct hypophosphatemia and for parenteral nutrition
Ruxolitinib Phosphate	Cream	1,5%	Opzelura® Incyte	Atopic dermatitis and vitiligo
Sodium Phosphate dibasic heptahydrate + Sodium phosphate monobasic anhydrous	Intravenous vial	142 mg/ml + 276 mg/ml	Sodium phosphates®	Source of phosphorus to correct hypophosphatemia and for parenteral nutrition
Trabectedin	Intravenous powder (vial)	1 mg (US/EU), 0,25 mg (EU)	Yondelis® PharmaMar / Janssen	Unresectable or metastatic liposarcoma or leiomyosarcoma



## AVAILABLE PORTFOLIO - MALTA





Apixaban	Micafungin Sodium	Sugammadex Sodium
Cinacalcet HCl	Prucalopride	Sunitinib Malate
Desvenlafaxine Succinate	Rasagiline Tartrate	
Edaravone	Revefenacin	
Lofexidine	Rivaroxaban	

## AVAILABLE PORTFOLIO - SPAIN

Adapalene	Guanfacine HCl	Paroxetine HCl
Brimonidine Tartrate	Lamotrigine	Pazopanib
Captopril	Loxapine Base	Pimecrolimus
Clozapine	Loxapine Succinate	Quetiapine Fumarate
Cyclobenzaprine HCl	Mexiletine HCl	Varenicline L-tartrate
Desvenlafaxine Base	Mirtazapine	
Felodipine	Nepafenac [sterile and non sterile]	
Fluvoxamine Maleate	Olopatadine HCl	





## UNDER DEVELOPMENT

ACTIVE PHARMACEUTICAL INGREDIENT	REFERENCE PRODUCT	INDICATION	DMF READINESS
 Ivacaftor	Kalydeco® Vertex	Cystic fibrosis	DMF Q4 2024
Opicapone	Ongentys® Bial and Neurocrine Biosciences	“Off” episodes in Parkinson	DMF Q1 2024
Relugolix	Orgovyx®, Myfembree® (US) / RYEQO (EU), Myovant Sciences	Prostate cancer and uterine fibroid bleeding Pain associated with endometriosis	DMF Q2 2024
 Ruxolitinib hemifumarate	Jakavi®, Novartis	Myelofibrosis, polycythemia vera and graft-versus-host-disease	DMF Q2 2024
 Ruxolitinib phosphate	Jakafi®, Novartis	Myelofibrosis, polycythemia vera Graft-versus-host-disease	DMF Q2 2025
Tezacaftor	Symdeko® (US) and Symkevi® (EU) Vertex	Cystic fibrosis	DMF Q1 2027
 Voclosporin	Lupkynis® Aurinia Pharmaceuticals and Otsuka Pharmaceutical	Lupus Nephritis	DMF Q2 2024



## UNDER CONSIDERATION

ACTIVE PHARMACEUTICAL INGREDIENT	REFERENCE PRODUCT	INDICATION
Amikacin	Arikayce kit <sup>®</sup> Insmed/PARI Pharma	Mycobacterium avium complex lung disease
Buprenorphine	Brixadi <sup>®</sup> , Butrans <sup>®</sup> and Sublocade <sup>®</sup> Braeburn, Purdue Pharma and Indivior	Opioid use disorder and pain management
Cenobamate	Xcopri <sup>®</sup> (US) and Ontozry <sup>®</sup> (EU) SK Biopharmaceuticals (US) and Angelini (EU)	Partial-onset seizures
 Elexacaftor	Trikafta <sup>®</sup> (US) and Kaftrio <sup>®</sup> (EU) Vertex	Cystic fibrosis
Encorafenib	Braftovi <sup>®</sup> Array (US) and Pierre Fabre (EU)	Unresectable or metastatic melanoma and metastatic colorectal cancer
Levoketoconazole	Recorlev <sup>®</sup> Strongbridge	Endogenous hypercortisolemia in adults with Cushing's syndrome
 Lumacaftor	Orkambi <sup>®</sup> Vertex	Cystic fibrosis
Lorlatinib	Lorbrena <sup>®</sup> (US) and Lorviqua <sup>®</sup> (EU) Pfizer	Metastatic non-small cell lung cancer
Lumateperone tosylate	Caplyta <sup>®</sup> Intra-Cellular Therapies and Bristol Myers Squibb	Schizophrenia and depressive episodes associated with bipolar disorders
Naltrexone	Vivitrol <sup>®</sup> Alkermes	Alcohol and opioid dependence
Naloxone hydrochloride	Kloxxado <sup>®</sup> , Narcan <sup>®</sup> Rextovy <sup>®</sup> , Rivive <sup>®</sup> Hikma, Emergent, Amphastar Pharms, Harm reduction therap	Opioid overdose
Potassium phosphates	Potassium phosphates <sup>®</sup>	Source of phosphorous when oral or enteral replacement is not possible, insufficient or contraindicated
Rimegepant sulphate	Nurtec <sup>®</sup> ODT (US) and Vydura <sup>®</sup> (EU) Pfizer and Biohaven	Migraine
Sodium phosphates	Sodium phosphates <sup>®</sup> , Hospira	Correction or prevention of hypophosphatemia in patients with restricted or no oral intake
Vibegron	Gemtesa <sup>®</sup> Urovant	Overactive bladder
Zanubrutinib	Brukinsa <sup>®</sup> BeiGene	Mantle cell lymphoma, Waldenström's macroglobulinemia, refractory marginal zone mymphoma, chronic lymphocytic leukemia and small lymphocytic lymphoma





# CHLORHEXIDINE AND OTHER ANTISEPTICS

APIs

## API - ANTISEPTICS - AVAILABLE

Chlorhexidine Base		Chlorhexidine Diacetate	CEP
Chlorhexidine Digluconate 20% Solution	CEP	Chlorhexidine Dihydrochloride	CEP
Octenidine Dihydrochloride	DMF		

## FDFs - PHARMACEUTICAL GRADE

### CHLORHEXIDINE DIGLUCONATE - AVAILABLE DOSSIERS

PRODUCT	STRENGTH	FORMATS AVAILABLE	
Hydroalcoholic solution Transparent	0,50%	Plastic bottles	30 ml, 100 ml, 250 ml More formats on request

### CHLORHEXIDINE DIGLUCONATE - UNDER DEVELOPMENT DOSSIERS


PRODUCT	STRENGTH	FORMATS AVAILABLE	
Hydroalcoholic solution Coloured	0,50%	Plastic bottles	30 ml, 100 ml, 250 ml More formats on request
Hydroalcoholic solution Transparent and coloured	2%	Plastic bottles	30 ml, 100 ml, 250 ml More formats on request



# CHLORHEXIDINE AND OTHER ANTISEPTICS

## FDFs - PHARMACEUTICAL GRADE


### OCTENIDINE DIHYDROCHLORIDE - UNDER DEVELOPMENT DOSSIERS

PRODUCT	STRENGTH	FORMATS AVAILABLE		REFERENCE PRODUCT	DOSSIER READINESS
 <b>Spray</b>	2% phenoxyethanol + 0,1% octenidine	Plastic bottles	50 ml, 250 ml and 1.000 ml	Octenisept®	Q1 2024
<b>Combination of two active ingredients</b>	TBD		Gel	NA	2028



## FDFs - COSMETIC GRADE

### OCTENIDINE DIHYDROCHLORIDE - UNDER DEVELOPMENT DOSSIERS

PRODUCT	FORMATS AVAILABLE		INDICATION	DOSSIER READINESS
 <b>Cream</b>	Bottle with pump biodegradable	500 ml	Coadyudant for atopic dermatitis	Product file ready for notification



# CHLORHEXIDINE AND OTHER ANTISEPTICS

## FDFs - BIOCIDES GRADE

### CHLORHEXIDINE DIGLUCONATE - AVAILABLE DOSSIERS

PRODUCT	STRENGTH	FORMATS AVAILABLE	
<b>Hydroalcoholic solution</b> Transparent and coloured	2% 0,50%	Plastic bottles	60 ml, 75 ml, 100 ml, 125 ml, 250 ml, 500 ml More formats on request
<b>Aqueous solution</b>	2% 0,50%		Blow-fill-seal ampoules and plastic bottles
<b>Wipes</b> Aqueous Alcoholic	2%	Individual sachet Flow pack of 8 wipes Individual sachet	20 x 20 cm, 6 x 7 cm
<b>Hand scrub</b> Transparent	4%	HDPE bottles with dosing pump	20 ml, 500 ml, 1000 ml

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