

# 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

## 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
 Spray	2% phenoxyethanol + 0,1% octenidine	Plastic bottles	50 ml, 250 ml and 1.000 ml	Octenisept®	Q1 2024
Combination of two active ingredients	TBD		Gel	NA	2028



## FDFs - COSMETIC GRADE

### OCTENIDINE DIHYDROCHLORIDE - UNDER DEVELOPMENT DOSSIERS

PRODUCT	FORMATS AVAILABLE		INDICATION	DOSSIER READINESS
 Cream	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%	Plastic bottles	60 ml, 75 ml, 100 ml, 125 ml, 250 ml, 500 ml
	0,50%		More formats on request
<b>Aqueous solution</b>	2%	Blow-fill-seal ampoules and plastic bottles	Single dose (10 ml), 60 ml, 75 ml, 100 ml, 125 ml, 250 ml, 500 ml
	0,50%		10 ml, 60 ml, 75 ml
<b>Wipes</b>			
Aqueous	2%	Individual sachet Flow pack of 8 wipes	20 x 20 cm, 6 x 7 cm
Alcoholic		Individual sachet	
<b>Hand scrub</b> Transparent	4%	HDPE bottles with dosing pump	20 ml, 500 ml, 1000 ml



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