

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 thrombosis and 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	Resotrans® Janssen Resolor® Shire	Chronic constipation	Approved: EU and 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 and 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
Axitinib	Film coated tablets	1 mg, 5 mg	Inlyta®	Advance renal cell carcinoma	(US only) Q4 2023
HP Dexmedetomidine	Infusion bag	4 mcg/ml	Precedex® Pfizer	Sedation of patients during treatment in intensive care	Ready for submission
⬡ Edaravone	Solution for infusion	30 mg / 100 ml 60 mg / 100 ml	Radicava® Mitsubishi Tanabe	Amyotrophic lateral sclerosis	Ready for submission
⬡ Fluvoxamine XR	Capsules extended release	100 and 150 mg	Luvox XR	Obsessive compulsive disorder	Q1 2025
⬡ Ivacaftor	Film coated tablets	150 mg	Kalydeco®	Cystic fibrosis	Q2 2025
⬡ Lofexidine	Film coated tablets	0,18 mg	Lucemyra®	Opioid withdrawal	Q1 2024
⬡ Revefenacin	Solution for inhalation	175 mcg / 3 ml	Yupelri® Mylan	Chronic obstructive pulmonary disease (COPD)	Already submitted on NCE-1
⬡ Ruxolitinib	Tablets	5 mg, 10 mg, 15 mg, 20 mg	Jakavi® (EU)	Myelofibrosis, polycythemia vera	Q3 2024
⬡ Varenicline L-tartrate	Tablets	0,5 mg, 1 mg	Chantix®, Champix® Pfizer	Smoking cessation	Ready for submission
⬡ Voclosporin	Soft gel capsules	7,9 mg	Lupkynis®	Lupus Nephritis	Q1 2025 (NCE-1)



DOSSIERS UNDER CONSIDERATION

MOLECULE	PHARMACEUTICAL FORM	STRENGTH	REFERENCE PRODUCT	INDICATION
Amiodarone	Intravenous injection	150 mg/ml, 360 mg/200 ml	Nexterone	Ventricular fibrillation and hemodynamically unstable ventricular tachycardia
Esmolol	Intravenous injection	2 gm/100 ml, 1 gm/100 ml	Brevibloc in plastic container	Supraventricular tachycardia or non-compensatory sinus tachycardia and intraoperative and postoperative tachycardia and hypertension
Isavuconazonium sulfate	Intravenous powder	372 mg	Cresemba	Invasive aspergillosis and mucormycotic
Lurbinectedin	Intravenous powder	4 mg/vial	Zepzelca	Metastatic small cell lung cancer
Remifentanil	Intravenous powder	1,2, 5 mg	Ultiva (EU)	Anesthesia/analgesia
Trabectedin	Intravenous powder	1 mg/vial, 0,25 mg/vial	Yondelis	Unresectable or metastatic liposarcoma or leiomyosarcoma
CNS long acting injectable	Subcutaneous or intramuscular injection	TBD	NA	Schizophrenia
Ruxolitinib Phosphate	Cream	1,5%	Opzelura	Atopic dermatitis



AVAILABLE PORTFOLIO - MALTA






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

AVAILABLE PORTFOLIO - SPAIN




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



UNDER DEVELOPMENT

ACTIVE PHARMACEUTICAL INGREDIENT	REFERENCE PRODUCT	INDICATION	DMF READINESS
 Ivacaftor	Kalydeco®	Cystic fibrosis	DMF Q4 2024
Opicapone	Ongentys®	“Off” episodes in Parkinson	DMF Q3 2023
Relugolix	Orgovyx®	Prostate cancer and uterine fibroid bleeding	DMF Q1 2024
 Revefenacin	Yupelri®, Theravance Biopharma	Chronic obstructive pulmonary disease (COPD)	Available for Reference
 Ruxolitinib hemifumarate	Jakafi®, Novartis	Myelofibrosis, polycythemia vera	DMF Q2 2024
 Ruxolitinib phosphate	Jakafi®, Novartis	Myelofibrosis, polycythemia vera	DMF Q2 2024
 Voclosporin	Lupkynis®	Lupus Nephritis	DMF Q1 2024

UNDER CONSIDERATION

ACTIVE PHARMACEUTICAL INGREDIENT	REFERENCE PRODUCT	INDICATION
 Elexacaftor	Trikafta® (US) and Kaftrio® (EU)	Cystic fibrosis
 Lumacaftor	Orkambi®	Cystic fibrosis
 Tezacaftor	Symdeko® (US) and Symkevi® (EU)	Cystic fibrosis



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
Spray	2% phenoxyethanol + 0,1% octenidine	Plastic bottles	50 ml	Octenisept



FDFs - COSMETIC GRADE

OCTENIDINE DIHYDROCHLORIDE - UNDER DEVELOPMENT DOSSIERS

PRODUCT	FORMATS AVAILABLE		INDICATION
Cream	Bottle with pump biodegradable	500 ml	Coadyudant for atopic dermatitis



CHLORHEXIDINE AND OTHER ANTISEPTICS

FDFs - BIOCIDES GRADE

CHLORHEXIDINE DIGLUCONATE - AVAILABLE DOSSIERS

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

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