



# PRODUCT LIST

2024

## GENERICs FDFs

Available Dossiers

Dossiers Under Development

Dossiers Under Consideration

## GENERICs APIs

Available Portfolio - Malta

Available Portfolio - Spain

Under Development

Under Consideration

## CHLORHEXIDINE AND OTHER ANTISEPTICS

APIs

FDFs

Biocide Grade

Pharmaceutical Grade

Cosmetic Grade





## AVAILABLE DOSSIERS

MOLECULE	PHARMACEUTICAL FORM	STRENGTH	REFERENCE PRODUCT	INDICATION	DOSSIER READINESS
Apixaban	Film-coated tablets	2,5 mg, 5 mg	Eliquis® BMS/Pfizer	Stroke and systemic embolism Deep vein and thrombosis Pulmonary embolism	Approved: CIS, EU, UK, US, SW, TH Filed: IL
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 Filed: MENA, US
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, FWA, IQ Filed: ESA, MX
Sugammadex Sodium	Solution for injection	200 mg / 2 ml 500 mg / 5 ml	Bridion® MSD	Reversal of neuromuscular blockade in anesthesia	Approved: EU, EC, HN, IL, UK, MX, NZ Filed: CA, KSA, PH, UAE, VN
Sunitinib Maleate	Capsules	12,5 mg, 25 mg, 37,5 mg, 50 mg	Sutent® Pfizer	Renal carcinoma Pancreatic and stromal tumors	Approved: EU, KSA, PE Filed: JO, MX, PE
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 Filed: AE, JO
Varenicline L-tartrate	Tablets	0,5 mg, 1 mg	Chantix®, Champix® Pfizer	Smoking cessation	Approved: AU, EU Filed: US



DOSSIERS UNDER DEVELOPMENT

MOLECULE	PHARMACEUTICAL FORM	STRENGTH	REFERENCE PRODUCT	INDICATION	DOSSIER READINESS
<b>Solid Dosage Form:</b>					
Fluvoxamine CR	Capsules extended release	100 and 150 mg	Luvox CR® Jazz Pharmaceuticals	Obsessive compulsive disorder	Q2 2025
Ivacaftor	Film coated tablets	150 mg	Kalydeco® Vertex	Cystic fibrosis	Q3 2025
Lofexidine	Film coated tablets	0,18 mg	Lucemyra® US WorldMeds	Opioid withdrawal	Q4 2024
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
Voclosporin	Soft gel capsules	7,9 mg	Lupkynis® Aurinia Pharmaceuticals / Otsuka Pharmaceutical	Lupus Nephritis	Q1 2025 (NCE-1)
<b>Liquid Dosage Form:</b>					
Calcium Gluconate	Intravenous plastic vials	100 mg/ml	Calcium gluconate® Fresenius Kabi	Treatment of acute symptomatic hypocalcemia	Q1 2026
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	Q4 2025
Potassium Phosphate, Dibasic; Potassium Phosphate, Monobasic	Intravenous plastic vial	236 mg/mL + 224 mg/mL	POTASSIUM PHOSPHATES®, Fresenius Kabi	Phosphorus replacement indicated as a source of phosphorus in intravenous fluids to correct hypophosphatemia and for parenteral nutrition	Q1 2026
Sodium Phosphate, Dibasic, Heptahydrate; Sodium Phosphate, Monobasic, Anhydrous	Intravenous plastic vial	142 mg/mL + 276 mg/mL	SODIUM PHOSPHATES®, Hospira	Source of phosphorus, for addition to large volume intravenous fluids, to prevent or correct hypophosphatemia. Also used as an additive for parenteral fluid	Q1 2026
Revefenacin	Solution for inhalation	175 mcg / 3 ml	Yupelri® Mylan	Chronic obstructive pulmonary disease (COPD)	Already submitted on NCE-1 (Nov 22)
<b>Innovation:</b>					
CNS long acting injectable	Subcutaneous or intramuscular injection	TBD	NA	Bipolar disorders	2028



DOSSIERS UNDER CONSIDERATION

MOLECULE	PHARMACEUTICAL FORM	STRENGTH	REFERENCE PRODUCT	INDICATION
<b>Solid Dosage Form:</b>				
Deutivacaftor + Tezacaftor + Vanzacaftor	Film-coated tablets	TBD	“Vanza triple”, Vertex	Cystic fibrosis
Elacestrant	Film-coated tablets	86 mg and 345 mg	Orserdu® Stemline Therapeutics	Breast cancer
Ivacaftor + Tezacaftor + Elexacaftor	Film-coated tablets	75/50/100 mg & 37.5/25/50 mg	Trikafta® (US) and Kaftrio® (EU) Vertex	Cystic fibrosis
Suvorexant	Tablet	5 mg, 10 mg, 15 mg & 20 mg	Belsomra® Merck & Co	Treatment of insomnia
<b>Liquid Dosage Form:</b>				
Cangrelor	Intravenous powder (vial)	50 mg/mL	Kengreal® (US) and Kengrexal® (EU) Chiesi	Adjunct to percutaneous coronary intervention
Casimersen	Vial	50 mg/mL	Amondys 45® Sarepta	Duchenne muscular dystrophy
Cupric Sulfate + Manganese Sulfate + Selenious Acid + Zinc Sulfate	Vial	0.3mg/ml (cupric sulfate) + 55mcg/ml (manganese sulfate) + 60mcg/ml (selenious acid) + 3mg/ml (Zinc sulfate)	Tralement®, AM Reagent	Source of zinc, copper, manganese, and selenium
Dalbavancin	Intravenous powder (vial)	500 mg	Dalvance®, Abbvie	Skin infections
Etelcalcetide	Vial	5 mg/mL	Parsabiv® Amgen	Secondary hyperparathyroidism
Inclisiran	Pre-filled syringes	189 mg/mL	Leqvio® Novartis	Primary hyperlipidemia
Isavuconazonium Sulfate	Intravenous powder (vial)	372 mg	Cresemba® Astellas	Invasive aspergillosis & mucormycosis



DOSSIERS UNDER CONSIDERATION

MOLECULE	PHARMACEUTICAL FORM	STRENGTH	REFERENCE PRODUCT	INDICATION
<b>Liquid Dosage Form:</b>				
Iron Ferric Carboxymaltose	Vial	50 mg/mL (2, 10, 15 & 20 ml vial)	Injectafer® / AM Regent (Daiichi) Ferinject® / CSL (Vifor)	Iron-deficiency anemia
Iron Ferric Derisomaltose	Vial	100 mg/mL (1, 5 & 10 ml vial)	Monover® / Monoferric® Pharmacosmos	Iron-deficiency anemia
Iron Ferric Sucrose	Vial	20 mg/mL (2.5, 5 & 10 ml vial)	Venofer® AM Regent (Daiichi) Ferrologic® Fresenius	Iron-deficiency anemia
Lanreotide Acetate	Pre-filled sryinge	60 mg/0,2 ml; 90 mg/0,3 ml; 120 mg/0,5 ml	Somatuline depot®, Ipsen	Acromegaly & gastrointestinal tumors
Lenacapavir Sodium	Pre-filled sryinge & Film-coated tablets	309 mg/ml (1,5 ml) & 300 mg	Sunleca®, Gilead Sciences	VIH
Trilaciclib	Intravenous powder (vial)	300 mg/mL	Cosela® G1 Therapeutics / Boehringer Ingelheim	Chemotherapy-induced bone marrow suppression
Triptorelin Pamoate	Intravenous powder (vial) & pre-filled sryinge	3,75 mg; 11,25 mg & 22,5 mg	Trelstar®, Verity	Prostate cancer
<b>Topical Dosage Form:</b>				
Ruxolitinib Phosphate	Cream	1.5%	Opzelura® Incyte	Atopic dermatitis and vitiligo
<b>Innovation:</b>				
High-dose oncological	Film-coated tablets	400 mg	NA	Leukemia







## AVAILABLE PORTFOLIO - MALTA






Apixaban	Micafungin Sodium	Rivaroxaban
Desvenlafaxine Succinate	Prucalopride	Sugammadex Sodium
Edaravone	Rasagiline Tartrate	Sunitinib Maleate
Lofexidine	Revefenacin	

## AVAILABLE PORTFOLIO - SPAIN

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



## UNDER DEVELOPMENT

ACTIVE PHARMACEUTICAL INGREDIENT	REFERENCE PRODUCT	INDICATION	DMF READINESS
Elacestrant	Orserdu® Stemline Therapeutics	Metastatic breast cancer	Q3 2026
Elexacaftor	Trikafta® (US) and Kaftrio® (EU) Vertex	Cystic fibrosis	Q1 2028
 Ivacaftor	Kalydeco® Vertex	Cystic fibrosis	Q4 2024
Opicapone	Ongentys® Bial and Neurocrine Biosciences	“Off” episodes in Parkinson	Q4 2024
Relugolix	Orgovyx®, Myfembree® (US) / Ryeqo® (EU), Myovant Sciences	Prostate cancer and uterine fibroid bleeding Pain associated with endometriosis	Q2 2024
 Ruxolitinib Hemifumarate	Jakavi®, Novartis	Myelofibrosis, polycythemia vera and graft-versus-host-disease	Q3 2024
 Ruxolitinib Phosphate	Jakafi®, Novartis	Myelofibrosis, polycythemia vera Graft-versus-host-disease	Q3 2025
Sitagliptin	Januvia® / Janument® / Janumet XR®, Merck & Co	Type 2 diabetes mellitus	Q3 2026
 Tezacaftor	Symdeko® (US) and Symkevi® (EU) Vertex	Cystic fibrosis	Q1 2027
 Voclosporin	Lupkynis® Aurinia Pharmaceuticals and Otsuka Pharmaceutical	Lupus Nephritis	US DMF filed





## UNDER CONSIDERATION

ACTIVE PHARMACEUTICAL INGREDIENT	REFERENCE PRODUCT	INDICATION
Deucravacitinib	Sotyktu® Bristol-Myers Squibb	Plaque psoriasis
 Deutivacaftor	“Vanza triple”, Vertex	Cystic fibrosis
Fezolinetant	Veozah® Astellas Pharma	Vasomotor symptoms due to menopause
Lonafarnib	Zokinvy®, Sentynt therapeutic	Progeria
Olodaterol Hydrochloride	Striverdi respimat®, Boehringer Ingelheim	Chronic obstructive pulmonary disease
Selexipag	Uptravi®, Actelion	Pulmonary hypertension
Suvorexant	Belsomra®, Merck & Co	Insomnia
 Vanzacaftor	“Vanza triple”, Vertex	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 - 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 More formats on request
	0,50%		
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 10 ml, 60 ml, 75 ml
	0,50%		
Wipes Aqueous	2%	Individual sachet	20 x 20 cm, 6 x 7 cm
		Flow pack of 8 wipes	
Alcoholic		Individual sachet	
Hand scrub Transparent	4%	HDPE bottles with dosing pump	20 ml, 500 ml, 1000 ml



# CHLORHEXIDINE AND OTHER ANTISEPTICS

## FDFs - PHARMACEUTICAL GRADE

### CHLORHEXIDINE DIGLUCONATE - AVAILABLE DOSSIERS

PRODUCT	STRENGTH	FORMATS AVAILABLE		REFERENCE PRODUCT	DOSSIER READINESS
Hydroalcoholic solution Transparent	2%	Plastic bottles	30 ml, 100 ml, 250 ml More formats on request		Submitted Q3 2023
Hydroalcoholic solution Transparent	0,50%	Plastic bottles	30 ml, 100 ml, 250 ml More formats on request		Approved: NL

### CHLORHEXIDINE DIGLUCONATE - UNDER DEVELOPMENT DOSSIER

PRODUCT	STRENGTH	FORMATS AVAILABLE		REFERENCE PRODUCT	DOSSIER READINESS
Hydroalcoholic solution Coloured	2%	Plastic bottles	30 ml, 100 ml, 250 ml More formats on request		
Hydroalcoholic solution Coloured	0,50%	Plastic bottles	30 ml, 100 ml, 250 ml More formats on request		

### OCTENIDINE DIHYDROCHLORIDE - UNDER DEVELOPMENT DOSSIERS

PRODUCT	STRENGTH	FORMATS AVAILABLE		REFERENCE PRODUCT	DOSSIER READINESS
Combination of two active ingredients	TBD		Gel	NA	2028



# CHLORHEXIDINE AND OTHER ANTISEPTICS

## FDFs - COSMETIC GRADE

### OCTENIDINE DIHYDROCHLORIDE - AVAILABLE 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
<b>Spray</b>	2% phenoxyethanol + 0,1% octenidine	Plastic bottles	50 ml, 250 ml and 1.000 ml	Octenisept®	Submitted (Feb 2024)





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