

# Product List

2026



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## Available Dossiers

## FDFs

Molecule	Pharmaceutical form	Strength	Reference product	Indication	Dossier readiness
 Apixaban	Film-coated tablets	2.5 mg, 5 mg	Eliquis®, BMS / Pfizer	Prevention of stroke and systemic embolism Treatment of Deep Vein Thrombosis and Pulmonary embolism and prevention of recurrence	Approved: CIS, EU, SW, TH, UK, US, RUS, 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: AU, CA, EU, KR, UA, UK, ZA
 Lofexidine	Film-coated tablets	0.18 mg	Lucemyra®, US WorldMeds	Opioid withdrawal	Ready to file: US
 Mirtazapine	Film-coated 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+012 Resolor®, Takeda	Chronic constipation	Approved: EU, UK, US Filed: MENA
 Revefenacin	Solution for inhalation	175 mcg/3 mL	Yupelri®, Mylan	Chronic obstructive pulmonary disease (COPD)	Filed: 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



## Available Dossiers

## FDFs

Molecule	Pharmaceutical form	Strength	Reference product	Indication	Dossier readiness
 Ruxolitinib Hemifumarate	Tablets	5 mg, 10 mg, 15 mg, 20 mg	Jakavi® (EU), Novartis Europharm / Incyte	Myelofibrosis Polycythemia vera Graft-versus-host disease (GvHD)	Approved: EU (NO, NL, MT, DK) Filed: EU (rest of EU in process), TR, CA, RS
 Sugammadex Sodium	Solution for injection	200 mg/2 mL, 500 mg/5 mL	Bridion®, MSD	Reversal of neuromuscular blockade in anesthesia	Approved: EU, HN, IL, MX, NZ, UK, SG, PH Filed: CA, KSA, UAE, VN
 Sunitinib Malate	Capsules	12.5 mg, 25 mg, 3.5 mg, 50 mg	Sutent®, Pfizer	Renal carcinoma Pancreatic and stromal tumors	Approved: EU, KSA, PE Filed: JO, MX
Thalidomide	Capsules	50 mg	Thalidomid Celgene®, Celgene	Multiple myeloma	Approved: EU, UK
Tobramycin	Vial	300 mg/5 mL	Tobi®, Viatris	Chronic lung infections due to Pseudomonas aeruginosa in patients with cystic fibrosis	Approved: AU, BR, EU, GT, KSA, NZ, UK, US
 Varenicline L-tartrate	Tablets	0.5 mg, 1 mg	Chantix®, Champix®, Pfizer	Smoking cessation	Approved: AU, EU Filed: US
 Voclosporin	Soft gel capsules	7.9 mg	Lupkynis®, Aurinia Pharmaceuticals / Otsuka Pharmaceutical	Lupus Nephritis	Filed: US



## Dossiers Under Development

# FDFs

Molecule	Pharmaceutical form	Strength	Reference product	Indication	Dossier readiness	Unique selling proposition
<b>Solid Dosage Form:</b>						
Abemaciclib	Film-coated tablets	50, 100, 150 & 200 mg (US) 50, 100 & 150 mg (EU)	Verzenio® (US) / Verzenios® (EU), Eli Lilly	Breast cancer	Q4 2028	Fully EU and US development
Darolutamide	Tablets	300 mg	Nubeqa®, Bayer	Prostate cancer	Q4 2030	VI and EU supplier before LoE, Form I, Alternative Formulation & Specific particle characteristics
Elacestrant	Film-coated tablets	86 mg, 345 mg	Orserdu®, Stemline Therapeutics	Breast cancer	2027	IP advantage, complex
Ivacaftor	Film-coated tablets	75 mg, 150 mg	Kalydeco®, Vertex	Cystic fibrosis	Q2 2026 (EU) Q3 2026 (US)	IP advantage, complex, spray drying technology
Osimertinib mesylate	Tablets	40 mg and 80 mg	Tagrisso®, AstraZeneca	Non-small cell lung cancer (NSCLC)	Q3 2028	IP advantage
<b>Liquid Dosage Form:</b>						
Amiodarone	Bags	150 mg/100 mL 360 mg/200 mL	Nexterone®, Baxter	Nausea or Vomiting	Q4 2027	
Calcium Gluconate	Intravenous plastic vial	100 mg/mL	Calcium gluconate, Fresenius Kabil	Treatment of acute symptomatic hypocalcemia	Q4 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	Q1 2027	IP advantage



## Dossiers Under Development

# FDFs

Molecule	Pharmaceutical form	Strength	Reference product	Indication	Dossier readiness	Unique selling proposition
<b>Liquid Dosage Form:</b>						
Inclisiran	Pre-filled syringe	189 mg/mL	Leqvio®, Novartis	Primary hyperlipidemia	Q3 2028	Complex
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	Q4 2026	
Sodium Phosphate, Dibasic, Heptahydrate; Sodium Phosphate, Monobasic, Anhydrous	Intravenous plastic vial	4.02 gm/15 mL; 4.14 gm/15 mL (268 mg/mL; 276 mg/mL)	Sodium Phosphates in plastic container, Hospira	Source of phosphorus, for addition to large volume intravenous fluids, to prevent or correct hypophosphatemia. Also used as an additive for parenteral fluid	Q4 2026	
<b>Topical Dosage Form:</b>						
Ruxolitinib Phosphate	Cream	1.5%	Opzelura®, Incyte	Atopic dermatitis and vitiligo	Q3 2028	Complex
<b>Innovation:</b>						
CNS long acting injectable	Subcutaneous or intramuscular injection	TBD	NA	Bipolar disorders	Q2 2028	IP advantage, complex
Gynecological product	Bags	30 IU/500 mL	NA	Women's health	Q4 2028	IP advantage, complex



## Dossiers Under Consideration

## FDFs

Molecule	Pharmaceutical form	Strength	Reference product	Indication
Solid Dosage Form:				
Atrasentan	Tablets	0.75 mg	Vanrafia®, Chinook/Novartis	IgA Nephropathy
Belzutifan	Tablets	40 mg	Welireg® MSD	Renal Cell Carciroma and Other Malignencies
Camizestrant	TBD	TBD	No brand name registered yet, AstraZeneca	Breast cancer
Elinzanetant	Soft-gel capsules	60 mg	Lynkuet®, Bayer	Moderate to severe vasomotor symptoms associated with menopause
Enlicitide	Tablets	20 mg	No brand name registered yet, MSD	Dyslipidemias
Giredestrant	Tablets	30 mg	No brand name registered yet, Roche	Breast Cancer
Ivacaftor + Tezacaftor + Elexacaftor	Film-coated tablets	75/50/100 mg, 37.5/25/50 mg	Trikafta® (US) / Kaftrio® (EU), Vertex	Cystic fibrosis
Obefazimod	TBD	TBD	No brand name registered yet, Abivax	Imflamatory Bowel Disease
Orforglipron	TBD	TBD	No brand name registered yet, Eli Lilly	Chronic weight management and Type II diabetes
Palazestrant	Tablets	90 mg, 120 mg	No brand name registered yet, Olema Oncology	Breast Cancer



## Dossiers Under Consideration

## FDFs

Molecule	Pharmaceutical form	Strength	Reference product	Indication
<b>Liquid Dosage Form:</b>				
Cangrelor	Intravenous powder (vial)	50 mg/mL	Kengreal® (US) / Kengrexal® (EU), Chiesi	Adjunct to percutaneous coronary intervention
Iron Ferric Derisomaltose	Vial	100 mg/mL (1, 5 & 10 mL vial)	Monover® / Monoferric®, Pharmacosmos	Iron-deficiency anemia
Landiolol	Lyophilized vial	280 mg/vial	Rapiblyk® AOP Orphan	
 Added-value product	PFS	EQ 500 mg Base/5 mL (100 mg Base/mL) EQ 200 mg Base/2 mL (100 mg Base/mL)	NA	Medical Procedures (not otherwise classified): Reversal of neuromuscular blockade



# Available Portfolio

# APIs

API	Indication	IP advantage	EU-DMF/CEP	US-DMF	CN-DMF	BR-DMF	JP-DMF
Adapalene	Acne vulgaris		✓	✓ (AfR)	⚡	⚡	⚡
⬡ Apixaban	Stroke and systemic embolism Deep vein and thrombosis Pulmonary embolism		✓	✓ (AfR)	✓	⚡	⚡
Brimonidine Tartrate	Glaucoma and ocular hypertension Rosacea erythema		✓ (CEP)	✓ (AfR)	⚡	⚡	⚡
⬡ Captopril	Hypertension Heart failure			✓ (AfR)			
Cinacalcet HCl	Hypercalcemia in hyperparathyroidism and parathyroid carcinoma		✓	✓ (AfR)	⚡	⚡	⚡
Clozapine	Schizophrenia		✓ (CEP)	✓ (AfR)	⚡	⚡	✓
Cyclobenzaprine HCl	Muscle relaxant			✓ (AfR)			
Desvenlafaxine Base	Major depression		⚡	⚡	⚡	⚡	⚡
Desvenlafaxine Succinate	Major depression		⚡	✓ (AfR)	⚡	⚡	⚡
Edaravone	Amyotrophic lateral sclerosis (ALS)		⚡	✓ (AfR)	⚡	⚡	⚡
Felodipine	High blood pressure (hypertension)		✓ (CEP)	✓ (AfR)	⚡	⚡	⚡
Fluvoxamine	Obsessive compulsive disorder			✓			
Guanfacine HCl	Attention deficit hyperactivity disorder (ADHD)		⚡	✓ (AfR)	✓	⚡	⚡
⬡ Ivacaftor	Cystic fibrosis	✓	⚡	✓ (AfR)	⚡	⚡	⚡
Lamotrigine	Epilepsy Bipolar disorder			✓			
⬡ Lofexidine	Opioid withdrawal		⚡	✓ (AfR)	⚡	⚡	⚡
Loxapine Base	Schizophrenia		✓	✓	⚡	⚡	⚡
Loxapine Succinate	Schizophrenia		✓	✓ (AfR)	⚡	⚡	⚡
Mexiletine HCl	Ventricular arrhythmias		⚡	✓ (AfR)	⚡	⚡	⚡
Micafungin Sodium	Candidemia, acute disseminated candidiasis and other invasive Candida infections		✓	✓ (AfR)	⚡	✓ (CADIFA)	⚡
⬡ Mirtazapine	Major depression		✓ (CEP)	✓ (AfR)			

⚡ Available for filing    ✓ Filed    ⬡ Vertically integrated [API / FDF]



# Available Portfolio

# APIs

API	Indication	IP advantage	EU-DMF/CEP	US-DMF	CN-DMF	BR-DMF	JP-DMF
Nepafenac Sterile	Ocular inflammation and pain associated with cataract surgery		Available for filing	✓ (AfR)	✓	Available for filing	Available for filing
Nepafenac Non Sterile	Ocular inflammation and pain associated with cataract surgery		Available for filing	✓ (AfR)	Available for filing	Available for filing	Available for filing
Olopatadine HCl	Allergic rhinoconjunctivitis		✓	✓ (AfR)	Available for filing	Available for filing	Available for filing
Opicapone	Ongentys®, Bial and Neurocrine Biosciences	✓	Available for filing				
Paroxetine HCl	Major depression, obsessive-compulsive, social anxiety, panic and posttraumatic stress disorders		✓ (CEP)	✓ (AfR)	✓	Available for filing	Available for filing
Pazopanib	Metastatic renal cell cancer		Available for filing	✓ (AfR)	Available for filing	Available for filing	Available for filing
Pimecrolimus	Atopic dermatitis		Available for filing	✓ (AfR)	Available for filing	Available for filing	Available for filing
Prucalopride Succinate	Chronic constipation		✓	✓ (AfR)	Available for filing	Available for filing	Available for filing
Quetiapine Fumarate	Bipolar disorder and schizophrenia		✓ (CEP)	✓ (AfR)	✓	✓	Available for filing
Rasagiline Tartrate	Parkinson		✓	Available for filing	Available for filing	Available for filing	Available for filing
Relugolix	Advanced prostate cancer		Available for filing				
Revefenacin	Chronic obstructive pulmonary disease (COPD)		Available for filing	✓ (AfR)	Available for filing	Available for filing	Available for filing
Rivaroxaban	Stroke and systemic embolism Deep vein thrombosis Pulmonary embolism		✓ (CEP)	✓ (AfR)	✓	Available for filing	Available for filing
Ruxolitinib Hemifumarate	Jakavi®, Novartis	✓	✓	Available for filing	Available for filing	Available for filing	Available for filing
Sugammadex Sodium	Reversal of neuromuscular blockade in anesthesia		✓	✓ (AfR)	✓	Available for filing	✓
Sunitinib Malate	Renal carcinoma Pancreatic and stromal tumors		✓	✓ (AfR)	✓	Available for filing	Available for filing
Varenicline L-Tartrate	Smoking cessation		✓	✓ (AfR)	✓	Available for filing	Available for filing
Voclosporin	Lupus nephritis		Available for filing	✓ (AfR)	Available for filing	Available for filing	Available for filing

Available for filing  
 Filed  
 Vertically integrated [API / FDF]



## Under Development

# APIs

Active pharmaceutical ingredient	Reference product	Indication	DMF readiness	Unique selling proposition
 Abemaciclib	Verzenio® (US) / Verzenios® (EU), Eli Lilly	Breast cancer	Q2 2027	
 Darolutamide	Nubeqa®, Bayer	Prostate cancer	Q2 2028	VI and EU supplier before LoE, Form I Alternative Formulation Specific particle characteristics
 Elexacaftor	Trikafta® (US) / Kaftrio® (EU), Vertex	Cystic fibrosis	Q4 2027	
Ruxolitinib Phosphate	Jakavi®, tablets and oral solution (EU) / Jakafi®, tablets (US), Opzelura® (EU/US)	Myelofibrosis, polycythemia vera and Graft-versus-host-disease	Q4 2027	Enzymatic route
Sitagliptin phosphate	Januvia® / Janument® / Janumet XR® Merck & Co	Type 2 diabetes mellitus	Q3 2026	Enzymatic route
 Tezacaftor	Symdeko® (US) / Symkevi® (EU), Vertex	Cystic fibrosis	Q4 2026	Spray drying technology



## Under consideration

## APIs

Active pharmaceutical ingredient	Reference product	Indication
Atrasentan	Vanrafia®, Chinook/Novartis	IgA Nefropathy
Belzutifan	Welireg®, Merck	Renal cell carcinoma and other malignancies
Camizestrant	No Brand name yet, AstraZeneca	Breast cancer
Enlicitide	No Brand name yet, Merck	Dyslipidemias
Elinzanetant	Lynkuet®, Bayer	Moderate to severe vasomotor symptoms associated with menopause
Gedatolisib	No Brand name yet, Celcuity/Pfizer	Breast cancer
Giredestrant	No Brand name yet, Genentech/Roche	Breast cancer
Landiolol	Rapiblyk®, AOP Orphan	Supraventricular Tachycardia
Obefazimod	No Brand name yet, Abivax	Inflammatory bowel diseases
Orforglipron	No Brand name yet, Eli Lilly	Chronic weight management and Type II diabetes
Palazestran	No Brand name yet, Olema Oncology	Breast cancer



# Antiseptics

## APIs

### API - Antiseptics - Available

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

## FDFS - biocide 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
	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	
Hand scrub Transparent	4%	HDPE bottles with dosing pump	20 mL, 500 mL, 1000mL



# Antiseptics

## FDFs - pharmaceutical grade

### Octenidine dihydrochloride - Under Development 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			
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 - Available dossiers

Product		Formats available		Indication	Dossier readiness
Spray	2% phenoxyethanol + 0.1% octenidine	Plastic bottles	1.000 mL	Octenisept®	Submitted (Feb 2024)



# Antiseptics

## FDFs - cosmetic grade

Octenidine dihydrochloride - available dossiers

Product	Formats available		Reference product	Dossier readiness
Cream	Bottle with pump biodegradable	500 mL	Coadyudant for atopic dermatitis	Product file ready for notification





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