

P O R T F O L I O
2021





GENERIC S

API, FDF, HPAPI & INTERMEDIATES

RELIABLE

Paying attention to every step of development, manufacturing and delivery, time and again.

CUSTOMER ORIENTED

Understanding the needs of our customers now and in the future, this is the foundation for mutual success.

QUALITY-DRIVEN

Aiming at the highest quality standards and with an unparalleled regulatory track record.






FIRST TO MARKET

Our customers' priority, hence our primary supply chain objective and IP strategy.

MADE WITH CARE



GENERICS FDF

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: ANDA, EU
 Captopril	Tablets 12.5 mg, 25 mg, 50 mg, 100 mg	Captopril Mylan	Hypertension Heart failure	Approved: ANDA
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, UK Filed: ZA
 Mirtazapine	Tablets 7.5, 15, 30 and 45 mg	Remeron® Organon	Major depression	Approved: EU Filed: US
 Prucalopride Succinate	Film-coated tablets 1 mg, 2 mg	Resotrans® Janssen Resolor® Shire	Chronic constipation	Approved: EU and UK, ANDA filing NCE: Dic'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




 Vertically integrated [API / FDF]

AVAILABLE DOSSIERS




MOLECULE	PHARMACEUTICAL FORM & STRENGTH	REFERENCE PRODUCT	INDICATION	DOSSIER STATUS
Sodium Oxybate	Oral Solution in bottle 300 mg/ml	Xyrem® UCB Pharma	Narcolepsy	Approved: EU
 Sugammadex Sodium	Solution for injection 200 mg / 2 ml 500 mg / 5 ml	Bridion® MSD	Reversal of neuromuscular blockade in anesthesia	Approved: EU Filed: KR, IL, MX, NZ
 Sunitinib Malate	Capsules 12.5 mg, 25 mg, 37.5 mg, 50 mg	Sutent® Pfizer	Renal carcinoma, pancreatic and stromal tumors	Approved: EU, MENA
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, BR, PA, GT, NZ, UK, US

GENERIC S FDF


DOSSIERS UNDER DEVELOPMENT

	MOLECULE	PHARMACEUTICAL FORM	STRENGTH	REFERENCE PRODUCT	INDICATION	DOSSIER READINESS
HP	Dexmedetomidine	Infusion bag	4 mcg/ml	Precedex® Pfizer	Sedation of patients during treatment in intensive care	Q4 2021
	Edaravone	Solution for infusion	30 mg / 100 ml 60 mg / 100 ml	Radicava® Mitsubishi Tanabe	Amyotrophic lateral sclerosis	Q4 2021 (NCE)
	Guanfacine HCl	Extended release tablets	1, 2, 3 and 4 mg	Intuniv® Takeda	Attention deficit hyperactivity disorder (ADHD)	Q4 2022
	Methylnaltrexone Bromide	Tablets	150 mg	Relistor® Salix Pharm.	Opioid induced constipation	Q2 2022
	Ponatinib	Film coated tablets	10, 15, 30 and 45 mg	Iclusig® Ariad	Acute lymphocytic leukemia	Q4 2024

DOSSIERS UNDER DEVELOPMENT

	MOLECULE	PHARMACEUTICAL FORM	STRENGTH	REFERENCE PRODUCT	INDICATION	DOSSIER READINESS
	Revefenacin	Solution for inhalation	175 mcg / 3 ml	Yupelri® Mylan	Chronic obstructive pulmonary disease (COPD)	Q4 2022 (NCE-1)
	Ruxolitinib	Tablets	5, 10, 15, 20 and 25 mg	Jakafi® Novartis	Myelofibrosis, polycythemia vera	Q4 2023
	Varenicline L-tartrate	Tablets	0.5 mg and 1 mg	Chantix®, Champix® Pfizer	Smoking cessation	Q4 2021

DOSSIERS UNDER CONSIDERATION

	MOLECULE	PHARMACEUTICAL FORM	STRENGTH	REFERENCE PRODUCT	INDICATION
	Axitinib	Film coated tablets	1 and 5 mg	Inlyta®	Advanced renal cell carcinoma
	Ixazomib	Hard capsules	3.3 mg, 4.3 mg and 5.7 mg	Ninlaro®	Multiple myeloma
	Tofacitinib citrate	Film coated tablets	5 and 10 mg	Xeljanz®	Rheumatoid arthritis

 Vertically integrated [API / FDF]

 High Potent

GENERICS API

AVAILABLE PORTFOLIO - MALTA

Ambrisentan	 Lofexidine New!	Saxagliptin HCl
 Apixaban	Micafungin Sodium	 Solifenacin Succinate
Cinacalcet HCl	 Prucalopride	 Sugammadex Sodium
Desvenlafaxine Succinate	 Rasagiline Tartrate	 Sunitinib Malate
 Edavarone	 Rivaroxaban	Vildagliptin

AVAILABLE PORTFOLIO - SPAIN

Adapalene

Amoxapine

Asenapine Maleate

Brimonidine Tartrate

 Captopril

Clozapine

Cyclobenzaprine HCl

Desvenlafaxine Base

Felodipine

Fluvoxamine Maleate

 Guanfacine HCl

Lamotrigine

Loxapine Base

Loxapine Succinate

Mexiletine HCl

 Mirtazapine

Nepafenac [sterile and non sterile]

Olopatadine HCl

Paroxetine HCl



Pimecrolimus

 Quetiapine Fumarate

Voriconazole



GENERICS API

UNDER DEVELOPMENT



ACTIVE PHARMACEUTICAL INGREDIENT	REFERENCE PRODUCT	INDICATION	DOSSIER READINESS
Lofexidine HCl	Lucemyra™, WorldMeds	Opioid withdrawal	DMF Q4 2022
Opicapone	Ongentys®	“Off” episodes in Parkinson	DMF Q3 2023
Pazopanib	Votrient®, Novartis	Advanced renal cell carcinoma and soft tissue sarcoma	DMF Q3 2021
 Ponatinib	Iclusig®, Ariad	Acute lymphocytic leukemia	DMF Q3 2023
Relugolix	Orgovyx®	Prostate cancer and uterine fibroid bleeding	DMF Q1 2024
 Revefenacin	Yupelri®, Theravance Biopharma	Chronic obstructive pulmonary disease (COPD)	DMF Q1 2022
Voclosporin	Lupkynis®	Lupus Nephritis	DMF Q1 2024

 Vertically integrated [API / FDF]

UNDER DEVELOPMENT

ACTIVE PHARMACEUTICAL INGREDIENT	REFERENCE PRODUCT	INDICATION	DOSSIER READINESS
 Ruxolitinib	Jakafi®, Novartis	Myelofibrosis, polycythemia vera	DMF Q2 2024
 Varenicline L-tartrate	Chantix®, Champix®, Pfizer	Smoking cessation	DMF filed

UNDER CONSIDERATION

ACTIVE PHARMACEUTICAL INGREDIENT	REFERENCE PRODUCT	INDICATION
  Ixazomib	Ninlaro®	Multiple myeloma

CHLORHEXIDINE & OTHER ANTISEPTICS

MADE WITH CARE



ANTISEPTICS - AVAILABLE

Chlorhexidine Base		Chlorhexidine Dihydrochloride	<i>CEP*</i>
Chlorhexidine Digluconate 20% Solution	<i>CEP*</i>	Octenidine Hydrochloride	<i>DMF*</i>
Chlorhexidine Diacetate	<i>CEP*</i>	<i>CEP*</i> Certificate of Suitability <i>DMF*</i> Drug Master File	

FDF - PHARMACEUTICAL GRADE

CHLORHEXIDINE DIGLUCONATE - AVAILABLE DOSSIERS

PRODUCT	STRENGTH	INDICATION	FORMATS AVAILABLE	
Hydroalcoholic solution Transparent	0.50%	Disinfection of the intact skin prior to invasive medical procedures Hygienic and pre-operative hand disinfection	Plastic bottles	30 ml, 100 ml, 250 ml More formats on request

CHLORHEXIDINE DIGLUCONATE - UNDER DEVELOPMENT DOSSIERS

Hydroalcoholic solution Coloured	0.50%	Disinfection of the intact skin prior to invasive medical procedures Hygienic and pre-operative hand disinfection	Plastic bottles	30 ml, 100 ml, 250 ml More formats on request
Hydroalcoholic solution Transparent and coloured	2%	Disinfection of the skin prior to invasive medical procedures	Plastic bottles	30 ml, 100 ml, 250 ml More formats on request

OCTENIDINE HYDRODHLORIDE - UNDER DEVELOPMENT DOSSIERS

PRODUCT	STRENGTH	INDICATION	FORMATS AVAILABLE	
Spray	2% phenoxyethanol + 0,1% octenidine	Antiseptic	Plastic bottles	50ml

FDF - BIOCIDES GRADE

CHLORHEXIDINE DIGLUCONATE - AVAILABLE DOSSIERS

PRODUCT	STRENGTH	INDICATION	FORMATS AVAILABLE	
Hydroalcoholic solution Transparent and coloured	2%	Antiseptic preoperative disinfection of the intact skin	Plastic bottles	60 ml, 75 ml, 100 ml, 125 ml, 250 ml, 500 ml More formats on request
	0.50%	Antiseptic		
Aqueous solution	2%	Antiseptic	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%	Disinfection of the intact skin Antiseptic	Individual sachet Flow pack of 8 wipes	20 x 20 cm, 6 x 7 cm
Alcoholic			Individual sachet	
Hand scrub Transparent	4%	Hygienic hand wash Disinfection of the intact skin	HDPE bottles with dosing pump	20 ml, 500 ml, 1000 ml

Products protected by valid patents are neither manufactured, nor offered for sale nor marketed in jurisdictions where such activities would constitute patent infringement. This brochure is informative only and it does not constitute any offer for sale, or be construed as representing an offer for sale. The current list only reflects the products and/or technologies that are available, under development or under consideration at Medichem, S.A., Medichem Manufacturing (Malta) Ltd. or Combino Pharm (Malta) Ltd., as applicable. Some products may be developed or produced for internal and/or experimental uses/purposes with no commercial aim. For any query or commercial request, please, refer to your contacts at Medichem, S.A., Medichem Manufacturing (Malta) Ltd. or Combino Pharm (Malta) Ltd., as applicable.

MADE WITH CARE

© Medichem – all rights reserved

www.medichem.es