MEDICHEM UNIQUE PHARMACEUTICALS AND MUCH MORE...

UPDATE: OCTOBER 2016





AVAILABLE DOSSIERS

APPROVED IN AT LEAST ONE EU COUNTRY

MOLECULE	PHARMACEUTICAL FORM	STRENGTH	REFERENCE PRODUCT	INDICATION	
Acyclovir [1][2]	Lyophilised powder for solution for infusion in glass vial	250 mg	<i>Zovirax®</i> GSK	Antiviral	
Chlorhexidine Digluconate [2] Miclorbic®	Aqueous cutaneous solution in plastic bottle and plastic ampoule blow-fill-seal	2% w/v [60 ml and 10 ml]		Antiseptic	
Other presentations under development	Alcoholic 70% v/v cutaneous solution in plastic bottle	Coloured 2% w/v 70% v/v [125 ml and 250 ml]			
Daptomycin [1] [2] MA under reg.	Powder for solution for injection or infusion in glass vial	350 mg, 500 mg	Cubicin® Novartis	Antibiotic	
Gabapentin [1]	Tablets	600 mg, 800 mg	Neurontin® Pfizer	Epilepsy	
	Capsules	100 mg, 300 mg, 400 mg			

Vertically integrated [API / FDF] [1] FDA inspection foreseen [2] US DMF [3] FDA inspected site [4] US DMF foreseen
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Linezolid	Solution for infusion in plastic bag	2 mg/ml [300 ml]	<i>Zyvoxid®</i> Pfizer	Antibiotic
 Meropenem [2] [3]	Powder for solution for injection in glass vial	500 mg, 1 g	<i>Meronem®</i> AstraZeneca	Antibiotic
Mirtazapine IR [1][2]	Film-coated tablets	15 mg, 30 mg, 45 mg	<i>Rexer®</i> Organon	Antidepressant
Pantoprazole Sodium ^[1]	Lyophilised powder for solution/infusion in glass vial	40 mg	Pantocarm® Altana Pharma	Gastrointestinal disorders
Paracetamol	Solution for infusion in glass vial	10 mg/ml [100 ml]	Perfalgan® Bristol Myers Squibb	Analgesic
Rasagiline Tartrate [1] MA Available	Tablets	1 mg	<i>Azilect®</i> Teva	Parkinson's disease
Sodium Oxybate	Oral Solution in bottle	300 mg/ml	<i>Xyrem®</i> UCB Pharma	Narcolepsy
Tobramycin ^[3]	Solution for inhalation in plastic ampoule blow-fill-seal	300 mg/5 ml	<i>Tobi®</i> Novartis	Cystic Fibrosis



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MOLECULE	PHARMACEUTICAL FORM	STRENGTH	REFERENCE PRODUCT	INDICATION	
Venlafaxine HCl IR [1] [2]	Tablets	37.5 mg, 50 mg, 75 mg	<i>Effexor</i> ® Pfizer	Antidepressant	
Zoledronic acid	Concentrate for solution for infusion in glass vial	4 mg/5 ml	Zometa® Novartis	Bisphosphonate	
	Solution ready to use in plastic bag	4 mg/100 ml			



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[2] US DMF [4] US DMF foreseen



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