

EU-CTD LIST

PRODUCT	DOSAGE FORM	STRENGTH	DOSSIER AVAILABILITY
Alogliptin	Tablet	6.25 mg , 12.5 mg, 25 mg	Q4/2020
Alogliptin + Metformin	Tablet	12.5 mg + 500 mg 12.5 mg + 1000 mg	Q1/2021
Alogliptin + Pioglitazone	Tablet	12.5 mg + 15 mg 12.5 mg + 30 mg 12.5 mg + 45 mg 25 mg + 15 mg 25 mg + 30 mg 25 mg + 45 mg	Q3/2021
Bupirone HCl	Tablet	5 mg, 10 mg	Q4/2020
Daclatasvir	Tablet	30 mg, 60 mg	Q1/2021
Dapagliflozin	Tablet	5 mg, 10 mg	Q4/2021
Dapagliflozin + Metformin	Tablet	5 mg + 850 mg 5 mg + 1000 mg	Q3/2021
Diclofenac Sodium	Transdermal Patch	140 mg 10 cm x 14 cm Patch	Q4/2021
Epinastine	Eye Drops	0.5 mg/ ml	Q2/2020
Febuxostat	Tablet	40 mg, 80 mg	Available
Flurbiprofen	Eye Drops	0.3% 0.4 ml single dose	Q2/2021
Flurbiprofen	Transdermal Patch	40 mg	Q4/2021
Indacaterol maleate + Glycopyrronium bromide	DPI	85 mcg + 43 mcg	Q3/2022
Lidocaine	Injection	1%, 2% 2 ml, 5 ml, 10 ml Ampoule	Q1/2021
Lidocaine	Transdermal Patch	700 mg 10 cm x 14 cm Patch	Q1/2021
Lidocaine + Prilocaine	Spray	150 mg/ml + 50 mg/ml 5 ml Bottle	Q4/2020
Linagliptin	Tablet	5 mg	Q3/2020
Linagliptin + Metformin	Tablet	2.5 mg + 850 mg 2.5 mg + 1000 mg	Q3/2020
Lornoxicam	Tablet	4 mg, 8 mg	Q2/2021
Moxifloxacin HCl	Tablet	400 mg	Available
Moxifloxacin HCl	Eye Drops	0.5%	Q2/2020
Netilmicin + Dexamethasone	Eye Drops	1 mg/ml + 3 mg/ml 0.3 ml single dose 5 ml multi-dose	Q4/2020
Ondansetron	Ampoule	4 mg, 8 mg	Available

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PRODUCT	DOSAGE FORM	STRENGTH	DOSSIER AVAILABILITY
Perindopril + Amlodipine + Indapamide	Tablet	2.5 mg + 0.625 mg + 5 mg 5 mg + 1.25 mg + 5 mg 5 mg + 1.25 mg + 10 mg 10 mg + 2.5 mg + 5 mg 10 mg + 2.5 mg + 10 mg	Q1/2022
Piribedil	Extended Release Tablet	50 mg	Q4/2020
Pyridostigmine Bromide	Tablet	60 mg	Q1/2021
Rotigotine	Transdermal Patch	1 mg, 2mg, 3 mg, 4 mg, 6 mg, 8 mg	Q2/2021
Silodosin	Capsule	4 mg, 8 mg	Available
Sofosbuvir	Tablet	400 mg	Q1/2021
Solifenacin + Mirabegron	Tablet	10 mg + 25 mg 10 mg + 50 mg 5 mg + 25 mg 5 mg + 50 mg	Q3/2020*
Solifenacin + Tamsulosin	Sustained Release Tablet	6 mg + 0.4 mg	Q4/2020
Sugammadex	Injection	100 mg/ml 2 ml & 5 ml vial	Q2/2021
Tadalafil	Tablet	20 mg	Q2/2020
Tadalafil	Tablet	5 mg	Q4/2020
Thioctic Acid	Tablet	600 mg	Available
Tiotropium Bromide	DPI	18 mcg	Q1/2021
Trospium	Tablet	20 mg	Q3/2020
Vardenafil	Tablet	20 mg	Available
Vardenafil	ODT	10 mg	Q3/2020
Vildagliptin	Tablet	50 mg	Available
Vildagliptin + Metformin	Tablet	50 mg + 850 mg 50 mg + 1000 mg	Q2/2021
Vortioxetine	Tablet	5 mg , 10 mg, 15 mg, 20 mg	Q2/2021

* Subject to availability of reference product

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