

General product overview

Kohne Pharma

March 2018

MA = Marketing authorisation, SDU = Single dose unit
CZ = Czech Republic, DE = Germany, NL = The Netherland, SK = Slovakia

API	Strength	Dosage form	Status of product	Dossier ready for submission	Date of submission	Time Slot	RMS	MRP/DCP possible	EU-Dossier/Format
Abiraterone	250 mg	Tablets	Development project	3Q/2018					Yes/CTD
Aprepitant	40 mg	Capsules	Development project	4Q/2018					Yes/CTD
Aprepitant	80 mg	Capsules	Development project	4Q/2018					Yes/CTD
Aprepitant	125 mg	Capsules	Development project	4Q/2018					Yes/CTD
Aprepitant	165 mg	Capsules	Development project	4Q/2018					Yes/CTD
Asenapine	5 mg	Sublingual tabs	Development project						Yes/CTD
Asenapine	10 mg	Sublingual tabs	Development project						Yes/CTD
Atomoxedin	10 mg	Capsules	Development project	1Q/2018					Yes/CTD
Atomoxedin	18 mg	Capsules	Development project	1Q/2018					Yes/CTD
Atomoxedin	25 mg	Capsules	Development project	1Q/2018					Yes/CTD
Atomoxedin	40 mg	Capsules	Development project	1Q/2018					Yes/CTD
Atomoxedin	60 mg	Capsules	Development project	1Q/2018					Yes/CTD
Atomoxedin	80 mg	Capsules	Development project	1Q/2018					Yes/CTD
Atomoxedin	100 mg	Capsules	Development project	2Q/2018					Yes/CTD
Atomoxedin	4 mg/ml	Oral solution	Development project	2Q/2018					Yes/CTD
Azelastin	0.05%	Eye drops	Dossier						Yes/CTD
Bimatoprost	0.01%	Eye drops	DCP				CZ		Yes/CTD
Bimatoprost	0.03%	Eye drops	DCP				CZ		Yes/CTD
Bimatoprost/Timolol	0.3/5 mg/ml	Eye drops	Development project						Yes/CTD
Bortezomib	1 mg	Powder for injection	Development project	4Q/2018					Yes/CTD
Bortezomib	3.5 mg	Powder for injection	Development project	4Q/2018					Yes/CTD
Brimonidin	0.2%	Eye drops	DCP				NL		Yes/CTD
Brimonidin/Timolol	2/5 mg/ml	Eye drops	Dossier						Yes/CTD
Brinzolamide	10 mg/ml	Eye drops	Development project						Yes/CTD
Brinzolamide/Brimonidin	10/2 mg/ml	Eye drops	Development project						Yes/CTD

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Bromfenac	0.9%	Eye drops	Development project						Yes/CTD
Carmellose	0.5%	Eye drops (SDU)	Dossier						Yes/CTD
Cinnarizine/Dimenhydrinate	20/40 mg	Film-coated tablets	Dossier						Yes/CTD
Dimethyl fumarat	120 mg	Capsules	Development project	2Q/2019					Yes/CTD
Dimethyl fumarat	240 mg	Capsules	Development project	2Q/2019					Yes/CTD
Dorzolamide	2%	Eye drops	DCP				NL		Yes/CTD
Dorzolamide/Timolol	20/5 mg/ml	Eye drops	DCP				CZ		Yes/CTD
Duloxetine	30 mg	Capsules	Dossier						Yes/CTD
Duloxetine	60 mg	Capsules	Dossier						Yes/CTD
Erlotinib	25 mg	Film-coated tablets	Development project	2Q/2019					Yes/CTD
Erlotinib	100 mg	Film-coated tablets	Development project	2Q/2019					Yes/CTD
Erlotinib	150 mg	Film-coated tablets	Development project	2Q/2019					Yes/CTD
Everolimus	2,5 mg	Film-coated tablets	Dossier						Yes/CTD
Everolimus	5 mg	Film-coated tablets	Dossier						Yes/CTD
Everolimus	10 mg	Film-coated tablets	Dossier						Yes/CTD
Fingolimod	0,5 mg	Capsules	Development project	4Q/2018					Yes/CTD
Fosaprepitant	150 mg	Powder for solution for injection	Development project						Yes/CTD
Fosfomycine	2 g	Granules for oral solution	Development project	3Q/2018					Yes/CTD
Fosfomycine	3 g	Granules for oral solution	Development project	3Q/2018					Yes/CTD
Gefitinib	250 mg	Film-coated tablets	Development project						Yes/CTD

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Hypromellose	3,2 mg/ml	Eye drops (SDU)	Dossier						Yes/CTD
Lacosamide	50 mg	Film-coated tablets	Dossier						Yes/CTD
Lacosamide	100 mg	Film-coated tablets	Dossier						Yes/CTD
Lacosamide	150 mg	Film-coated tablets	Dossier						Yes/CTD
Lacosamide	200 mg	Film-coated tablets	Dossier						Yes/CTD
Lacosamide	10 mg/ml	Solution for infusion	Development project	3Q/2019					Yes/CTD
Lacosamide	10 mg/ml	Syrup	Development project	3Q/2019					Yes/CTD
Latanoprost	50 µg/ml	Eye drops	Dossier						Yes/CTD
Latanoprost/Timolol	50 µg/5 mg/ml	Eye drops	DCP				CZ		Yes/CTD
Latanoprost/Timolol	50 µg/5 mg/ml	Eye drops (SDU)	Development project						Yes/CTD
Lenalidomide	2,5 mg	Capsules	Development project						Yes/CTD
Lenalidomide	5 mg	Capsules	Development project						Yes/CTD
Lenalidomide	7,5 mg	Capsules	Development project						Yes/CTD
Lenalidomide	10 mg	Capsules	Development project						Yes/CTD
Lenalidomide	15 mg	Capsules	Development project	2Q/2018					Yes/CTD
Lenalidomide	20 mg	Capsules	Development project						Yes/CTD
Lenalidomide	25 mg	Capsules	Development project						Yes/CTD
Loteprednol	0.5%	Eye drops	Development project						Yes/CTD
Lurasidone	18,5 mg	Coated tablets	Development project	2Q/2019					Yes/CTD
Lurasidone	37 mg	Coated tablets	Development project	2Q/2019					Yes/CTD
Lurasidone	74 mg	Coated tablets	Development project	2Q/2019					Yes/CTD
Macitentan	10 mg	Coated tablets	Development project	4Q/2019					Yes/CTD
Nepafenac	0.3%	Eye drops	Development project						Yes/CTD
Olanzapine	2.5 mg	Coated tablets	MA 2008 in DE						Yes/CTD
Olanzapine	5 mg	Coated tablets	MA 2008 in DE						Yes/CTD
Olanzapine	7.5 mg	Coated tablets	MA 2008 in DE						Yes/CTD
Olanzapine	10 mg	Coated tablets	MA 2008 in DE						Yes/CTD

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Olanzapine	15 mg	Coated tablets	MA 2011 in DE						Yes/CTD
Olanzapine	20 mg	Coated tablets	MA 2011 in DE						Yes/CTD
Olmesartan	5 mg	Tablets	Dossier						Yes/CTD
Olmesartan	10 mg	Tablets	Dossier						Yes/CTD
Olmesartan	20 mg	Tablets	Dossier						Yes/CTD
Olmesartan	40 mg	Tablets	Dossier						Yes/CTD
Olmesartan/Amlodipin	20/5 mg	Coated tablets	Dossier						Yes/CTD
Olmesartan/Amlodipin	40/5 mg	Coated tablets	Dossier						Yes/CTD
Olmesartan/Amlodipin	40/10 mg	Coated tablets	Dossier						Yes/CTD
Olmesartan/Amlodipin/HCT	20/5/12,5 mg	Coated tablets	Development project						Yes/CTD
Olmesartan/Amlodipin/HCT	40/5/12,5 mg	Coated tablets	Development project						Yes/CTD
Olmesartan/Amlodipin/HCT	40/5/25 mg	Coated tablets	Development project						Yes/CTD
Olmesartan/Amlodipin/HCT	40/10/12,5 mg	Coated tablets	Development project						Yes/CTD
Olmesartan/Amlodipin/HCT	40/10/25 mg	Coated tablets	Development project						Yes/CTD
Olmesartan/Chlortalidone	40	Coated tablets	Development project	2Q/2019					Yes/CTD
Olmesartan/Chlortalidone		Coated tablets	Development project	3Q/2018					Yes/CTD
Olopatadin	0.1%	Eye drops	MA in CZ, SK						Yes/CTD
Olopatadin	0.2%	Eye drops	MA in CZ, SK						Yes/CTD
Palonosetron	250 mcg	Solution for injection	Dossier						Yes/CTD
Rasagilin	1 mg	Tablets	MA in DE						Yes/CTD
Sorafenib	200 mg	Film-coated tablets	Development project	2Q/2019					Yes/CTD
Sunitinib	12,5 mg	Capsules	Development project	1Q/2019					Yes/CTD
Sunitinib	25 mg	Capsules	Development project	1Q/2019					Yes/CTD
Sunitinib	37,5 mg	Capsules	Development project	1Q/2019					Yes/CTD
Sunitinib	50 mg	Capsules	Development project	1Q/2019					Yes/CTD
Telmisartan/Amlodipin	40/5 mg	Tablets	Development project						Yes/CTD

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Telmisartan/Amlodipin	40/10 mg	Tablets	Development project						Yes/CTD
Telmisartan/Amlodipin	80/5 mg	Tablets	Development project						Yes/CTD
Telmisartan/Amlodipin	80/10 mg	Tablets	Development project						Yes/CTD
Tigecycline	50 mg/5ml	Solution for infusion	Development project	3Q/2018					Yes/CTD
Vortioxetine	5 mg	Coated tablets	Development project	2Q/2019					Yes/CTD
Vortioxetine	10 mg	Coated tablets	Development project	2Q/2019					Yes/CTD
Vortioxetine	15 mg	Coated tablets	Development project	2Q/2019					Yes/CTD
Vortioxetine	20 mg	Coated tablets	Development project	2Q/2019					Yes/CTD
Vortioxetine	20 mg/ml	Oral solution	Development project	2Q/2019					Yes/CTD