Inke

Mar. 2021

THERAPEUTIC AREA	PRODUCT	INDICATION	API MICRONIZED CEP/DMF		
Antiallergics	Loratadine <sup>p</sup>	Allergy	√ JP DMF		
Antiarrhythmics	Dronedarone <sup>P</sup>	Atrial fibrillation & general arrhythmia	DMF		
Antiasthmatics, COPD and respiratory diseases	Arformoterol tartrate <sup>P</sup> polymorph A and D	COPD		US-CN DMF	
	Formoterol fumarate	Asthma and COPD	V	CEP/US-JP-KR-CN DMF	
	Glycopyrronium bromide <sup>P</sup>	COPD		CEP/ US-CN DMF	
	Indacaterol maleate <sup>p</sup>	Asthma and COPD	$\sqrt{}$	EU/US DMF	
	Montelukast sodium <sup>p</sup>	Asthma, allergic & seasonal rhinitis		EU-JP DMF	
	Salmeterol xinafoate <sup>p</sup>	Asthma and COPD	$\sqrt{}$	CEP/ US-CN-KR DMF	
	Tiotropium Bromide	COPD	$\sqrt{}$	CEP/US-CN DMF	
	Vilanterol Trifenatate	Asthma and COPD	$\sqrt{}$	EU DMF	
	Aprepitant	Emesis		US DMF	
	Granisetron base <sup>p</sup>	Emesis		US DMF	
Antiemetics	Granisetron hydrochloride <sup>p</sup>	Emesis		CEP/ US-JP-KR DMF	
	Ondansetron base <sup>p</sup>	Emesis		EU-US DMF	
	Ondansetron hydrochloride <sup>P</sup>	Emesis		CEP/US DMF	
Antifungals	Fluconazole <sup>P</sup>	Antifungal		CEP/US-KR DMF	
	Carvedilol <sup>p</sup>	Hypertension, angina, heart failure		JP DMF	
Antihipertensive	Enalapril maleate <sup>p</sup>	Hypertension		CEP/KR DMF	
	Imidapril	Hypertension	A. Comment	EU DMF	
	Nitrendipine	Hypertension	V	CEP/DMF	
Antimigrainics	Eletriptan HBr <sup>P</sup>	Migraine	V	JP DMF	
	Rizatriptan benzoate <sup>p</sup>	Migraine	V	EU-US DMF	
	Zolmitriptan <sup>p</sup>	Migraine	V	EU-US DMF	
Antipsychotics	Asenapine maleate <sup>p</sup>	Schizophrenia and acute mania	V	JP DMF	
	Olanzapine <sup>p</sup>	Schizophrenia, psychosis		EU-US- DMF	
	Quetiapine hemifumarate P	Schizophrenia, psychosis		JP-KR DMF	
	Risperidone <sup>P</sup>	Schizophrenia, psychosis	<b>√</b>	CEP/US-KR DMF	
A - PH P P	Prasugrel base <sup>p</sup>	Prophylaxis and therapy of thrombosis		EU DMF	
Antithrombotics	Rivaroxaban	Thrombosis. Stroke		DMF	
Spasmolytic	Otilonium bromide	Irritable bowel syndrome		EU DMF	

CEP = Products with Certificate of Suitability / P = Patent applications/granted patents owned by Neuraxpharm

Listed products protected by valid patents are developed solely for purposes related to the development, preparation and submission of information to obtain a Marketing Authorization. In particular these products are under development for uses related to the activities stated in Art. 10.6 of Directive 2001/83/EC amended by the Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004, i.e. activities carried out to obtain a Marketing Authorization. None of the products are offered for sale or supplied to countries in which they could be in conflict with valid patents.

Mar. 2021

THERAPEUTIC AREA	PRODUCT	INDICATION	SAMPLES	TECHNICAL PACKAGE	VALIDATION BATCH	DMF
Antiasthmatics, COPD and respiratory diseases	Abediterol	Asthma and COPD			2023	2023
	Aclidinium bromide	COPD	√	V	V	Q3 2021
	Batefenterol	COPD			2023	2024
	Olodaterol <sup>p</sup>	COPD	√	V	V	Q2 2022
	Revefenacin	COPD			Q2 2021	Q4 2021
	Umeclidinium bromide	COPD	√	V	Q2 2021	Q4 2021
Antihipertensive	Clevidipine <sup>P</sup>	Hypertension	√	V	$\checkmark$	Q2 2021
Antiparkinson	Benserazide	Parkinson's disease		/	Q2 2021	Q1 2022
	Tetrabenazine	Huntington's disease chorea and Tardive dyskinesia	√	V	√	<b>√</b>
Antipsychotics	Olanzapine pamoate	Schizophrenia, psychosis	V	V	$\sqrt{}$	Q4 2021
	Paliperidone Palmitate	Schizophrenia, bipolar mania				
Other disorders	Tafamidis meglumine	Transthyretin amyloidosis	√	Q3/Q4 2020	V	Q3 2021
	Tolvaptan	Hyponatremia	V	V	Q2 2021	Q1 2022

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