

API PRODUCT PORTFOLIO

Jun. 2020

THERAPEUTIC AREA	PRODUCT	PRODUCT INDICATION		CEP/DMF	
Antiallergics	Loratadine ^p	Allergy	V	√ JP DMF	
Antiarrhythmics	Dronedarone ^p	Atrial fibrillation & general arrhythmia		DMF	
Antiasthmatics, COPD and respiratory diseases	Arformoterol tartrate ^P polymorph A and D	COPD		US-CN DMF	
	Formoterol fumarate	Asthma and COPD	$\sqrt{}$	CEP/US-JP-KR-CN DMF	
	Glycopyrronium bromide ^p	e ^p COPD		CEP/ US-CN DMF	
	Indacaterol maleate ^P	Asthma and COPD	$\sqrt{}$	EU/US DMF	
	Montelukast sodium ^p	Asthma, allergic & seasonal rhinitis		EU-JP DMF	
	Salmeterol xinafoate ^p	Asthma and COPD	V	CEP/ US-CN-KR DMF	
	Tiotropium Bromide	COPD	V	CEP/US-CN DMF	
Antiemetics	Granisetron base ^p	Emesis		US DMF	
	Granisetron hydrochloride ^p	Emesis		CEP/ US-JP-KR DMF	
	Ondansetron base ^p	Emesis		EU-US DMF	
	Ondansetron hydrochloride ^p	Emesis	V	CEP/US DMF	
Antifungals	Fluconazole ^p	Antifungal		CEP/US-KR DMF	
Antihipertensive	Carvedilol ^p	Hypertension, angina, heart failure		JP DMF	
	Enalapril maleate ^p	Hypertension		CEP/KR DMF	
	Imidapril	Hypertension	A	EU DMF	
	Nitrendipine	Hypertension	V	CEP/DMF	
Antimigrainics	Eletriptan HBr ^p	Migraine	V	JP DMF	
	Rizatriptan benzoate ^p	Migraine	V	EU-US DMF	
	Zolmitriptan ^P	Migraine	$\sqrt{}$	EU-US DMF	
Antipsychotics	Asenapine maleate ^p	Schizophrenia and acute mania	V		
	Olanzapine ^p	Schizophrenia, psychosis		EU-US- DMF	
	Quetiapine hemifumarate P	Schizophrenia, psychosis		JP-KR DMF	
	Risperidone ^P	Schizophrenia, psychosis	1	CEP/US-KR DMF	
Antithrombotics	Prasugrel base ^P	Prophylaxis and therapy of thrombosis		EU DMF	
	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.

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THERAPEUTIC AREA	PRODUCT	INDICATION	SAMPLES	TECHNICAL PACKAGE	VALIDATION BATCH	DMF
Antiasthmatics, COPD and respiratory diseases	Abediterol	Asthma and COPD			2023	2023
	Aclidinium bromide	COPD	√	√	Q3 2020	Q1 2021
	Batefenterol	COPD			2023	2024
	Olodaterol ^p	COPD	V	√	Q3 2020	Q1 2022
	Revefenacin	COPD			Q2 2021	Q4 2021
	Umeclidinium bromide	COPD	V	V	Q4 2020	Q3 2021
	Vilanterol	Asthma and COPD	V	√	V	Q2 2020
Antiemetics	Aprepitant	Emesis	V	V	V	Q4 2020
Antihipertensive	Clevidipine ^p	Hypertension	√	√	Q3 2020	Q2 2021
Antiparkinson	Benserazide	Parkinson's disease			Q4 2020	Q2 2021
	Tetrabenazine	Huntington's disease chorea and Tardive dyskinesia	√	V	V	Q3 2020
Antipsychotics	Olanzapine pamoate	Schizophrenia, psychosis	$\sqrt{}$	V	\checkmark	Q1 2021
	Paliperidone Palmitate	Schizophrenia, bipolar mania				
	Pipamperone	Schizophrenia	√	√	Q3 2020	Q1 2021
Antithrombotics	Apixaban ^p	Venous thromboembolism	√	√	\checkmark	V
Other disorders	Tafamidis	Transthyretin amyloidosis	V	Q3/Q4 2020	Q4 2020	Q3 2021
	Tolvaptan	Hyponatremia	V	V	Q4 2020	Q1 2022
Urologics	lmidafenacin ^p	Urinary incontinence	1	V		

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