

THERAPEUTIC AREA	PRODUCT	INDICATION	API MICRONIZED	CEP/DMF
Antiallergics	Desloratadine	Allergy	√	EU-CN DMF
	Loratadine^P	Allergy	√	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	√	CEP/US-JP-KR-CN DMF
	Glycopyrronium bromide^P	COPD	√	CEP/ US DMF
	Montelukast sodium^P	Asthma, allergic & seasonal rhinitis		EU-JP DMF
	Salbutamol sulfate	Asthma and COPD	√	
	Salmeterol xinafoate^P	Asthma and COPD	√	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	√	CEP/US DMF
Antifungals	Fluconazol^P	Antifungal		CEP/US-KR DMF
Antihypertensive	Carvedilol^P	Hypertension, angina, heart failure		JP DMF
	Enalapril maleate^P	Hypertension		CEP/KR DMF
	Imidapril	Hypertension		EU DMF
	Nitrendipine	Hypertension	√	CEP/DMF
Antimigrainics	Eletriptan HBr^P	Migraine	√	JP DMF
	Rizatriptan benzoate^P	Migraine	√	EU-US DMF
	Zolmitriptan^P	Migraine	√	EU-US DMF
Antipsychotics	Asenapine maleate^P	Schizophrenia and acute mania	√	
	Clomethiazole	Insomnia		EU DMF
	Olanzapine^P	Schizophrenia, psychosis		EU-US- DMF
	Quetiapine hemifumarate^P	Schizophrenia, psychosis		JP-KR DMF
Antithrombotics	Risperidone^P	Schizophrenia, psychosis	√	CEP/US-KR DMF
	Prasugrel base^P	Prophylaxis and therapy of thrombosis		EU DMF
Spasmolytic	Rivaroxaban	Thrombosis. Stroke		DMF
	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.

May 2019

THERAPEUTIC AREA	PRODUCT	INDICATION	SAMPLES	TECHNICAL PACKAGE	VALIDATION BATCH	DMF
Antiasthmatics, COPD and respiratory diseases	Abediterol	Asthma and COPD			Early R&D	
	Acclidinium bromide	COPD	√	Q2/Q3 2019	Q4 2019	2020
	Batefenterol	COPD			Early R&D	
	Indacaterol maleate^P	COPD	√	√	√	Q2 2019
	Olodaterol^P	COPD	Q2 2019	Q3 2019	Q1 2020	2020
	Revefenacin	COPD			Early R&D	
	Roflumilast	COPD with chronic bronchitis	√			
	Tiotropium Bromide	COPD	√	√	√	Q2/Q3 2019
	Umeclidinium bromide	COPD	√	√	Q3 2019	2019
	Vilanterol	Asthma and COPD	√	√	Q2 2019	Q4 2019
Antiemetics	Aprepitant	Emesis	√	√	√	2019
Antihypertensive	Clevidipine^P	Hypertension	√	√		
Antihyperparathyroidism	Cinacalcet	Hyperparathyroidism/Hypercalcaemia	√	√	√	
Antiparkinson	Benserazide	Parkinson's disease			Early R&D	2020
	Tetrabenazine	Huntington's disease chorea and Tardive dyskinesia	√	√	√	2019
	(+) Tetrabenazine	Huntington's disease chorea and Tardive dyskinesia	√	√		
Antipsychotics	Brexpiprazole	Schizophrenia and major depressive disorders				
	Olanzapine pamoate	Schizophrenia, psychosis	√	√	Q2 2019	2019
	Paliperidone	Schizophrenia, bipolar mania				
	Paliperidone palmitate	Schizophrenia, bipolar mania				2020
	Pipamperone	Schizophrenia			Q4 2019	2020
Antithrombotics	Apixaban^P	Venous thromboembolism	√	√	√	
Other disorders	Tafamidis	Dealy nerve damage caused by transthyretin amyloidosis			Early R&D	
	Tolvaptan	Hiponatremia	√	√		
Urologics	Imidafenacin^P	Urinary incontinence	√	√		

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