

API PRODUCT PORTFOLIO

PRODUCT	INDICATION	API MICRONIZED	CEP/DMF
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
Indacaterol maleate^P	Asthma and COPD	√	EU/US DMF
Salmeterol xinafoate^P	Asthma and COPD	√	CEP / US-CN-KR DMF
Tiotropium Bromide	COPD	√	CEP / US DMF

API PRODUCT PIPELINE

PRODUCT	INDICATION	SAMPLES	TECHNICAL PACKAGE	VALIDATION BATCH	DMF
Abediterol	Asthma and COPD			2023	2023
Aclidinium bromide	COPD	√	Q4 2019	Q1 2020	Q4 2020
Batefenterol	COPD			2023	2024
Olodaterol^P	COPD	√	Q4 2019	Q1 2020	Q4 2020
Revefenacin	COPD			Q1 2022	Q4 2022
Umeclidinium bromide	COPD	√	√	Q1/Q2 2020	Q3/Q4 2020
Vilanterol	Asthma and COPD	√	√	Q4 2019	Q2 2020

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.

THERAPEUTIC AREA	PRODUCT	INDICATION	API MICRONIZED	CEP/DMF
Antiallergics	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
	Indacaterol maleate ^P	Asthma and COPD	√	EU/US DMF
	Montelukast sodium ^P	Asthma, allergic & seasonal rhinitis		EU-JP DMF
	Salmeterol xinafoate ^P	Asthma and COPD	√	CEP/ US-CN-KR DMF
	Tiotropium Bromide	COPD	√	CEP/US US DMF
Antiemetics	Granisetron base ^P	Emesis		US DMF
	Granisetron hydrochloride ^P	Emesis		CEP/ US-JP-KR DMF
Antifungals	Fluconazole ^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	√	
	Olanzapine ^P	Schizophrenia, psychosis		EU-US- DMF
	Quetiapine hemifumarate ^P	Schizophrenia, psychosis		JP-KR DMF
	Risperidone ^P	Schizophrenia, psychosis	√	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.

THERAPEUTIC AREA	PRODUCT	INDICATION	SAMPLES	TECHNICAL PACKAGE	VALIDATION BATCH	DMF
Antiasthmatics, COPD and respiratory diseases	Abediterol	Asthma and COPD			2023	2023
	Aclidinium bromide	COPD	√	Q4 2019	Q1 2020	Q4 2020
	Batefenterol	COPD			2023	2024
	Olodaterol^P	COPD	√	Q4 2019	Q1 2020	Q4 2020
	Revefenacin	COPD			Q1 2022	Q4 2022
	Umeclidinium bromide	COPD	√	√	Q1/Q2 2020	Q3/Q4 2020
	Vilanterol	Asthma and COPD	√	√	Q4 2019	Q2 2020
Antiemetics	Aprepitant	Emesis	√	√	√	2020
Antihypertensive	Clevidipine^P	Hypertension	√	√	Q2 2020	Q4 2020
Antiparkinson	Benserazide	Parkinson's disease			Q3/Q4 2020	Q1/Q2 2021
	Tetrabenazine	Huntington's disease chorea and Tardive dyskinesia	√	√	√	2019
Antipsychotics	Olanzapine pamoate	Schizophrenia, psychosis	√	√	Q4 2019	2020
	Paliperidone Palmitate	Schizophrenia, bipolar mania				Q4 2020
	Pipamperone	Schizophrenia	√	√	Q3 2020	Q1 2021
Antithrombotics	Apixaban^P	Venous thromboembolism	√	√	√	2020
Other disorders	Tafamidis	Transthyretin amyloidosis	√	Q4 2019	Q3/Q4 2020	Q1/Q2 2021
	Tolvaptan	Hyponatremia	√	√		
Urologics	Imidafenacin^P	Urinary incontinence	√	√		

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 Authorisation. 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 Authorisation. None of the products are offered for sale or supplied to countries in which they could be in conflict with valid patents.