

THERAPEUTIC AREA	PRODUCT	INDICATION	API MICRONIZED	CEP/DMF
Antiallergics	<b>Loratadine<sup>P</sup></b>	Allergy	√	JP DMF
Antiasthmatics, COPD and respiratory diseases	<b>Aclidinium bromide</b>	COPD	√	EU-US DMF
	<b>Arformoterol tartrate<sup>P</sup> polymorph A and D</b>	COPD	√	US-CN –KR DMF
	<b>Formoterol fumarate</b>	Asthma and COPD	√	CEP/US-JP-KR-CN-RU DMF
	<b>Glycopyrronium bromide</b>	COPD	√	CEP/ US-CN-KR-RU DMF
	<b>Indacaterol maleate<sup>P</sup></b>	Asthma and COPD	√	EU/US-KR-RU-CN DMF
	<b>Montelukast sodium</b>	Asthma, allergic & seasonal rhinitis		EU-JP DMF
	<b>Revefenacin</b>	COPD		EU & US-DMF
	<b>Salmeterol xinafoate<sup>P</sup></b>	Asthma and COPD	√	CEP/ US-CN-KR DMF
	<b>Tiotropium bromide</b>	COPD	√	CEP/US-CN-RU DMF
	<b>Umeclidinium bromide</b>	COPD	√	EU/US DMF
	<b>Vilanterol trifenate</b>	Asthma and COPD	√	EU/US DMF
	Antiemetics	<b>Aprepitant</b>	Emesis	√
<b>Granisetron base<sup>P</sup></b>		Emesis		US DMF
<b>Granisetron hydrochloride<sup>P</sup></b>		Emesis		CEP/ US-JP-KR DMF
<b>Ondansetron base<sup>P</sup></b>		Emesis	√	EU-US DMF
<b>Ondansetron hydrochloride<sup>P</sup></b>		Emesis	√	CEP/US DMF
Antihypertensive	<b>Carvedilol<sup>P</sup></b>	Hypertension, angina, heart failure		JP DMF
	<b>Clevidipine<sup>P</sup></b>	Hypertension		EU/US-CN DMF
	<b>Enalapril maleate<sup>P</sup></b>	Hypertension		CEP/KR DMF
	<b>Imidapril</b>	Hypertension		EU DMF
	<b>Nitrendipine</b>	Hypertension	√	CEP/DMF
Antimigrainics	<b>Eletriptan HBr<sup>P</sup></b>	Migraine	√	JP/RU DMF
	<b>Rizatriptan benzoate<sup>P</sup></b>	Migraine	√	EU-US DMF
	<b>Zolmitriptan<sup>P</sup></b>	Migraine	√	EU-US DMF
Antiparkinson	<b>Tetrabenazine</b>	Huntington's disease chorea and Tardive dyskinesia		EU-US DMF
Antipsychotics	<b>Asenapine maleate<sup>P</sup></b>	Schizophrenia and acute mania	√	JP DMF
	<b>Olanzapine<sup>P</sup></b>	Schizophrenia, psychosis		EU-US/KR DMF
	<b>Quetiapine hemifumarate<sup>P</sup></b>	Schizophrenia, psychosis		JP-KR DMF
	<b>Risperidone<sup>P</sup></b>	Schizophrenia, psychosis	√	CEP/US-KR/CN DMF
Antithrombotics	<b>Prasugrel base<sup>P</sup></b>	Prophylaxis & therapy of thrombosis		EU DMF
	<b>Rivaroxaban</b>	Thrombosis. Stroke		DMF
Spasmolytic	<b>Otilonium bromide</b>	Irritable bowel syndrome		EU DMF

CEP = Products with Certificate of Suitability / P = Patent applications/granted patents owned by INKE S.A.

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	<b>Olodaterol<sup>P</sup></b>	COPD	√	√	√	Q3 2023
	<b>Indacaterol acetate</b>	Asthma	Q3 2023	Q4 2023	Q1 2024	Q3 2024
Antiparkinson	<b>Benserazide</b>	Parkinson's disease	√	√	pending	pending
Other disorders	<b>Tafamidis meglumine</b>	Transthyretin amyloidosis	√	√	√	Q3 2024
	<b>Lasmiditan succinate</b>	Migraine	Q2 2023	Q2 2023	Q4 2023	Q4 2024
	<b>Solriamfetol</b>	Narcolepsy	Q3 2023	Q4 2023	Q1 2024	Q3 2024
	<b>Prasugrel HCl</b>	Prophylaxis & therapy of thrombosis	Q3 2023	Q4 2023	Q4 2023	Q2 2024
	<b>Mavacamten</b>	Cardiomyopathy	Q3 2023	Q1 2024	Q2 2024	Q1 2025

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## API PRODUCT PORTFOLIO

PRODUCT	INDICATION	API MICRONIZED	CEP/DMF
<b>Acclidinium bromide</b>	COPD	√	EU-US DMF
<b>Arformoterol tartrate<sup>P</sup> polymorph A and D</b>	COPD	√	US-CN-KR DMF
<b>Formoterol fumarate</b>	Asthma and COPD	√	CEP/US-JP-KR-CN-RU DMF
<b>Glycopyrronium bromide<sup>P</sup></b>	COPD	√	CEP/US-CN-KR-RU DMF
<b>Indacaterol maleate<sup>P</sup></b>	Asthma and COPD	√	EU/US-KR-RU-CN DMF
<b>Revefenacin</b>	COPD		EU & US-DMF
<b>Salmeterol xinafoate<sup>P</sup></b>	Asthma and COPD	√	CEP/US-CN-KR DMF
<b>Tiotropium bromide monohydrate</b>	COPD	√	CEP/US-CN-RU DMF
<b>Umeclidinium bromide</b>	COPD	√	EU/US DMF
<b>Vilanterol trifenate</b>	Asthma and COPD	√	EU/US DMF

## API PRODUCT PIPELINE

PRODUCT	INDICATION	SAMPLES	TECHNICAL PACKAGE	VALIDATION BATCH	DMF
<b>Indacaterol acetate</b>	Asthma	Q3 2023	Q4 2023	Q1 2024	Q3 2024
<b>Olodaterol<sup>P</sup></b>	COPD	√	√	√	Q3 2023

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