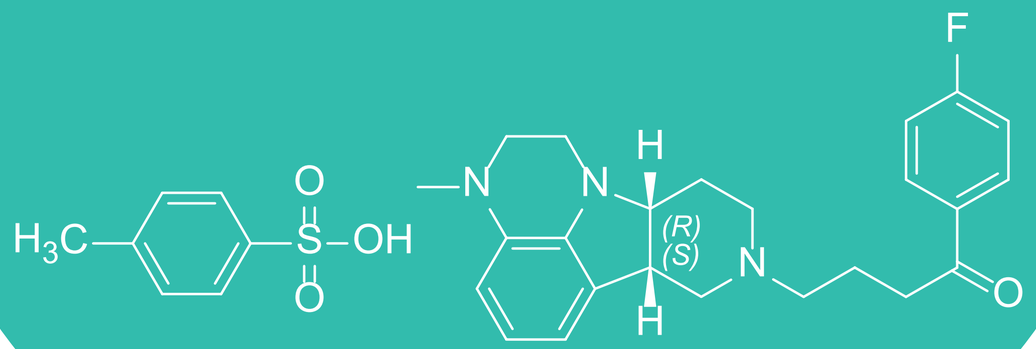
Lumateperone Tosylate

Product Alert!



Dr.Reddy's

Chemical Name	1-(4-fluorophenyl)-4-((6bS,10aR)-3-methyl-2,3,6b,9,10,10a-hexahydro-1H-pyrido[3',4':4,5]pyrrolo[1,2,3-de]quinoxalin-8(7H)-yl)butan-1-one; 4-methylbenzenesulfonic acid
Chemical Formula	$C_{31}H_{36}FN_3O_4S$
Molecular Weight	565.71 g/mol
Therapeutic Category	Anti-Schizophrenic/Central Nervous System (CNS).
Indication	Lumateperone is a second-generation atypical antipsychotic drug currently indicated for the treatment of schizophrenia, bipolar depression, and other neuropsychiatric disorders.

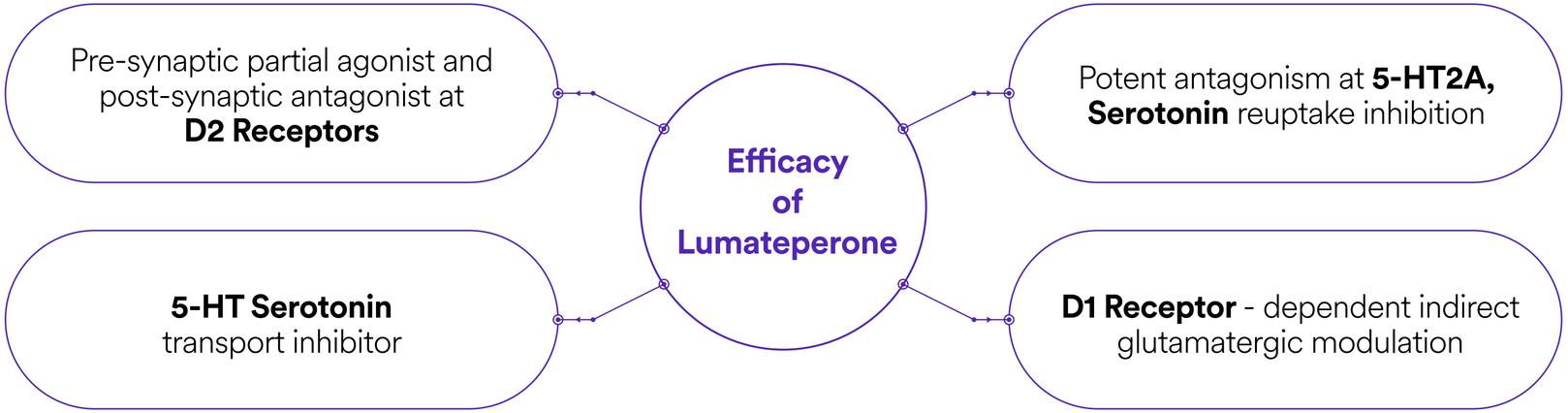
Product Details | FDA Approvals | Mechanism of Action | Patent Situation | Dr. Reddys API Offerings*

US FDA approval timelines of Ripretinib across indications:

Approval Date	Approved Indication
April 22, 2022	Intra-cellular therapies announced FDA approval of new dosage strengths for Lumateperone Tosylate (Caplyta®) for specific patient populations [1].
December 20, 2019	USFDA approved Lumateperone Tosylate (Caplyta®) to treat schizophrenia in adults [1].

Mechanism of Action:

Lumateperone is a serotonin 5HT2A receptor antagonist, a dopamine receptor phosphoprotein modulator (DPPM), and a serotonin transporter (SERT) inhibitor. Unlike existing schizophrenia treatments, Lumateperone is a first-in-class molecule that provides selective and simultaneous modulation of serotonin, dopamine, and glutamate—three neurotransmitter pathways implicated in severe mental illness.



Approvals and Data Exclusivity

Country	Approval Date	Exclusivity Expiry
United States	20 December 2019	20 December 2024; NCE-1: 20 December 2023
Europe	Phase III	Not Applicable
Canada	Not Approved	Not Applicable
Japan	Not Approved	Not Applicable
Brazil	Not Approved	Not Applicable
India	Not Approved	Not Applicable
Turkey	Not Approved	Not Applicable

Note:
NCE: New Chemical Entity.

Dr. Reddys API Offerings*:

We offer the crystalline form-A*

Early mover in API development and filed USDMF. Planning to file the DMF in key markets such as the China, Japan, Brazil, Europe, and Korea.

PSD D(90) : PSD below 10 micron & 30-60 micron. Customized PSD options are available through size reduction and crystallization techniques to meet the most desired PSD.

Ready to file in different geographies with selected route of synthesis (ROS).

Current batch size of 10-15 kg. Adequate capacity available to supply development quantity in a short lead time of 90-120 days.

cGMP API manufacturing facilitites, successfully inspected by international regulatory authorities.

Control strategies for GTIs & Nitrosamines. Sensitive analytical methods to manage potential impurities and degradation products.

Quality as per ICH guidelines. Quality control (QC) labs have the necessary capabilities to test and release all critical quality attributes (CQAs).

The route of synthesis (ROS) of Lumateperone Tosylate consists of four chemical conversions and one salt/polymorph preparation. IP compliant Process for United States & Europe.

Green chemistry: Dr. Reddy's process involves less hazardous chemicals, solvents & reagents. Hence, ensuring robustness in ability to scale up.

Product Details | FDA Approvals | Mechanism of Action | Patent Situation | Dr. Reddys API Offerings*

If you want to learn more about our Lumateperone API , please get in touch with us at api@drreddys.com.

References:

[1] https://www.accessdata.fda.gov/scripts/cder/ob/search_product.cfm

* Products protected under valid patents are not offered or supplied for commercial use. However, the research quantities of such products may be offered for the purpose of regulatory submissions. Whenever such regulatory exemptions exist. The buyers should make their independent evaluation of the patent scenario for their respective markets and will be responsible for all patent related liabilities.

\# The genotoxic, nitrosamine impurities profile and stability data will be conducted as per guidelines.

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Good Health Can't Wait.