



MAYNE PHARMA LAUNCHES CLOZAPINE TABLETS IN THE US

9 Nov 2017, Adelaide Australia: Mayne Pharma Group Limited (ASX: MYX) is pleased to announce the launch of the full range of clozapine tablets (25mg, 50mg, 100mg and 200mg) in the United States. Clozapine tablets are a generic alternative to Clozaril®, indicated as an antipsychotic.

Mayne Pharma's CEO Scott Richards said, "The launch of the full range of Clozapine tablets is our 6th product launch in 2017 and will further diversify our product offering. This product which is currently manufactured by Teva Pharmaceuticals Industries Limited, will ultimately be manufactured at our facility in Greenville, North Carolina and benefit from the investment underway to expand capacity. The new solid oral dose manufacturing facility is poised to open in early 2018 and will quadruple the Company's U.S. manufacturing capacity to well over 1 billion doses, and importantly introduces significant new capacity to manufacture high potent compounds and new capability to manufacture modified-release bead/pellet products."

Mayne Pharma directly markets more than 55 products and has a growing pipeline of more than 40 drug products targeting U.S. markets with QuintilesIMS sales greater than \$6.5 billion. According to QuintilesIMS, annual US sales of clozapine tablets were approximately US\$125 million for the 12 months ending 31 August 2017.

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About Mayne Pharma

Mayne Pharma is an ASX-listed specialty pharmaceutical company focused on applying its drug delivery expertise to commercialise branded and generic pharmaceuticals. Mayne Pharma also provides contract development and manufacturing services to more than 100 clients worldwide.

Mayne Pharma has a 30-year track record of innovation and success in developing new oral drug delivery systems and these technologies have been successfully commercialised in numerous products that have been marketed around the world.

Mayne Pharma has two product development and manufacturing facilities based in Salisbury, Australia and Greenville, USA with expertise in formulation complex oral dose forms including highly potent compounds, controlled substances, modified release products and inherently unstable compounds.

Clozaril® is a registered trademark of Novartis AG Corporation.



About Clozapine

Indication: Clozapine is an atypical antipsychotic indicated for:

- The treatment of severely ill patients with schizophrenia who fail to respond adequately to standard antipsychotic treatment
- Reduction in the risk of recurrent suicidal behavior in schizophrenia or schizoaffective disorder

Contradictions: Known serious hypersensitivity to Clozapine or any other component of Clozapine.

Boxed Warning:

SEVERE NEUTROPENIA; ORTHOSTATIC HYPOTENSION, BRADYCARDIA, AND SYNCOPE; SEIZURE; MYOCARDITIS AND CARDIOMYOPATHY; INCREASED MORTALITY IN ELDERLY PATIENTS WITH DEMENTIA-RELATED PSYCHOSIS.

See full prescribing information for complete boxed warning.

- Severe Neutropenia: Clozapine treatment can cause severe neutropenia, which can lead to serious and fatal infections. Patients initiating and continuing treatment with Clozapine must have a baseline blood absolute neutrophil count (ANC) measured before treatment initiation and regular ANC monitoring during treatment.
- Because of the risk of severe neutropenia, Clozapine is available only through a restricted program under a Risk Evaluation Mitigation Strategy (REMS) called the Clozapine REMS Program.
- Orthostatic hypotension, bradycardia, syncope, and cardiac arrest have occurred with Clozapine treatment. The risk is highest during the initial titration period, particularly with rapid dose escalation. These reactions can occur with the first dose, with doses as low as 12.5 mg per day. Initiate treatment at 12.5 mg once or twice daily; titrate slowly; and use divided dosages. Use Clozapine cautiously in patients with cardiovascular or cerebrovascular disease or conditions predisposing to hypotension (e.g., dehydration, use of antihypertensive medications).
- Seizures have occurred with Clozapine treatment. The risk is dose-related. Initiate treatment at 12.5 mg, titrate gradually, and use divided dosing. Use caution when administering Clozapine to patients with a history of seizures or other predisposing risk factors for seizure (CNS pathology, medications that lower the seizure threshold, alcohol abuse). Caution patients about engaging in any activity where sudden loss of consciousness could cause serious risk to themselves or others.
- Fatal myocarditis and cardiomyopathy have occurred with Clozapine treatment. Discontinue Clozapine and obtain a cardiac evaluation upon suspicion of these reactions. Generally, patients with Clozapine-related myocarditis or cardiomyopathy should not be rechallenged with Clozapine. Consider the possibility of myocarditis or cardiomyopathy if chest pain, tachycardia, palpitations, dyspnea, fever, flu-like symptoms, hypotension, or ECG changes occur.
- Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death. Clozapine is not approved for use in patients with dementia-related psychosis.

Full prescribing information, including warnings, can be found [here](#). To report a suspected adverse reaction from one of our products, please contact Mayne Pharma at 1-844-825-8500 or maynepharmamc@dlss.com, or the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.