ASX Announcement

MAYNE PHARMA LAUNCHES FIRST GENERIC METHYLPHENIDATE EXTENDED-RELEASE 10MG CAPSULES IN THE US

28 Feb 2018, Adelaide Australia: Mayne Pharma Group Limited (ASX: MYX) is pleased to announce the launch of methylphenidate extended-release (ER) capsules, 10mg, in the United States.

Methylphenidate ER capsules are a generic alternative to Ritalin LA® capsules, indicated for attention deficit hyperactivity disorder (ADHD). This launch complements the existing methylphenidate product range that includes 20mg, 30mg, 40mg and 60mg dose strengths.

Mayne Pharma's CEO Scott Richards said, "This launch reinforces Mayne Pharma's commitment to expanding its on-market portfolio. This will be the first generic alternative of the 10mg dose strength, providing more choices to patients in terms of medication affordability. Mayne Pharma directly markets more than 55 products and has a growing pipeline of more than 30 products targeting U.S. markets with QuintilesIMS sales greater than US$5 billion."

According to IQVIA, US brand sales of methylphenidate 10mg capsules were approximately US$21 million for the 12 months ending 31 December 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.

Ritalin LA® is a registered trademark of Novartis AG Corporation.

Drug Dependence

Methylphenidate hydrochloride extended-release capsules (LA) should be given cautiously to patients with a history of drug dependence or alcoholism. Chronic abusive use can lead to marked and psychological dependence with varying degrees of abnormal behaviour. Frank psychotic episodes can occur, especially with parenteral abuse. Careful supervision is required during withdrawal from abusive use, since severe depression may occur. Withdrawal following chronic therapeutic use may unmask symptoms of the underlying disorder that may require follow-up.

Indication and Usage

Methylphenidate hydrochloride extended-release capsules (LA) are indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD).

The efficacy of methylphenidate hydrochloride extended-release capsules (LA) in the treatment of ADHD was established in 1 controlled trial of children aged 6 to 12 who met DSM-IV criteria for ADHD.

Description

Methylphenidate hydrochloride USP is a central nervous system (CNS) stimulant.

Methylphenidate hydrochloride extended-release capsules (LA) are an extended-release formulation of methylphenidate with bi-modal release profile. Each bead-filled methylphenidate hydrochloride extended-release capsule (LA) contains half the dose of immediate-release beads and half as enteric-coated, delayed-release beads, thus providing an immediate release of methylphenidate and a second delayed release of methylphenidate.

Methylphenidate hydrochloride extended-release 20, 30, 40 and 60 mg capsules (LA) provide in a single dose the same amount of methylphenidate as dosages of 10, 15, 20 or 30 mg of methylphenidate hydrochloride tablets given twice a day.

Selected Safety Information about Methylphenidate extended-release capsules (LA).
Sudden death, stroke and myocardial infarction have been reported in adults taking stimulant drugs at usual doses for ADHD. Although the role of stimulants in these adult cases is also unknown, adults have a greater likelihood than children of having serious structural cardiac abnormalities, cardiomyopathy, serious heart rhythm abnormalities, coronary artery disease or other serious cardiac problems. Adults with such abnormalities should also generally not be treated with stimulant drugs.

Methylphenidate hydrochloride extended-release capsules (LA) is contraindicated under the following conditions:

- *Agitation* - Methylphenidate hydrochloride extended-release capsules (LA) are contraindicated in marked anxiety, tension and agitation, since the drug may aggravate these symptoms.
- *Hypersensitivity to Methylphenidate* - Methylphenidate hydrochloride extended-release capsules (LA) are contraindicated in patients known to be hypersensitive to methylphenidate or other components of the product.
- *Glaucoma* - Methylphenidate hydrochloride extended-release capsules (LA) are contraindicated in patients with glaucoma.
- *Tics* - Methylphenidate hydrochloride extended-release capsules (LA) are contraindicated in patients with motor tics or with a family history or diagnosis of Tourette's syndrome.
- *Monoamine Oxidase Inhibitors* - Methylphenidate hydrochloride extended-release capsules (LA) are contraindicated during treatment with monoamine oxidase inhibitors, and also within a minimum of 14 days following discontinuation of treatment with a monoamine oxidase inhibitor (hypertensive crises may result).

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.