News Release

MAYNE PHARMA LAUNCHES METHYLPHENIDATE EXTENDED-RELEASE 60MG CAPSULES IN THE UNITED STATES

Feb. 21, 2017, Greenville, North Carolina: Mayne Pharma Inc. is pleased to announce the launch of methylphenidate extended-release capsules, 60mg, in the United States.

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

Mayne Pharma's CEO Scott Richards said, "This will be the first generic alternative of the 60mg dose strength, providing more choices to patients in terms of medication affordability. The launch of methylphenidate is Mayne Pharma's sixth new product launch since the beginning of FY16."

Mayne Pharma directly markets more than 50 products and has a growing pipeline of more than 40 generic and branded drug products targeting U.S. markets with IMS sales greater than $6 billion.

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About Mayne Pharma

Mayne Pharma is an ASX-listed specialty pharmaceutical company focused on applying its drug delivery expertise to commercialize branded and generic pharmaceuticals, providing patients with access to better and more affordable medicines. 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 commercialized 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, North Carolina, with expertise in the formulation of 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.