



MAYNE PHARMA LAUNCHES BUTALBITAL ACETAMINOPHEN TABLETS IN THE UNITED STATES

16 February 2017, Adelaide Australia: Mayne Pharma Group Limited (ASX: MYX) is pleased to announce the launch of butalbital acetaminophen (APAP) tablets 50 mg/300 mg in the United States. Butalbital / APAP is indicated for the treatment of tension headache (migraine).

Mayne Pharma will distribute the drug on behalf of its partner, Mikart Inc. which developed the product and is also manufacturing the product.

According to IMS Health, US brand sales were approximately US\$27 million for the 12 months ending 31 December 2016.

Mayne Pharma's CEO, Mr Scott Richards, said "We are very pleased to have licensed this product from Mikart, Inc, one of our strategic partners. This will be the first generic alternative to BUPAP® and will bring patients and payers improved medication affordability."

Mayne Pharma continues to aggressively expand its product portfolio through internal product development, strategic acquisition, in-licensing and working collaboratively with partners like Mikart. Today, the Company directly markets more than 50 products and has a growing pipeline of more than 40 generic and branded drug products targeting US markets with IMS sales greater than US\$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 commercialise 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 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 the formulation of complex oral dose forms including highly potent compounds, controlled substances, modified-release products and inherently unstable compounds.

Bupap® is a registered trademark of ECR Pharmaceuticals Co., Inc.

Warning

Acetaminophen has been associated with cases of acute liver failure, at times resulting in liver transplant and death. Most of the cases of liver injury are associated with the use of acetaminophen at doses that exceed 4000 milligrams per day, and often involve more than one acetaminophen-containing product.

Acetaminophen Indication and Usage

Butalbital and acetaminophen tablets, 50mg/300mg are indicated for the relief of the symptom of complex tension (or muscle contraction) headache. Evidence supporting the efficacy and safety of this combination product in the treatment of multiple recurrent headaches is unavailable. Caution in this regard is required because Butalbital is habit-forming and potentially abusable.

Selected Safety Information about Butalbital and acetaminophen tablets, 50mg/300mg.

Hepatotoxicity: Acetaminophen has been associated with cases of acute liver failure, at times resulting in liver transplant and death. Most of the cases of liver injury are associated with the use of acetaminophen at doses that exceed 4000 milligrams per day, and often involve more than one acetaminophen containing product.

Butalbital acetaminophen tablets, 50mg/300mg is contraindicated under the following conditions:

- *Hypersensitivity or intolerance to any component of this product.*
- *Patients with porphyria.*
- *Butalbital is habit-forming and potentially abusable. Consequently, the extended use of this product is not recommended.*
- *The risk of acute liver failure is higher in individuals with underlying liver disease and in individuals who ingest alcohol while taking acetaminophen.*
- *Acetaminophen may cause serious skin reactions such as acute generalized exanthematous pustulosis (AGEP), Stevens-Johnson Syndrome (SJS), and toxic epidermal necrolysis (TEN), which can be fatal. 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 FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.