



## MAYNE PHARMA LAUNCHES BUTALBITAL ACETAMINOPHEN CAPSULES IN THE UNITED STATES

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**July 30, 2018, Adelaide, Australia:** Mayne Pharma Group Limited (ASX: MYX) is pleased to announce the launch of butalbital acetaminophen (APAP) capsule 50mg/300mg in the United States. This is a new capsule formulation of Butalbital / APAP which is indicated for the treatment of tension headache (migraine). Mayne Pharma currently markets Butalbital / APAP tablet 50mg/300mg.

Mayne Pharma's CEO Scott Richards said, "We are pleased to bring this new capsule formulation to market providing alternate treatment options to patients who previously only had a tablet option. This new product is highly complementary to our Butalbital / APAP / Caffeine tablet and capsule portfolio, which are also used to treat migraines. Mayne Pharma continues to expand its product portfolio through internal product development, in-licensing, acquisition and working collaboratively with partners."

Mayne Pharma directly markets more than 60 products and has a growing pipeline of approximately 30 products targeting U.S. markets with IQVIA sales greater than \$5 billion. Mayne Pharma expects several product launches over the coming year with 14 drug applications pending at the U.S. Food and Drug Administration targeting U.S. markets with sales greater than \$2.5 billion.

### For further information contact:

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### Indication and Usage

*Butalbital and acetaminophen capsules, 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 capsules, 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 capsules, 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](mailto:maynepharmamc@dlss.com), or FDA at 1-800-FDA-1088 or [www.fda.gov/medwatch](http://www.fda.gov/medwatch).*



## 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. 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 Greenville, North Carolina, USA, and Salisbury, Australia, with expertise in formulation complex oral dose forms including potent compounds, controlled substances, modified release products and inherently unstable compounds. For further information, visit [www.maynepharma.com](http://www.maynepharma.com)*

