ASX Announcement

MAYNE PHARMA ANNOUNCES PBS LISTING OF KAPANOL® FOR CHRONIC BREATHLESSNESS

27 August 2019, Adelaide Australia: Mayne Pharma Group Limited (ASX: MYX) is pleased to announce the Pharmaceutical Benefits Scheme (PBS) has approved the reimbursement of KAPANOL® low dose sustained-release 10mg and 20mg morphine capsules for the treatment of chronic breathlessness in palliative care patients with advanced disease.

From 1 September 2019, the use of KAPANOL for chronic breathlessness will be a new indication on the PBS Palliative Care Schedule. This is an addition to KAPANOL's current PBS General Schedule listing for use in chronic severe disabling pain unresponsive to non-opioid analgesics.

Health Minister Greg Hunt said, "KAPANOL helps with the relief of distressing chronic breathlessness in the palliative care of patients with severe chronic obstructive pulmonary disease (COPD), cardiac failure, malignancy or other causes and this listing will benefit around 20,000 Australian patients per year."

Many of the patients suffering from this condition are housebound and very limited in their day-to-day activities.

The clinical studies undertaken by Palliative Care Clinical Studies Collaborative (PaCCSC), under Professor David Currow, have shown the use of KAPANOL in severe chronic breathlessness can reduce this debilitating symptom in patients with advanced disease.

Professor David Currow said, "This PBS listing is fantastic news and provides patients with a more affordable treatment option. The repurposing of low dose morphine for chronic breathlessness is a world first registration for this indication."

For further information contact:
Lisa Pendlebury +61 419 548 434, lisa.pendlebury@maynepharma.com

About Mayne Pharma

At Mayne Pharma we believe that everyone deserves medicines that are better, safe and more affordable. That's why our people are determined to create innovative products and services for our changing world.

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 of complex oral and topical dose forms including potent compounds, modified-release products and inherently unstable compounds.

About KAPANOL

KAPANOL (morphine sulfate pentahydrate) 10mg, 20mg, 50mg and 100mg capsules, modified release, are an opioid analgesic indicated for the relief of chronic pain unresponsive to non-narcotic analgesia. KAPANOL capsules contain polymer-coated pellets which provide sustained-release of morphine sulfate after they are swallowed.

KAPANOL (morphine sulfate pentahydrate) 10mg and 20mg capsules are also indicated for the symptomatic reduction of chronic breathlessness in the palliative care of patients with distressing breathless due to severe chronic obstructive pulmonary disease (COPD), cardiac failure, malignancy or other cause. KAPANOL should only be used after treatments for the underlying cause(s) of the breathlessness have been optimised and non-pharmacological treatment are not effective. Treatment with KAPANOL in this setting should only be initiated by a specialist knowledgeable in its use.

From 1st September 2019, KAPANOL (morphine sulfate pentahydrate) is expected to be listed on the PBS as a restricted benefit for chronic breathlessness in addition to its current listing for use in chronic severe disabling pain. The condition must be unresponsive to non-opioid analgesics.

Healthcare professionals in consultation with their patients should consider both the potential risks and benefits of each medicine. Information is available from the Product Information and Consumer Medicines Information (CMI). A summary of this information is provided below, please review the CMI for further information[1].

KAPANOL should not be used in patients with an allergy to morphine sulfate pentahydrate, other opioids or any of the ingredients in the medicine. KAPANOL should not be used in the following: patients taking a medicine for depression called a 'monoamine oxidase inhibitor' or have taken one within the past two weeks; patients with heart problems which affect the rhythm of the heartbeat and patients with a prior history of drug abuse. Patients with any lung or breathing problems should not take KAPANOL, it helps breathing but may also cause uncomfortable side effects or side effects that may shorten their life. Not for use in children[1].

Treatment with KAPANOL for chronic breathlessness should only be started by a specialist. KAPANOL has physical and psychological drug dependence potential and withdrawal symptoms. Tolerance may occur. Prescription and monitoring of the patient's opioid use should be one doctor's responsibility. KAPANOL may cause serious, life-threatening, or fatal respiratory depression. Use with caution in patients with the following conditions: kidney or liver disease, under activity of the adrenal or thyroid gland, increased prostate size, narrowing of the urinary bladder tract, biliary tract disease or inflammation of the pancreas,

a condition associated with fits or convulsions, or diarrhoea. Use with caution in patients who have had a head injury or increased pressure in the head, low blood pressure or abnormal curvature of the spine[1].

Like other medicines, KAPANOL can cause some side-effects. The most commonly reported side-effects are: drowsiness, sweating, confusion, dizziness, headache, nausea or vomiting, constipation, dry mouth or itchy skin. Other side effects include: allergic reaction, withdrawal symptoms, blurred vision, flushing of the face, faintness or heart palpitations and hallucinations[1].

Some combinations of medicines may increase the risk of having serious side effects, such as central nervous system depressants, sedatives, benzodiazepines, hypnotics, general anaesthetics, phenothiazines, other tranquilizers and alcohol. Immediate release oral morphine solution should NOT be used with KAPANOL when KAPANOL is prescribed for the reduction of chronic breathlessness. Some medicines and KAPANOL may interfere with each other. These include: medicines to treat depression, psychiatric or mental disorders; other pain relievers and other opioids. These also include medicines used to relieve heartburn or treat stomach ulcers, medicines to help sleep, relax muscles, lower blood pressure, diuretics and St John's wort (Hypericum perforatum), a herbal remedy[1].

References

1. The KAPANOL (morphine sulfate pentahydrate) Approved Product Information, dated 6 February 2019.

To access the Consumer Medicines Information Leaflet:
https://www.maynepharma.com/products/australian-products/specialty-brands/kapanol-capsules/