

Consumer Medicine Information

WARNING

Limitations of use in treatment of pain

KAPANOL should only be used when your doctor decides that other treatment options are not able to effectively manage your pain, or you cannot tolerate them.

Hazardous and harmful use

KAPANOL poses risks of abuse, misuse and addiction which can lead to overdose and death. Your doctor will monitor you regularly during treatment.

Life threatening respiratory depression

KAPANOL can cause life-threatening or fatal breathing problems (slow, shallow, unusual or no breathing) even when used as recommended. These problems can occur at any time during use, but the risk is higher when first starting KAPANOL and after a dose increase, if you are older, or have an existing problem with your lungs. Your doctor will monitor you and change the dose as appropriate.

Use of other medicines while using KAPANOL

Using KAPANOL with other medicines that can make you feel drowsy such as sleeping tablets (e.g. benzodiazepines), other pain relievers, antihistamines, antidepressants, antipsychotics, gabapentinoids (e.g. gabapentin and pregabalin), cannabis and alcohol may result in severe drowsiness, decreased awareness, breathing problems, coma and death. Your doctor will minimise the dose and duration of use; and monitor you for signs and symptoms of breathing difficulties and sedation. You must not drink alcohol while using KAPANOL.

What is in this leaflet?

Please read this leaflet carefully before you start KAPANOL.

This leaflet answers some common questions about KAPANOL. It does not contain all of the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking KAPANOL against the benefits this medicine is expected to have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What KAPANOL is used for

KAPANOL contains morphine sulfate pentahydrate which belongs to a group of medicines called opioid analgesics.

KAPANOL 10, 20, 50 and 100 mg capsules are used for the relief of severe pain which is opioid responsive, and requires daily, continuous, long-term treatment.

KAPANOL 10 and 20 mg capsules are also used for 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.

KAPANOL should only be used after optimal treatments of the underlying causes and if other non-drug treatments are not effective. Treatment with KAPANOL for chronic breathlessness should only be started by a specialist.

Your doctor may have prescribed KAPANOL for another reason.

Ask your doctor if you have any questions about why KAPANOL has been prescribed for you.

Addiction

You can become addicted to KAPANOL even if you take it exactly as prescribed. KAPANOL may become habit forming causing mental and physical dependence. If abused it may become less able to reduce pain.

Dependence

As with all other opioid containing products, your body may become used to you taking KAPANOL. Taking it may result in physical dependence. Physical dependence means that

you may experience withdrawal symptoms if you stop taking KAPANOL suddenly, so it is important to take it exactly as directed by your doctor.

Tolerance

Tolerance to KAPANOL may develop, which means that the effect of the medicine may decrease. If this happens, more may be needed to maintain the same effect.

Withdrawal

Continue taking your medicine for as long as your doctor tells you. If you stop having this medicine suddenly, your pain may worsen and you may experience some or all of the following withdrawal symptoms:

- nervousness, restlessness, agitation, trouble sleeping or anxiety
- body aches, weakness or stomach cramps
- loss of appetite, nausea, vomiting or diarrhoea
- increased heart rate, breathing rate, blood pressure or pupil size
- watery eyes, runny nose, chills or yawning
- increased sweating.

KAPANOL given to the mother during labour can cause breathing problems and signs of withdrawal in the newborn.

Before you take KAPANOL

When you must not take it

- **Do not take KAPANOL if you have ever had an allergic reaction to morphine sulfate pentahydrate, other opioids or any of the ingredients listed at the end of this leaflet.**
Symptoms of an allergic reaction may be mild or severe. They usually include some or all of the following: wheezing, swelling of the lips/mouth, difficulty in breathing, hay fever, lumpy rash ("hives") or fainting.
- **Do not take KAPANOL if you are pregnant, or trying to become pregnant, unless your doctor says you should.**
Your doctor will discuss the risks and benefits of using KAPANOL if you are pregnant.
- **Do not drink alcohol or take other central nervous system depressants (e.g. sleeping medications, tranquilisers), benzodiazepines, illicit**

drugs or other opioids whilst taking KAPANOL.

- Do not take KAPANOL if you are severely drowsy or have a reduced level of consciousness
- Do not take KAPANOL if you have an addiction or history of abuse of alcohol or drugs.
- Do not take KAPANOL if you suffer from convulsions, fits or seizures.
- Do not take KAPANOL if you have a head injury, brain tumour, increased pressure in your head or spine.
- Do not take KAPANOL if you have sudden, severe abdominal pain or have an obstruction of the bowel or a condition where it could occur, or you have **biliary tract disease**.
- **Do not take KAPANOL if you are taking a medicine for depression called a 'monoamine oxidase inhibitor' or have taken one within the past two weeks.**
- If you have any lung or breathing problems, you and your carer should discuss the risks and benefits of using KAPANOL in this situation with your doctor. The use of KAPANOL may help your breathing but may also cause uncomfortable side effects or side effects that may shorten your life.
- Do not take KAPANOL if you have heart problems which affect the rhythm of your heartbeat.
- **Do not take KAPANOL if you have heart disease due to long term lung disease.**
- **Do not take KAPANOL if you have severe kidney or liver disease or a disease of the brain caused by liver disease.**
- **Do not take KAPANOL if you are about to have an operation or have had one within the last 24 hours, including surgery on your spine for relief.**
- **Do not take KAPANOL after the expiry date (EXP) printed on the pack.**
If you take it after the expiry date has passed, it may not work as well.
- **Do not take KAPANOL if the packaging is torn or shows signs of tampering, or if the capsules look damaged or discoloured.**

Speak to your doctor if you have tummy pains, vomiting or constipation.

If you're not sure whether you should be taking KAPANOL, talk to your doctor.

Before you start to take it

KAPANOL may cause serious, life-threatening, or fatal respiratory depression. This risk is increased when taken together with alcohol, or benzodiazepines, other central nervous system (CNS) depressants, or if the pellets in the KAPANOL capsules are chewed or crushed.

You must tell your doctor if:

- you are allergic to foods, dyes, preservatives or any other medicines.
- you have any of 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 surgery or inflammation of the pancreas, a condition associated with fits or convulsions, or diarrhoea.
- you have inflammatory bowel disease or recent abdominal surgery.
- you have abnormal curvature of the spine or you have low blood pressure.

KAPANOL is not recommended to be taken during and immediately before labour.

Morphine given to the mother during labour can cause breathing problems in the newborn.

Tell your doctor if you are breast feeding or planning to breast feed.

Morphine can pass into your breast milk and can affect your baby. Your doctor can discuss the risks involved with you.

KAPANOL frequently causes constipation, talk to your doctor about how this can be minimised.

Taking other medicines

Tell your doctor if you are taking any other medicines, including medicines you buy without a prescription from a pharmacy, supermarket or health food shop.

Some combinations of medicines may increase the risk of having serious side effects, such as respiratory depression, low blood pressure and profound sedation or coma. These serious side effects may be life-threatening. These combinations of medicines with KAPANOL include:

- medicines which are central nervous system depressants, such as sedatives, benzodiazepines, hypnotics, general anaesthetics, phenothiazines, amphetamines, other tranquilizers and alcohol. Your doctor may reduce the dose of one or both of your medicines. Your doctor will advise you.

Some medicines, alcohol and KAPANOL may interfere with each other. These include:

- medicines to treat depression, psychiatric or mental disorders
- medicines to treat depression belonging to a group called 'monoamine oxidase inhibitors' must be stopped 14 days before KAPANOL is taken

- other pain relievers including other opioids
- medicines used to relieve heartburn or treat stomach ulcers such as cimetidine or antacids (take antacids at least 2 hours before or after taking KAPANOL)
- alkalising agents used to manage disorders associated with low pH
- gabapentin or barbiturates, medicines to treat seizures,
- medicines to help you sleep
- medicines to relax your muscles
- propranolol or other medicines to lower blood pressure
- medicines to prevent or relieve the symptoms of allergy such as antihistamines
- diuretics, medicines to reduce the amount of excess fluid in the body by increasing the amount of urine produced
- medicines to thin the blood, such as coumarin derivatives or warfarin
- medicines to treat HIV infection and AIDS, such as, ritonavir or zidovudine
- medicines to treat Parkinson's disease
- medicines to stop vomiting or nausea
- rifampicin, a medicine to treat tuberculosis
- St John's wort (*Hypericum perforatum*), a herbal remedy

Immediate release oral morphine solution should NOT be used with KAPANOL when KAPANOL is prescribed for the reduction of chronic breathlessness.

These medicines may be affected by KAPANOL or may affect how well it works. You may need to take different amounts of your medicine, or you may need to take different medicines. Your doctor will advise you.

Your doctor and pharmacist may have more information on medicines to be careful with or avoid while taking KAPANOL.

Use in children

KAPANOL is not to be used for children.

Use in elderly

KAPANOL should be taken with caution, and in reduced dosages, in elderly.

How to take KAPANOL

The Pharmacist's label on the pack will tell you how to take KAPANOL. If there is something you do not understand, ask your doctor or pharmacist.

How much to take

For Severe Pain

- KAPANOL should be taken either once (every 24 hours) or twice (every 12 hours) daily, whichever your doctor has advised.
- The amount of KAPANOL needed to give good pain relief varies. The doctor will take into account your age, weight, level of pain, any previous treatment for that pain and medical history when choosing your dose and how often to take it.
- DO NOT take more capsules than your doctor tells you to. If pain occurs between doses DO NOT take extra doses of KAPANOL. Tell your doctor as soon as possible. Taking more KAPANOL

than the doctor told you to can be dangerous.

For Chronic Breathlessness

- The amount of KAPANOL needed to provide relief in chronic breathlessness varies. Your doctor will start you on one 10 mg capsule per day.
- DO NOT take more capsules than your doctor tells you to. If this dose is not enough to relieve your breathlessness, your doctor may ask you to increase your dose of KAPANOL, after taking into account your response to the starting dose. You should not take more than 30mg daily to treat chronic breathlessness.

How to take it

The individual pellets in KAPANOL capsules must not be chewed or crushed.

- KAPANOL are designed to work properly only if swallowed whole. The capsules may release all their contents at once if broken, chewed, crushed or dissolved, which can be dangerous and cause serious problems, such as an overdose which may be fatal. Unless stated otherwise, they should be swallowed whole.
- If you have difficulty swallowing the capsule whole, take it in one of the following ways:
 - Just before use, sprinkle the pellets from the capsule onto a small amount of soft food (such as yoghurt, custard, ice cream, apple sauce or jam), and swallow this without chewing or crushing the pellets. Rinse your mouth with water and swallow to ensure all the pellets are taken, or
 - Just before use, mix the pellets from the capsule into about 30 mL of water, orange juice or milk (1/8 of a standard 250 mL glass). Swirl the glass and swallow the pellets with the liquid, being careful not to chew or crush the pellets. To make sure that all the pellets are taken, rinse the glass with a little more liquid and again, swirl the glass and swallow the pellets with the liquid until all pellets are taken.
 - If you have a gastrostomy tube, your doctor may decide to administer your KAPANOL pellets through the tube.

When to take it

- KAPANOL can be taken before, with or after food. It should be taken at about the same time or times each day.

How long to take it

- It is important that KAPANOL is taken regularly, not 'as needed' to relieve symptoms. Taking KAPANOL at regular times means that the onset of symptoms is prevented.
- If you feel your symptoms are less and you don't need as much KAPANOL, tell your doctor. You should not stop taking KAPANOL or reduce the dose suddenly without asking your doctor first.

If you forget to take it

If you forget to take a dose, contact your doctor or pharmacist for advice.

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice or go to Accident and

Emergency at the nearest hospital, if you think that you or anyone else may have taken too much KAPANOL. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

While you are taking KAPANOL

Things you must do

Tell your doctor or pharmacist that you are taking KAPANOL if you are about to be started on any new medicines.

Tell your doctor if you become pregnant or are trying to become pregnant.

Tell your doctor if, for any reason, you have not taken your medicine exactly as prescribed.

Otherwise, your doctor may think that it was not effective and change your treatment unnecessarily.

If you are about to have surgery, tell the surgeon or anaesthetist you are taking this medicine.

Keep all your doctor's appointments so that your progress can be checked.

Keep enough KAPANOL capsules with you to last over weekends and holidays.

Things you must not do

Do not stop taking KAPANOL or change the dose without first checking with your doctor.

Do not give this medicine to anyone else, even if their symptoms seem similar to yours.

Do not use KAPANOL to treat any other complaints unless your doctor says to.

If taking KAPANOL to reduce chronic breathlessness, do not take additional doses of immediate release morphine.

Do not drink alcohol while you are taking KAPANOL.

Things to be careful of

Be careful driving or operating machinery until you know how KAPANOL affects you.

As with many other medicines, KAPANOL may cause dizziness or drowsiness or tiredness in some people and may affect your ability to drive a car or operate machinery.

- If you drink alcohol, dizziness or light-headedness may be worse. Morphine may have potential combined effects when used with other CNS depressants, including other opioids, phenothiazines, sedatives/hypnotics, benzodiazepines, alcohol and illicit drugs.
- Do not take medicines that might make you drowsy while you are taking KAPANOL unless otherwise advised by your doctor.
- If you are taking KAPANOL for breathlessness, you should not take any alcohol as the combination may dangerously suppress your breathing. You should not take any medicines that make you drowsy as these may also suppress your breathing unless you have discussed this with your doctor.

There is potential for abuse and misuse of morphine and the development of addiction to morphine. It is important that you discuss this issue with your doctor.

Side effects

Check with your doctor as soon as possible if you have any problems while taking KAPANOL, even if you do not think the problems are connected with the medicine or are not listed in this leaflet.

Like other medicines, KAPANOL can cause some side-effects. If they occur, they are most likely to be minor and temporary. However, some may be serious and may need medical attention.

The most commonly reported side-effects are:

- drowsiness
- sweating
- confusion
- dizziness or unsteadiness
- headache
- nausea or vomiting
- constipation
- itchy skin
- sedation
- dysphoria
- euphoria

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist immediately if you notice any of the following:

- blurred vision
- flushing of the face, faintness or heart palpitations
- hallucinations or abnormal thinking
- changes in passing urine such as the volume passed, pain or feeling the need to urinate urgently
- unusual weakness or loss of strength

TELL YOUR DOCTOR IMMEDIATELY or go to the emergency department at your nearest hospital:

- **If you think you are having an allergic reaction to KAPANOL. Symptoms usually include some or all of the following: wheezing, swelling of the lips/mouth, difficulty in breathing, hay fever, lumpy rash ("hives"), fainting**
- breathing slows or weakens
- seizures, fits or convulsions

This is not a complete list of all possible side-effects. Others may occur in some people and there may be some side-effects not yet known.

Tell your doctor if you notice anything else that is making you feel unwell, even if it is not on this list.

Ask your doctor or pharmacist if you don't understand anything in this list.

Do not be alarmed by this list of possible side-effects. You may not experience any of them.

After taking KAPANOL

Storage

Keep this medicine where young children cannot reach it.

A locked cupboard at least one-and-a half metres above the ground is a good place to store medicines.

Keep KAPANOL in a cool, dry place where it stays below 30°C.

Do not store it, or any other medicine, in a bathroom or near a sink.

Do not leave it in the car or on windowsills.

Heat and dampness can destroy some medicines.

Keep your KAPANOL in its pack until it is time to take it.

If you take KAPANOL out of its pack it may not keep well.

Disposal

If the medicine is damaged, you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

Product description

What KAPANOL looks like

Each box contains 28 capsules. KAPANOL capsules are available in four strengths.

- Amount of morphine sulfate pentahydrate per capsule (strength): 10 milligrams
Appearance of capsules: The capsules are clear and have one black band and K10 printed on them
- Amount of morphine sulfate pentahydrate per capsule (strength): 20 milligrams
Appearance of capsules: The capsules are clear and have two black bands and K20 printed on them
- Amount of morphine sulfate pentahydrate per capsule (strength): 50 milligrams
Appearance of capsules: The capsules are clear and have three black bands and K50 printed on them
- Amount of morphine sulfate pentahydrate per capsule (strength): 100 milligrams
Appearance of capsules: The capsules are clear and have four black bands and K100 printed on them

Ingredients

KAPANOL contains the active ingredient morphine sulfate pentahydrate. It also contains the following inactive ingredients:

Sucrose (sugar), maize starch, hypromellose, ethylcellulose, methacrylic acid copolymer, macrogol 6000, diethyl phthalate, purified talc, purified water, gelatin, and SW-9009 Black Ink.

KAPANOL does not contain gluten or lactose.

Sponsor

Mayne Pharma International Pty Ltd
1538 Main North Road
Salisbury South, SA 5106
www.maynepharma.com/products/australian-products/

This leaflet was updated in August 2020.

The information provided applies only to: KAPANOL.

KAPANOL® is a registered trademark of Mayne Pharma International Pty Ltd.

KAPANOL capsules:

AUST R 68439 (10 mg)

AUST R 48134 (20 mg)

AUST R 48135 (50 mg)

AUST R 48136 (100 mg)

