KAPANOL®

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

WARNING: Important safety information is provided in a boxed warning in the full CMI. Read before using this medicine.

1. Why am I using KAPANOL?

KAPANOL contains the active ingredient morphine sulfate pentahydrate. KAPANOL 10, 20, 50 and 100 mg capsules are used for the relief of severe pain which is opioid-responsive. 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. For more information, see Section 1. Why am I using KAPANOL? in the full CMI.

2. What should I know before I use KAPANOL?

Do not use if you have ever had an allergic reaction to morphine or any of the ingredients listed at the end of the CMI. **Talk to your doctor if you have any other medical conditions, take any other medicines, are pregnant or plan to become pregnant or are breastfeeding.** For more information, see Section 2. What should I know before I use KAPANOL? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with KAPANOL and affect how it works. A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How do I use KAPANOL?

Take KAPANOL by mouth. Your doctor will choose your dose and how often to take it. More instructions can be found in Section 4. How do I use KAPANOL? in the full CMI.

5. What should I know while using KAPANOL?

Things you should do	• Remind any doctor, dentist, pharmacist, surgeon or anaesthetist you visit that you are using KAPANOL. • Tell your doctor if you become pregnant or are trying to become pregnant and if for any reason, you have not taken your medicine exactly as prescribed. • 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 should 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.
Driving or using machines	• Be careful driving or operating machinery until you know how KAPANOL affects you. • KAPANOL may cause dizziness or drowsiness.
Drinking alcohol	• Do not drink alcohol while you are taking KAPANOL.
Looking after your medicine	• Keep KAPANOL in a cool, dry place where it stays below 30°C.

For more information, see Section 5. What should I know while using KAPANOL? in the full CMI.

6. Are there any side effects?

The most commonly reported side effects are: drowsiness, sweating, confusion, dizziness or unsteadiness, headache, nausea or vomiting, constipation, itchy skin, sedation, dysphoria and euphoria. Serious side effects include: 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 and unusual weakness or loss of strength. For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

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.

KAPANOL

Active ingredient: *morphine sulfate pentahydrate*

Consumer Medicine Information (CMI)

This leaflet provides important information about using KAPANOL. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using KAPANOL.**

Keep this leaflet with the medicine. You may need to read it again.

Where to find information in this leaflet:

1. Why am I using KAPANOL?
2. What should I know before I use KAPANOL?
3. What if I am taking other medicines?
4. How do I use KAPANOL?
5. What should I know while using KAPANOL?
6. Are there any side effects?
7. Product details

1. Why am I using KAPANOL?

KAPANOL contains the active ingredient morphine sulfate pentahydrate. KAPANOL 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.

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.

2. What should I know before I use KAPANOL?

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.

Warnings

Do not use KAPANOL if:

- you are allergic to morphine, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine. 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.
- 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.
- you are severely drowsy or have a reduced level of consciousness.
- you have an addiction or history of abuse of alcohol or drugs.
- you suffer from convulsions, fits or seizures.
- you have a head injury, brain tumour, increased pressure in your head or spine.
- 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.
- you are taking a medicine for depression called a 'monoamine oxidase inhibitor' or have taken one within the past two weeks.

- you have heart problems which affect the rhythm of your heartbeat.
- you have heart disease due to long term lung disease.
- you have severe kidney or liver disease or a disease of the brain caused by liver disease.
- 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 drink alcohol or take other central nervous system depressants (e.g. sleeping medications, tranquilisers), benzodiazepines, illicit drugs or other opioids whilst taking KAPANOL.

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 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.

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.

Check with your doctor if you:

- are allergic to foods, dyes, preservatives or any other medicines.
- have any other medical conditions (in particular: 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).
- notice that your pain gets worse when your dose increases, or feel pain in new areas or from things that shouldn't hurt (e.g. light touch)'.
- experience weakness, fatigue, lack of appetite, nausea, vomiting or low blood pressure.
- have a loss of libido, impotence or your menstrual cycle stops.
- have difficulty swallowing, regurgitation, chest pain that is not related to your heart, especially if you have been taking this medicine for a long time.
- have inflammatory bowel disease or recent abdominal surgery.
- have abnormal curvature of the spine or you have low blood pressure.

- take any medicines for any other condition (including medicines called P2Y12 inhibitors)

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

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

KAPANOL, is not recommended to be taken during pregnancy. Morphine given to the mother can cause dependency and signs of withdrawal in the newborn (such as high-pitched crying, irritability and restlessness, shaking (tremor), feeding difficulties and sweating).

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.

Talk to your doctor if you are breastfeeding or intend to breastfeed. Morphine can pass into your breast milk and can affect your baby. Your doctor can discuss the risks involved with you.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your 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 tranquilisers 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).

- alkalinising agents used to manage disorders associated with low pH.
- medicines to treat seizures, gabapentin or barbiturates.
- 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.

P2Y12 inhibitors, medicines used to prevent clots from forming and growing.

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

These medicines may interfere with KAPANOL and affect how 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.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect 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.

4. How do I use KAPANOL?

Before starting treatment and regularly during treatment, your doctor will discuss with you what you may expect from using KAPANOL, when and how long you need to take it, when to contact your doctor and when you need to stop it.

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.

Follow the instructions provided and use KAPANOL until your doctor tells you to stop.

How to take KAPANOL

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

- KAPANOL is 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 KAPANOL

- 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 KAPANOL

- 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 use KAPANOL

KAPANOL should be used regularly at the same time each day. If you forget to take a dose, contact your doctor or pharmacist for advice.

If you use too much KAPANOL

If you think that you have used too much KAPANOL, you may need urgent medical attention.

An overdose may result in a brain disorder (known as toxic leukoencephalopathy).

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using KAPANOL?

Things you should do

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

Call your doctor straight away if you:

- become pregnant or are trying to become pregnant.
- for any reason, have not taken your medicine exactly as prescribed. Otherwise, your doctor may think that it was not effective and change your treatment unnecessarily.

KAPANOL can cause sleep-related breathing disorders such as sleep apnoea and sleep related hypoxemia (low oxygen level in the blood). The symptoms can include breathing pauses during sleep, night awakening due to shortness of breath, difficulties to maintain sleep or excessive drowsiness during the day. If you or another person observe these symptoms, contact your doctor. A dose reduction may be considered by your doctor.

Acute generalized exanthematous pustulosis (AGEP) has been reported in association with morphine treatment. Symptoms usually occur within the first 10 days of treatment. Tell your doctor if you have ever

developed a severe skin rash or skin peeling, blistering and/or mouth sores after taking KAPANOL or other opioids. Stop using KAPANOL and seek medical attention immediately, if you notice any of the following symptoms: blistering, widespread scaly skin or pus-filled spots together with fever.

Contact your doctor if you experience severe upper abdominal pain possibly radiating to the back, nausea, vomiting or fever as this could be symptoms associated with inflammation of the pancreas (pancreatitis) and the biliary tract system.

If you are about to have surgery, tell the surgeon or anaesthetist you are taking this medicine. Your doctor may adjust your treatment. These tablets should not be used for short-term pain after an operation owing to the increased risk of dependence and breathlessness.

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.

Remind any doctor, dentist, pharmacist, surgeon or anaesthetist you visit that you are using KAPANOL.

Things you should 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.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how KAPANOL affects you.

KAPANOL may cause dizziness or drowsiness in some people and may affect your ability to drive a car or operate machinery.

Tell your doctor if you drink alcohol.

- 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.

Looking after your medicine

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

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- 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.

Keep it where young children cannot reach it. A locked cupboard at least one-and-a half meters above the ground is a good place to store medicines.

Getting rid of any unwanted medicine

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.

6. Are there any 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.

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
• drowsiness • sweating • confusion • dizziness or unsteadiness • headache • nausea or vomiting • constipation • itchy skin • sedation • dysphoria • euphoria	**Speak to your doctor if you have any of these less serious side effects and they worry you.**

Serious side effects

Serious side effects	What to do
• 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 • sleep apnoea (breathing pauses during sleep) • severe skin reaction with blistering, widespread scaly skin, pus-filled spots together with fever. This could be a condition called Acute Generalized Exanthematous Pustulosis (AGEP) • symptoms associated with inflammation of the	**Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.**

Serious side effects	What to do
pancreas (pancreatitis) and the biliary tract system, e.g. severe upper abdominal pain possibly radiating to the back, nausea, vomiting or fever	

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

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

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.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What KAPANOL contains

Each box contains 28 capsules.

Active ingredient **(main ingredient)**	morphine sulfate pentahydrate
Other ingredients **(inactive ingredients)**	sucrose (sugar) maize starch hypromellose ethylcellulose

	methacrylic acid copolymer macrogol 6000 diethyl phthalate purified talc purified water gelatin SW-9009 Black Ink
Potential allergens	KAPANOL does not contain gluten or lactose

Do not take this medicine if you are allergic to any of these ingredients.

What KAPANOL looks like

KAPANOL capsules are available in four strengths:

- The 10 milligram capsules are clear and have one black band and K10 printed on them (Aust R 68439).
- The 20 milligram capsules are clear and have two black bands and K20 printed on them (Aust R 48134).
- The 50 milligram capsules are clear and have three black bands and K50 printed on them (Aust R 48135).
- The 100 milligram capsules are clear and have four black bands and K100 printed on them (Aust R 48136).

Who distributes KAPANOL

Mayne Pharma International Pty Ltd

1538 Main North Road

Salisbury South SA, 5106

maynepharma.com

The information provided applies only to: KAPANOL.

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This leaflet was prepared in August 2025.