

KAPANOL(R)

Morphine Sulfate

Consumer Medicine Information

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 which belongs to a group of medicines called opioid analgesics.

Kapanol is used for the relief of chronic, moderate to severe pain.

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.

Although Kapanol contains morphine, people who take morphine for a long time to treat their pain rarely become addicted to it. However, with time, your body will

become used to taking morphine and you may experience symptoms due to withdrawal if you suddenly stop taking this medicine. If you have not done so already, you should discuss this further with your doctor.

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 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, hayfever, 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 breastfeed while taking Kapanol as some of the medicine will be taken in by the baby through your milk.**
- * **DO NOT drink alcohol while taking Kapanol.**
- * **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,

- * **Do not take Kapanol if you have any lung or breathing problems,**
- * **Do not take Kapanol if you have heart problems which affect the rhythm of your heartbeat.**
- * **Do not take Kapanol if you are having tummy pains or vomiting or constipation.**
- * **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.**
- If you're not sure whether you should be taking Kapanol, talk to your doctor.**

Before you start to take it

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 inflammation of the pancreas, a condition associated with fits or convulsions, or diarrhoea.**

- * you have had a head injury or increased pressure in the head,
- * you regularly drink large amounts of alcohol,
- * you have abnormal curvature of the spine
- * you have low blood pressure.

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 medicines may affect the way others work. Your doctor or pharmacist will be able to tell you what to do when taking Kapanol with other medicines.

Use in children

Kapanol is not to be used for children.

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

- * 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 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.

How to take it

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

- * **Each capsule should preferably 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 but 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 pain once it has returned. Taking Kapanol at regular times means that the onset of pain is prevented.

- * If you feel your pain is 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 Poisons Information Centre (telephone 131126) for advice, if you think you or anyone else may have taken too much Kapanol, even if there are no signs of discomfort or poisoning. Urgent medical attention may be required.

Keep telephone numbers for these places handy.

If you are not sure what to do, contact your doctor or pharmacist.

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.

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.

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.

- * Try to take as little alcohol as possible while you are being treated with Kapanol. If you drink alcohol, dizziness or light-headedness may be worse.
- * Do not take medicines that might make you drowsy while you are taking Kapanol unless otherwise advised by 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,
- * headache,
- * nausea or vomiting,
- * constipation,
- * dry mouth,
- * itchy skin.

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

If you think you are having an allergic reaction to Kapanol, TELL YOUR DOCTOR IMMEDIATELY or go to the casualty department at your nearest hospital. Symptoms usually include some or all of the following:

- * wheezing
- * swelling of the lips/mouth
- * difficulty in breathing
- * hay fever
- * lumpy rash ("hives")
- * fainting

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 degrees 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 window sills.

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 your doctor tells you to stop taking Kapanol, or it has passed its expiry date, ask your pharmacist what to do with any Kapanol left over.

Product description

What Kapanol looks like.

Your Kapanol is made up of creamy white pellets inside a capsule. Kapanol capsules are packed in foil sheets. Each box contains either 20 or 60 capsules. Kapanol capsules are available in four strengths.

Amount of morphine sulfate 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 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 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 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. It also contains the following inactive ingredients:

Sucrose (sugar), maize starch, hypromellose (464), ethylcellulose, methacrylic acid copolymer, macrogol 6000, diethyl phthalate, talc, gelatin, and SW-9009 Black Ink.

Kapanol does not contain gluten.

Kapanol does not contain lactose.

Manufacturer

Your Kapanol is supplied by:

GlaxoSmithKline Australia Pty Ltd
1061 Mountain Highway
Boronia Victoria 3155

Your Kapanol is packaged and distributed by GlaxoSmithKline under licence from the manufacturer:

Faulding Pharmaceuticals
1538 Main North Road
Salisbury South Australia 5108

Further Information

Pharmaceutical companies are not in a position to give people an individual diagnosis or medical advice. Your doctor or pharmacist is the best person to give you advice on the treatment of your condition. You may also be able to find general information about your disease and its treatment from books, for example in public libraries.

Do not throw this leaflet away.

You may need to read it again.

This leaflet was prepared on 26 April 2006

The information provided applies only to: Kapanol(R).

(R) Kapanol is a registered trade mark of the GlaxoSmithKline group of companies.

Kapanol capsules:
AUST R 68439 (10 mg)
AUST R 48134 (20 mg)
AUST R 48135 (50 mg)
AUST R 48136 (100 mg).

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