

Kripton

contains the active ingredient bromocriptine (mesylate)

CONSUMER MEDICINE INFORMATION

What is in this leaflet

This leaflet answers some common questions about Kripton.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have benefits and risks. Your doctor has weighed the risks of you taking Kripton against the benefits expected for you.

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

Keep this leaflet with your medicine.

You may need to read it again.

What Kripton is used for

Kripton contains the active ingredient bromocriptine which belongs to a group of medicines called ergot alkaloids.

Bromocriptine has an effect on the body similar to that of a chemical messenger occurring naturally in the body called dopamine.

Kripton has several uses that have been outlined below.

- * Prevention of breast milk production (lactation) in women who cannot breastfeed for medical reasons. If breast milk production has already begun, your doctor can advise you about other methods of stopping lactation.

- * Treatment of abnormally high blood levels of a hormone called prolactin. This condition is sometimes caused by a tumour called prolactinoma. Kripton can be used alone or in combination with surgery to treat this tumour.
- * Treatment of acromegaly, a disease in which the body produces too much growth hormone. Kripton treats this disease by reducing the excessive amounts of growth hormone in the blood.
- * Treatment of Parkinson's disease, a condition where people experience shaking (tremor), muscle stiffness and slow and unsteady body movements. Kripton is often used in combination with other medicines such as levodopa to treat Parkinson's disease.

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

Your doctor may have prescribed Kripton for another reason.

There is not enough information available to recommend the use of Kripton in children.

Kripton is available only with a doctor's prescription.

There is no evidence that Kripton is addictive.

Before you take Kripton

When you must not take it

Do not take Kripton if you are allergic to:

- * medicines containing bromocriptine
- * ergot alkaloids, such as ergotamine or dihydroergotamine, which are medicines usually used to treat migraine headaches
- * any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include skin rash, itching or hives; swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing; wheezing or shortness of breath.

Do not take Kripton if you have or have had any of the following medical conditions:

- * severe heart disease
- * mental illness
- * high blood pressure that is not controlled
- * toxemia (a condition where women experience high blood pressure, fluid build up or convulsions during pregnancy, immediately after giving birth or within several weeks of child birth).

Do not take this medicine if you are lactose or galactose intolerant.

This medicine contains lactose.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it

Tell your doctor if you are allergic to any other medicines, foods, dyes or preservatives.

This medicine contains lactose and allura red AC (an azo dye).

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

Your doctor will discuss the risks and benefits of taking Kripton during pregnancy.

Tell your doctor if you are breastfeeding or wish to breastfeed.

Kripton is not recommended in women who wish to breastfeed as it stops breast milk production.

Tell your doctor if you have or have had, any of the following medical conditions:

- * diabetes
- * stomach and/or duodenal ulcers
- * liver problems
- * underactive thyroid gland
- * poor blood circulation.

Your doctor may want to take special care if you have any of these conditions.

If you have not told your doctor about any of the above, tell them before you start taking Kripton.

Taking other medicines

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

Some medicines may be affected by Kripton, or may affect how well it

works. These include:

- * levodopa, a medicine used to treat Parkinson's disease
- * medicines used to treat high blood pressure (the combination may cause a sudden and excessive drop in blood pressure)
- * other medicines that may raise or lower blood pressure such as ergometrine, adrenaline and ephedrine
- * medicines used to treat migraine headaches (e.g. ergotamine, dihydroergotamine)
- * some medicines used to treat fungal infections (e.g. fluconazole, ketoconazole)
- * macrolide antibiotics (e.g. erythromycin, clarithromycin, roxithromycin)
- * some medicines used to treat HIV virus infections
- * octreotide, an injection used in the treatment of acromegaly
- * metoclopramide or domperidone, medicines used to treat nausea
- * certain medicines used to treat mental illnesses, depression and psychotic conditions.

Your doctor can tell you what to do if you are taking any of these medicines.

If you are not sure whether you are taking any of these medicines, check with your doctor or pharmacist.

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

How to take Kripton

Follow all directions given to you by your doctor and pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the bottle, ask your doctor or pharmacist.

How much to take

The dose varies from patient to patient.

A different dose may be required for patients with liver problems.

Prevention of breast milk production

One tablet (2.5 mg) is taken twice daily for 2 weeks. Some patients may require a further 1 week course of Kripton to bring the breast milk production under control.

Reducing prolactin levels

The usual starting dose is half a tablet (1.25 mg) two to three times a day. This dose may be gradually increased, if necessary, to one tablet three times each day. If the high prolactin levels are caused by a prolactinoma, the dose may be increased up to 15 mg daily, usually divided into 2 to 4 doses per day.

Acromegaly

The usual starting dose is half a tablet (1.25 mg) each night. The dose is then slowly increased over a period of 1 to 2 weeks, to one tablet (5 mg) four times a day. The dose can be further increased if needed. Most patients need between 10 mg and 30 mg per day. The maximum dose is not usually more than 40 mg per day.

Parkinson's disease

The usually starting dose is half a tablet (1.25 mg) once or twice a day for the first week. The dose may then be increased by half a tablet (1.25 mg) per week until the best effect is achieved. Most patients need between 5 mg and 40 mg per day in 3 or 4 divided doses.

How to take it

Swallow the tablets or capsules with a glass of water.

When to take it

Take Kripton during or immediately after food.

This will lessen the chance of nausea or stomach upset.

Take your medicine at about the same time each day.

Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

How long to take it

Keep taking Kripton for as long as your doctor recommends.

The length of treatment with Kripton will depend on the condition you are being treated for.

If you forget to take it

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Otherwise, take the missed dose as soon as you remember, and then go back to taking your medicine as you would normally.

Do not take a double dose to make up for the dose you missed.

If you are not sure what to do or have any questions, ask your doctor or pharmacist.

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 you or anyone else may have taken too much Kripton. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

If you take too much Kripton, you may vomit, feel sick, sleepy, dizzy or faint. You may also have hallucinations (see or hear things that are not there).

While you are taking Kripton

Things you must do

If you are taking Kripton to prevent breast milk production or to lower prolactin levels and you do not wish to become pregnant, talk to your doctor about the need to use a reliable method of contraception.

Breastfeeding and high prolactin levels tend to reduce a woman's ability to fall pregnant. Taking Kripton may restore this ability.

If you become pregnant while taking Kripton, tell your doctor.

Tell all the doctors, dentists and pharmacists who are treating you that you are taking Kripton.

Before starting any new medicine, tell your doctor or pharmacist that you are taking Kripton.

Visit your doctor regularly so that they can check on your progress, especially if you are taking Kripton for a long time.

Your doctor may want to check your blood, lungs, heart, blood pressure and womb from time to time. This helps to prevent unwanted side effects.

Things you must not do

Do not use Kripton to treat any other complaints unless your doctor tells you to.

Do not give this medicine to anyone else, even if they have the same condition as you.

Things to be careful of

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

Kripton may cause episodes of sudden sleep onset, excessive drowsiness, dizziness, lightheadedness or tiredness in some people, especially when first starting to take Kripton. Kripton may also

cause confusion and hallucinations in a few people. If any of these occur, do not drive, operate machinery or do anything else that could be dangerous.

Be careful getting up from a sitting or lying position.

Dizziness, lightheadedness or fainting may occur, especially when you get up quickly. Getting up slowly may help. Be especially careful when you first start to take Kripton.

Be careful when drinking alcohol while taking Kripton.

Your tolerance for alcohol may be lower than usual when taking Kripton. Combining Kripton and alcohol may cause unwanted side effects.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Kripton.

Like all other medicines, Kripton may have unwanted side effects in some people. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

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

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

When you first start taking Kripton

Tell your doctor if you notice any of the following and they worry you:

- * feeling sick (nausea), vomiting
- * dizziness, lightheadedness or fainting, especially on standing up
- * headache
- * tiredness

- * blocked or stuffy nose.

The above list includes the more common side effects of Kripton. They are usually mild and short-lived.

While you are taking Kripton

Tell your doctor if you notice any of the following and they worry you:

- * constipation, stomach pain
- * dry mouth, metallic taste
- * loss of appetite
- * drowsiness or sleepiness which may be extreme, sudden or occurring during daytime (this has been reported very rarely)
- * difficulty sleeping
- * depression, nervousness
- * sore eyes, blurred vision
- * swelling due to fluid build up
- * pain, numbness, tingling or colour change in the fingers and toes when exposed to cold
- * buzzing, hissing, whistling, ringing or other persistent noise in the ears
- * burning sensation in the breasts
- * leg cramps or burning feeling in the feet
- * hair loss.

The list above contains the less common side effects of Kripton.

Tell your doctor immediately if you notice any of the following

- * uncontrollable twitching, jerking or writhing movements of the body
- * unsteadiness when walking
- * confusion, changes in behaviour
- * hallucinations (seeing or hearing things that are not there)
- * severe continuing headaches, sometimes with vision problems
- * irregular heart beat
- * passing more urine than normal or passing no urine
- * blood in the urine.

The above list includes serious side effects. You may need urgent medical attention.

If any of the following happen, stop taking Kripton and tell your doctor immediately, or go to Accident and Emergency at the nearest hospital:

- * vomiting blood or material that looks like coffee grounds
- * bleeding from the back passage
- * black sticky bowel motions (stools) or bloody diarrhoea
- * cough, shortness of breath, sharp chest pain with breathing that can also be in the neck, back or abdomen
- * collapse
- * difficulty swallowing, slurred speech or loss of speech
- * seizures (fits)
- * skin rash, itching or hives
- * swelling of the face, lips, tongue, which may cause difficulty in breathing or swallowing.

The above list includes rare but very serious side effects that may require urgent medical attention or hospitalisation.

Other reported side effects include compulsive behaviours such as gambling (failure to resist gambling impulses despite serious personal or family consequences), increased sex drive and hypersexuality (altered sexual interest and behaviour of significant concern to the patient or to others), shopping, eating, medication use and repetitive purposeless activities.

These side effects occur mainly in patients treated with high doses of the medicine. They are usually reversible if the dose of the medicine is reduced or stopped.

Contact your doctor as soon as possible if you or someone you know is showing signs of unusual behaviour while taking Kripton.

Tell your doctor if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some patients.

After taking Kripton

Storage

Keep Kripton where 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 your tablets or capsules in the pack until it is time to take them.

If you take the tablets or capsules out of the pack they will not keep well.

Keep Kripton tablets in a cool dry place where the temperature stays below 25 degrees C. Keep the tablets away from light.

Keep Kripton capsules in a cool dry place where the temperature stays below 30 degrees C.

Do not store Kripton or any other medicine in the bathroom or near a sink.

Do not leave Kripton in the car or on window sills.

Heat and dampness can destroy some medicines.

Disposal

If your doctor tells you to stop taking Kripton, or your medicine has passed its expiry date, ask your pharmacist what to do with any that is left over.

Product description

What it looks like

Kripton is available in 3 strengths and comes as tablets or capsules:

- * Kripton 2.5 - round, white, scored tablet marked BE/2.5 on one side and a Greek Alpha symbol on the reverse
- * Kripton 5 - grey and red capsule with "BE 5" printed on the grey

half and a Greek Alpha symbol on the red half

- * Kripton 10 - yellow and red capsule with "BE 10" printed on the yellow half and a Greek Alpha symbol on the red half.

Kripton 2.5 is available in bottles of 30 and 60 tablets.

Kripton 5 is available in bottles of 60 capsules.

Kripton 10 is available in bottles of 100 capsules.

Ingredients

The active ingredient in Kripton tablets and capsules is bromocriptine (as bromocriptine mesylate):

- * each Kripton 2.5 tablet contains 2.5 mg of bromocriptine
- * each Kripton 5 capsule contains 5 mg of bromocriptine
- * each Kripton 10 capsule contains 10 mg of bromocriptine.

Kripton 2.5 tablets also contain the following inactive ingredients:

- * lactose
- * maize starch
- * colloidal anhydrous silica
- * maleic acid
- * magnesium stearate
- * disodium edetate.

Kripton 5 and 10 capsules also contain the following inactive ingredients:

- * lactose
- * maize starch
- * colloidal anhydrous silica
- * maleic acid
- * magnesium stearate
- * sodium lauryl sulfate
- * gelatin
- * shellac
- * propylene glycol
- * ammonium hydroxide
- * potassium hydroxide
- * titanium dioxide CI 77891 (E171)
- * iron oxide black CI 77499 (E172)
- * allura red AC CI 16035 (E129)
- * iron oxide yellow CI 77499

(E172) (10 mg only).

Kripton tablets and capsules are gluten free.

Manufacturer

Kripton is made in Australia by:

Alphapharm Pty Limited

(ABN 93 002 359 739)

Chase Building 2

Wentworth Park Road

Glebe NSW 2037

Phone: (02) 9298 3999

www.alphapharm.com.au

Medical Information

Phone: 1800 028 365

Australian registration numbers:

Kripton 2.5 - AUST R 53168

Kripton 5 - AUST R 53170

Kripton 10 - AUST R 53171

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