

SICAL(TM)

calcitriol 0.25 mcg capsules

CONSUMER MEDICINE INFORMATION

What is in this leaflet

This leaflet answers some common questions about Sical capsules.

It does not contain all 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 Sical capsules against the benefits they expect it will 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 Sical is used for

Sical contains the active ingredient calcitriol, one of the naturally occurring and biologically active forms of Vitamin D. Calcitriol acts in the body in a similar manner to Vitamin D.

Sical is used to treat people with osteoporosis, a disease where the bones of the body weaken, and in the prevention of osteoporosis in people taking oral corticosteroids.

Sical capsules are also prescribed for patients who have low blood calcium levels due to osteodystrophy (a type of bone disease), hypoparathyroidism (a condition where the parathyroid glands have decreased function) and rickets.

Sical increases calcium absorption in the intestine and stimulates healthy bone growth.

There are many different types of medicines used to treat bone conditions. Sical belongs to a group of medicines known as vitamin D compounds.

Your doctor may have prescribed Sical for another purpose.

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

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

Sical is not addictive.

Before you take Sical

When you must not take it

Do not take Sical if:

- * **You have had an allergic reaction to Sical, calcitriol or any ingredients listed in the Ingredients section of this leaflet**
- * **You have high blood calcium levels (hypercalcaemia)**
- * **You have vitamin D toxicity**
- * **You are breastfeeding or wish to breastfeed.**
- * Sical may pass into the breastmilk and have unwanted effects in the baby.

Do not take Sical if the package shows signs of tampering or if the capsules do not look quite right.

Do not take Sical if the expiry date (EXP) printed on the bottle has passed.

If you take this medicine after the expiry date has passed, it may not work as well.

If you are not sure if you should be taking Sical, talk to your doctor.

Before you start to take it

You must tell your doctor if:

- 1. You are allergic to any other medicines, foods, dyes or preservatives**
- 2. You have any other health problems including:**
 - * kidney problems.
 - * you are bedridden or in a wheelchair
 - * Vitamin D resistant rickets
 - * an abnormal heartbeat
- 3. You are pregnant or intend to become pregnant.**

Your doctor will discuss the risks and benefits of taking Sical when pregnant.

If you have not told your doctor about any of the above, tell them before you take any Sical.

Taking other medicines

Tell your doctor if you are taking any other medicines including any that you have bought from a pharmacy, supermarket or healthfood shop.

Some medicines and Sical may interfere with each other. These include:

- * medicines, vitamin tablets or health supplements containing vitamin D or calcium

- * cholestyramine
- * antacids containing magnesium
- * digoxin
- * thiazide diuretics
- * phenytoin
- * phenobarbital
- * corticosteroids

These medicines may be affected by Sical, 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 have a complete list of medicines to be careful with or avoid while taking Sical.

Ask your doctor or pharmacist if you are not sure about this list of medicines.

Use in Children

When children are taking Sical for a long time, the dose should be well controlled and blood levels of calcium should be monitored so that kidney stones don't develop.

How to take Sical

How much to take

Your doctor will tell you how many Sical capsules to take each day. This will vary depending on the nature of your illness, the level of calcium in your blood and your individual response to Sical. Your doctor will need to make regular measurements of the calcium level in your blood while you are taking Sical.

How to take it

Capsules should be swallowed whole with a glass of water.

Do not open the capsules and do not take any capsules that are damaged.

When to take it

Sical can be taken at any time of day with or without food.

How long to take Sical

Sical is usually taken continuously for long term treatment.

Always tell your doctor if you want to stop taking Sical as stopping suddenly can lead to a rapid fall in calcium levels.

If you forget to take Sical

Do not take an extra dose. Wait until the next dose and take your normal dose then. Do not try to make up for the dose that you missed by taking more than one dose at a time.

In case of an overdose

Immediately telephone your doctor or Poisons Information Centre (telephone 13 11 26 in Australia or 0800 764 766 in New Zealand) for advice or go to Accident and Emergency at your nearest hospital if you think that you or anyone else may have taken too much Sical, even if there are no signs of discomfort or poisoning.

You may need urgent medical attention. Signs of overdosage include loss of appetite, headache, excessive thirst, feeling sick, vomiting and constipation.

Keep telephone numbers for these places handy.

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

While you are taking Sical

Things you must do

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

Do not take any other medicines whether they require a prescription or not without first telling your doctor.

Tell your doctor if you become pregnant while taking Sical.

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.

Tell your doctor if you feel the capsules are not helping your condition.

Be sure to keep all of your appointments with your doctor so that your progress can be checked.

Always discuss with your doctor any problems or difficulties during or after taking Sical capsules.

Sical and Diet

You should discuss your diet with your doctor and adhere strictly to your dietary recommendations.

Sudden changes in diet, particularly the amount of dairy products, may lead to increased calcium in your blood. If this happens, you may feel sick, vomit, be confused, experience weakness, be constipated and experience increased urination.

Sical and Laboratory Tests

Make sure that you keep all blood test appointments with your doctor.

These are to check your blood calcium levels while you are taking Sical. Your doctor will discuss your specific needs with you.

Things you must not do

Do not suddenly stop taking Sical or change the dose without first checking with your doctor. Your doctor will tell you the best way to slowly reduce the amount of Sical you are taking before stopping completely.

Do not let yourself run out of medicine over the weekend or on holidays.

Do not give Sical to anyone else even if their symptoms seem similar to yours.

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

Things to be careful of

Your ability to drive a car or operate machinery may be affected by medicines. Normally, your ability to drive a car or operate machinery will not be affected by Sical.

Side Effects

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

Sical helps most people but it may have unwanted side effects in a few. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

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

- * not feeling hungry (loss of appetite)
- * feeling sick
- * headache
- * fever
- * vomiting or stomach ache
- * constipation
- * weakness or muscle weakness
- * dry mouth or thirst
- * irregular and/or rapid heart beat
- * urinary tract infection

These are all symptoms of high levels of calcium in your blood. If you experience any of these, tell your doctor immediately. 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.

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

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

Ask your doctor or pharmacist if you do not 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 Sical

Storage

Keep your capsules in the bottle until it is time to take them.

If you take the capsules out of the bottle they may not keep well.

Keep Sical in a cool dry place where the temperature stays below 25 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 Sical 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.

Disposal

If your doctor tells you to stop taking Sical, or the capsules have passed their expiry date, ask your pharmacist what to do with any capsules that are left over.

Product Description

What Sical looks like

Sical 0.25 microgram capsules are oval with one half red and the other half white.

Ingredients

Sical does not contain sucrose, gluten, tartrazine or any other azo dyes.

Active ingredient -

calcitriol

Each Sical capsule contains 0.25 micrograms of calcitriol.

Inactive ingredients -

The capsules also contain:

- * butylated hydroxyanisole (320)
- * butylated hydroxytoluene (321)
- * fractionated coconut oil
- * gelatin
- * glycerol
- * sorbitol and the colours titanium dioxide (C177891), iron oxide red (C177491) and iron oxide yellow (C177492).

Sical is available in bottles of 100 capsules.

Australian Registration Number: AUST R 126438

Distributor

Sical is distributed by:

Alphapharm Pty Limited

Chase Building 2, Wentworth Park Road

GLEBE NSW 2037

This leaflet was prepared on: 17 March 2006