

## 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.

### 1. Why am I using SICAL?

SICAL contains the active ingredient calcitriol. 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.

For more information, see Section [1. Why am I using SICAL?](#) in the full CMI.

### 2. What should I know before I use SICAL?

Do not use if you have ever had an allergic reaction to SICAL 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, or are pregnant or plan to become pregnant or are breastfeeding.**

For more information, see Section [2. What should I know before I use SICAL?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with SICAL 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 SICAL?

- Your doctor will tell you how many SICAL capsules to take each day.
- Generally the daily dose for adults is 0.25 micrograms (one capsule) taken twice daily.

More instructions can be found in Section [4. How do I use SICAL?](#) in the full CMI.

### 5. What should I know while using SICAL?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Remind any doctor, dentist or pharmacist you visit that you are using SICAL.</li><li>• Do not take any other medicines whether they require a prescription or not without first telling your doctor.</li><li>• Tell your doctor if you become pregnant while taking SICAL.</li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>• Do not stop using this medicine suddenly or change the dose without first checking with your doctor.</li><li>• Do not let yourself run out of SICAL over the weekend or on holidays.</li><li>• Do not give SICAL to anyone else even if their symptoms seem similar to yours.</li><li>• Do not use SICAL to treat other complaints unless your doctor says to.</li></ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"><li>• Your ability to drive a car or operate machinery should not be affected by SICAL.</li></ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>• Store below 25°C.</li><li>• Do not leave SICAL in direct sunlight.</li></ul>

For more information, see Section [5. What should I know while using SICAL?](#) in the full CMI.

### 6. Are there any side effects?

Possible side effects include loss of appetite, feeling sick, headache, feeling tired, sleepy or drowsy, fever, vomiting or stomach ache, constipation, weakness or muscle weakness, dry mouth or thirst, irregular and/or rapid heart beat, and urinary tract infection. These are all symptoms of high levels of calcium in the blood.

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.

# SICAL®

Active ingredient(s): *calcitrol*

## Consumer Medicine Information (CMI)

This leaflet provides important information about using SICAL. **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 SICAL.**

**Where to find information in this leaflet:**

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

### 1. Why am I using SICAL?

**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.**

### 2. What should I know before I use SICAL?

#### Warnings

**Do not use SICAL if:**

- you are allergic to calcitrol, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.
- you have high levels of calcium in your blood (called hypercalcaemia)
- you have vitamin D toxicity.

**Check with your doctor if you:**

- have any other medical conditions particularly if you have kidney problems
- take any medicines for any other condition
- you are allergic to any other medicines, foods, dyes or preservatives.

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.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

**Do not take SICAL if you are breastfeeding or intend to breastfeed.** SICAL may pass into the breastmilk and have unwanted effects in the baby.

### 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 medicines may interfere with SICAL and affect how it works.**

- medicines or vitamin tablets containing vitamin D or calcium.
- cholestyramine, medicine used to lower cholesterol levels in the blood.
- sevelamer, a medicine used to lower phosphorus levels in your body.
- antacids containing magnesium.
- digoxin, medicine used to treat heart conditions.
- thiazide diuretics, medicines used to treat hypertension (high blood pressure) and oedema (water retention).
- phenytoin and phenobarbital. medicines used to control epilepsy and/or seizures.
- Corticosteroids.

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

### 4. How do I use 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.

#### Osteoporosis Patients

- Generally the daily dose for adults is 0.25 micrograms (one capsule) taken twice daily.

#### Osteodystrophy, hypoparathyroidism and rickets

- Generally the initial daily dose for adults is 0.25 micrograms (one capsule) given in the morning. If calcium levels have not improved significantly after 2 to 4 weeks treatment with SICAL, your doctor may gradually increase the dose in 0.25 microgram steps until a satisfactory calcium level in your blood is achieved.

#### Paediatric Patients

- The safety and efficacy of SICAL capsules in children has not been sufficiently investigated to enable dosing recommendations

#### How to take

- Swallow whole capsules with a glass of water.
- Do not open the capsules and do not take any capsules that are damaged.

## When to take / use SICAL

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

## If you forget to use 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.**

## If you use too much SICAL

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

### You should immediately:

- phone the Poisons Information Centre (Australia telephone 13 11 26) for advice, 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 SICAL?

### Things you should 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.

**Call your doctor straight away if you:**

- Are not feeling hungry (loss of appetite)

- feeling sick
- headache
- feeling tired, sleepy or drowsy
- fever
- vomiting or stomach ache
- constipation
- weakness or muscle weakness
- dry mouth or thirst
- irregular and/or rapid heart beat
- urinary tract infection

Remind any doctor, dentist or pharmacist you visit that you are using SICAL.

### Things you should 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.**

### Driving or using machines

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

### Looking after your medicine

- Keep SICAL in a cool dry place where the temperature stays below 25°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 window sills.

**Keep it where young children cannot reach it.**

### Getting rid of any unwanted medicine

If 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?

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
<b>Skin related</b> <ul style="list-style-type: none"><li>• rash, itching or hives on the skin</li></ul>	<b>Speak to your doctor if you have any of these less serious side</b>

<b>Less serious side effects</b>	<b>What to do</b>
	<b>effects and they worry you.</b>

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

**What SICAL looks like**

SICAL is a red coloured, oval shaped soft gelatin capsule containing clear oily fluid (AUST R 236776).

**Who distributes SICAL**

Alphapharm Pty Ltd trading as Viatris

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

[www.viatris.com.au](http://www.viatris.com.au)

Phone: 1800 274 276

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SICAL® is a Viatris company trade mark

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**Serious side effects**

<b>Serious side effects</b>	<b>What to do</b>
<p><b>Gastrointestinal related:</b></p> <ul style="list-style-type: none"> <li>• loss of appetite</li> <li>• feeling sick</li> <li>• vomiting or stomach ache</li> <li>• constipation</li> <li>• dry mouth or thirst</li> </ul> <p><b>Neurological or brain related:</b></p> <ul style="list-style-type: none"> <li>• headache</li> <li>• feeling tired, sleepy or drowsy</li> </ul> <p><b>Musculoskeletal or muscle related:</b></p> <ul style="list-style-type: none"> <li>• weakness or muscle weakness</li> <li>• Cardiovascular or heart related:</li> <li>• irregular and/or rapid heart beat</li> </ul> <p><b>Urinary related:</b></p> <ul style="list-style-type: none"> <li>• urinary tract infection</li> </ul> <p><b>Other side effects:</b></p> <ul style="list-style-type: none"> <li>• fever</li> </ul>	<p><b>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.</b></p>

**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.

**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](http://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 SICAL contains**

<b>Active ingredient (main ingredient)</b>	calcitrol
<b>Other ingredients (inactive ingredients)</b>	<ul style="list-style-type: none"> <li>• butylated hydroxyanisole</li> <li>• butylated hydroxytoluene</li> <li>• fractionated coconut oil</li> <li>• Gelatin</li> <li>• glycerol</li> <li>• iron oxide red</li> <li>• iron oxide yellow</li> <li>• purified water</li> <li>• sorbitol solution (70 per cent) (non-crystallising)</li> </ul>
<b>Potential allergens</b>	sulfites