

ACRIS®; ACRIS® Once-a-Month

contains the active ingredient risedronate sodium

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about ACRIS.

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 ACRIS against the benefits this medicine is expected to have 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 ACRIS is used for

ACRIS is used for bone disease and belongs to a group of medicines called bisphosphonates. It is used to treat:

- osteoporosis (brittle or fragile bones that may fracture easily)
- osteoporosis caused by taking steroids.

Understanding bone

Bone is a living tissue consisting of calcium and other minerals.

Throughout life, old bone is constantly broken down and replaced with new bone. After the age of 35, bone loss may occur faster than your body can replace it. If you lose too much bone then they become weaker and are more likely to break.

ACRIS works by helping to:

- slow down the process of removing old bone. This allows the bone-forming cells time to rebuild normal bone.
- maintaining and increasing bone density by rebuilding bone mass.
- reverse the progression of osteoporosis.

Osteoporosis

Osteoporosis (brittle bone disease) is a disease that causes bones to become less dense, gradually making them weaker, more brittle and consequently, more likely to break.

Broken bones may result from injury or falls. Breaks may occur in normal, everyday activity, such as lifting, or from minor injury that would not usually fracture normal bone.

Fractures usually occur at the hip, spine or wrist, although can occur in any bone of the body.

Osteoporosis can also cause back pain, height loss and a curvature of the spine.

Many patients with osteoporosis have no symptoms and may not know that they have osteoporosis.

Osteoporosis can occur in men and women, however it is more common in post menopausal women.

It is also more likely to occur in women who have had an early menopause.

Long term steroid treatment can lead to osteoporosis in both men and women.

This medicine is not addictive.

ACRIS may be used alone, or in combination with other medicines, to treat your condition.

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

Your doctor may have prescribed it for another reason.

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

Before you take ACRIS

When you must not take it

Do not take ACRIS if you have an allergy to:

- any medicine containing risedronate
- any of the ingredients listed at the end of this leaflet

Some of the symptoms of an allergic reaction may include

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin

Do not take this medicine if you are unable to stand or sit upright for at least 30 minutes.

Do not take this medicine if you have hypocalcaemia.

Hypocalcaemia is a condition where there is low calcium levels present in the blood.

Do not give this medicine to a child under the age of 18 years.

Safety and effectiveness in children younger than 18 years has not been established.

Do not take this medicine if you are pregnant.

ACRIS is not recommended for use during pregnancy, unless you and your doctor have discussed the risks and benefits involved.

Do not breast-feed if you are taking this medicine.

It is not known whether ACRIS passes into breast milk.

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 have allergies to any other medicines, foods, preservatives or dyes.

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

- Hypocalcaemia, a condition in which there are low calcium levels present in the blood. Your doctor will treat this condition before prescribing ACRIS.
- kidney disease
- problems with your oesophagus (food pipe) such as inflammation or ulcers

Tell your doctor if you have or have had any disturbances of bone and mineral metabolism, for example:

- vitamin D deficiency
- parathyroid abnormalities. Parathyroid is a hormone produced by the parathyroid glands in the neck which help control the level of calcium in the body.

Ask your doctor or dentist if you require a dental checkup before starting ACRIS.

A checkup with your dentist is particularly important if you are being given:

- any medicines (or having therapy) to treat cancer
- corticosteroids, medicines which reduce the activity of your immune system, such as prednisone or cortisone.

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

Your doctor can discuss with you the risks and benefits involved.

If you have not told your doctor about any of the above, tell him/her before you start taking ACRIS.

Taking other medicines

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

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

- antacids, medicines used to treat heartburn and indigestion such as Gaviscon and Mylanta
- other products containing calcium
- iron supplements

These medicines may be affected by ACRIS or may affect how well it works. You may need to take your medicine at a different time of day to ACRIS, or you may need to take different medicines.

You can take aspirin while you are being treated with ACRIS.

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

How to take ACRIS

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 box, ask your doctor or pharmacist for help.

How much to take

For osteoporosis, the usual dose for ACRIS is one 35 mg tablet once a week.

The usual dose for ACRIS Once-a-Month is one 150 mg tablet once a month.

How to take it

Take your ACRIS tablet in the morning, at least 30 minutes before your first meal, drink or medication of the day.

ACRIS is most effective when your stomach is empty.

Take your ACRIS tablet while sitting or standing upright.

Do not lie down immediately after swallowing it.

It is important to stay upright, for example, sitting, standing or walking around, for at least 30 minutes after swallowing your tablet. It is also very important to stay upright until after you have eaten your first food of the day. This will help make sure the tablet reaches your stomach quickly and helps avoid irritation to your oesophagus (food pipe).

Swallow the tablets whole with a glass of plain water.

It is important to take ACRIS with plain water only (120 mL), not mineral water. Mineral water and other drinks, including fruit juices, coffee and tea, will reduce the effect of ACRIS.

Do not chew or suck the tablets.

When to take it

Take your ACRIS 35 mg once-a-week tablet on the same day each week.

This tablet should be taken once a week. Choose a day of the week that suits you the best.

Take your ACRIS Once-a-Month 150 mg tablet on the same day each month.

This tablet should be taken each month. Choose a day of the month that suits you the best.

Take ACRIS in the morning, 30 minutes to 1 hour before your first meal, drink or medication of the day.

How long to take it

Continue taking your medicine for as long as your doctor tells you to.

Do not stop taking Acris without checking with your doctor or pharmacist.

If you forget to take it

For ACRIS Once-a-Week 35 mg tablets:

- **If you have forgotten to take your 35 mg tablet, just take your tablet on the day you remember.**
- **Do not take two tablets in one day to make up for the tablet you missed. Return to taking one tablet once a week, as originally scheduled on your chosen day.**

For ACRIS Once-a-Month 150 mg tablets:

- **If you have forgotten to take your 150 mg tablet, and your next monthly dose is more than 7 days ahead just take one tablet the next morning.**
- **If you have forgotten to take your 150 mg tablet, and your next monthly dose is within 7 days do not take it. Return to taking one tablet once a month, as originally scheduled on your chosen day.**

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

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

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 that you or anyone else may have taken too much ACRIS, drink a full glass of milk or take antacids. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

While you are taking ACRIS

Things you must do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking ACRIS.

Tell any other doctors and pharmacists who treat you that you are taking this medicine.

If you require a dental procedure, tell your dentist that you are taking ACRIS.

Invasive dental procedures should be avoided where possible.

This type of medicine may cause jaw-bone problems in some people. Jaw-bone problems may include infection, and delayed healing after teeth are pulled out or other work that involves drilling into the jaw.

If you develop a toothache, jaw pain, painful exposed bone or swelling, especially following dental work, tell your doctor or dentist immediately.

Speak to your doctor and dentist about good oral hygiene and regular dental check-ups while you are using ACRIS.

If you develop a degenerative disease of the jaw (osteonecrosis) while taking ACRIS, any dental surgery may exacerbate the condition.

If you become pregnant while taking this medicine, tell your doctor immediately.

Tell your doctor if you develop new or unusual pain in your hip or thigh.

Rarely, patients have experienced fracture in a specific part of the thigh bone.

Things you must not do

Do not lie down for 30 minutes after taking ACRIS.

Do not have any food or drink, except for plain water for 30 minutes after taking ACRIS.

Do not take ACRIS to treat any other complaints unless your doctor tells you to.

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

Do not stop taking your medicine or change the dosage without checking with your doctor or pharmacist.

Things to be careful of

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

This medicine may cause dizziness or blurred vision in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

If you feel light-headed, dizzy or faint when getting out of bed or standing up, get up slowly.

Standing up slowly, especially when you get up from bed or chairs, will help your body get used to the change in position and blood pressure. If this problem continues or gets worse, talk to your doctor.

Side effects

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

This medicine helps most people with osteoporosis, but it may have unwanted side effects in some people.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following list of side effects.

You may not experience any of them.

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

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

- stomach pain
- indigestion, an uncomfortable feeling in the stomach or belching after eating
- diarrhoea
- aching muscles, muscle tenderness or weakness, not caused by exercise
- painful, swollen joints
- painful bones
- headache
- nausea
- runny or blocked nose, sneezing, facial pressure or pain
- sore throat and discomfort when swallowing
- dizziness
- unusual weakness.

The above list includes the more common side effects of your medicine. They are usually mild.

Tell your doctor immediately if you notice any of the following:

- itchiness, skin rash or redness of the skin, sometimes made worse by sunlight
- blurred vision, difficulty seeing or pain and redness of the of the eye
- problems with your jaw or teeth, associated with delayed healing and/or infection of the jaw or teeth, most commonly following a tooth extraction or invasive dental work.

The above list includes serious side effects that may require medical attention. Serious side effects are rare.

If any of the following happen, stop taking ACRIS and tell your doctor immediately:

- difficulty or pain on swallowing
- chest pain
- new or worsening heartburn

These side effects may be due to the irritation or ulceration of the food pipe. They may worsen if you continue taking the tablets. These side effects are rare.

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

- signs of allergy such as swelling of the face, lips, tongue or other parts of the body; shortness of breath, wheezing or troubled breathing difficulty or pain on swallowing
- severe skin reaction

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

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

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

After taking ACRIS

Storage

Keep your tablets in the pack until it is time to take them.

If you take the tablets out of the pack they may not keep well.

Keep your tablets in a cool dry place where the temperature stays below 25°C.

Do not store ACRIS or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep it 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.

Disposal

If your doctor or pharmacist tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any tablets that are left over.

Product description

What it looks like

- ACRIS 35 mg: light orange film-coated, round, biconvex, tablets marked M on one side of the tablet and 714 on the other side.
- ACRIS Once-a-Month 150 mg: blue, round, biconvex, beveled edge film-coated tablets and debossed with RR|2 on one side and M on the other side.

Ingredients

- ACRIS contains 35 mg of risedronate sodium as the active ingredient.
- ACRIS Once-a-Month contains 150 mg of risedronate sodium as the active ingredient.

Both medicines contain the following inactive ingredients:

- mannitol
- cellulose - microcrystalline
- crospovidone
- silicon dioxide
- magnesium stearate

In addition to the above inactive ingredients, ACRIS contains:

- Opadry II complete film coating system 40L97490 beige (ARTG No. 107225)
- Opadry complete film coating system YS-1-7006 clear (ARTG No. 12789).

In addition to the above inactive ingredients, ACRIS Once-a-Month contains:

- Opadry II Blue 40C10881 (ARTG No. 108066).

This medicine does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

Supplier

ACRIS is supplied in Australia by:

Alphapharm Pty Limited

(ABN 93 002 359 739)

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

Phone: (02) 9298 3999

www.alphapharm.com.au

Australian registration numbers:

- ACRIS risedronate sodium 35 mg film-coated tablet blister pack
- AUST R 163785
- ACRIS Once-a-Month risedronate sodium 150 mg film-coated tablet blister pack
- AUST R 196060

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