Package leaflet: Information for the patient

Acrel GR 35 mg gastro-resistant tablets

risedronate sodium

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Acrel GR is and what it is used for
2. What you need to know before you take Acrel GR
3. How to take Acrel GR
4. Possible side effects
5. How to store Acrel GR
6. Contents of the pack and other information

1. What Acrel GR is and what it is used for

Acrel GR belongs to a group of non-hormonal medicines called bisphosphonates which are used to treat bone diseases. It works directly on your bones to make them stronger and therefore less likely to break.

Bone is a living tissue. Old bone is constantly removed from your skeleton and replaced with new bone.

Postmenopausal osteoporosis is a condition occurring in women after the menopause where the bones become weaker, more fragile and more likely to break after a fall or strain.
Osteoporosis can also occur in men due to a number of causes including ageing and/or a low level of the male hormone, testosterone.

The spine, hip and wrist are the most likely bones to break, although this can happen to any bone in your body. Osteoporosis–related fractures can also cause back pain, height loss and a curved back. Many patients with osteoporosis have no symptoms and you may not even have known that you had it.

What Acrel GR is used for
Treatment of osteoporosis in postmenopausal women, even if osteoporosis is severe. It reduces the risk of spinal and hip fractures.

2. What you need to know before you take Acrel GR

Do not take Acrel GR:
- If you are allergic to risedronate sodium or any of the other ingredients of this medicine (listed in section 6)
- If your doctor has told you that you have a condition called hypocalcaemia (a low blood calcium level)
- If you may be pregnant, are pregnant or planning to become pregnant
- If you are breast-feeding
- If you have severe kidney problems.

Warnings and precautions
Talk to your doctor or pharmacist before taking Acrel GR:
- If you are unable to stay in an upright position (sitting or standing) for at least 30 minutes.
- If you have abnormal bone and mineral metabolism (for example lack of vitamin D, parathyroid hormone abnormalities, both leading to a low blood calcium level).
- If you have or have had problems in the past with your oesophagus (the tube that connects your mouth with your stomach). For instance you may have or have had pain or difficulty in swallowing food or you have previously been told that you have Barrett's oesophagus (a condition associated with changes in the cells that line the lower oesophagus).
- If you have had or have pain, swelling or numbness of the jaw or a "heavy jaw feeling" or loosening of a tooth.
- If you are under dental treatment or will undergo dental surgery, tell your dentist that you are being treated with Acrel GR.

Your doctor will advise you on what to do when taking Acrel GR if you have any of the above.

Children and adolescents
Acrel GR is not recommended for use in children below 18 due to insufficient data on safety and efficacy.

Other medicines and Acrel GR
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.
Medicines containing one of the following lessen the effect of Acrel GR if taken at the same time:
- Calcium
- Magnesium
- Aluminium (for example some indigestion mixtures)
- Iron

Take these medicines at a different time of day to your Acrel GR tablets.

Acrel GR with food and drink
Acrel GR should be taken immediately after breakfast.

Pregnancy and breast-feeding
Do not take Acrel GR if you may be pregnant, are pregnant or planning to become pregnant (see section 2, "Do not take Acrel GR").

Do not take Acrel GR if you are breast-feeding (see section 2, "Do not take Acrel GR").

Acrel GR should only be used to treat postmenopausal women.

Driving and using machines
Acrel GR is not known to affect your ability to drive and use machines.

Acrel GR contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per gastro-resistant tablet, that is to say essentially 'sodium-free'.

3. How to take Acrel GR

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is one Acrel GR tablet (35 mg of risedronate sodium) once a week. Choose one day of the week that best fits your schedule. Every week, take the Acrel GR tablet on your

chosen day.

For your convenience, so that you take your tablet on the right day every week, there is a feature included with Acrel GR pack:
There are boxes/spaces on the back of the blister card. Please mark the day of the week you have chosen to take your Acrel GR. Also, write in the dates you will take the tablet.

When to take Acrel GR
Acrel GR should be taken immediately after breakfast. If taken on an empty stomach there is an increased risk of abdominal pain.

How to take Acrel GR
- Acrel GR is for oral use.
- Take the tablet whilst you are in an upright position (you may sit or stand) to avoid heartburn.
- Swallow the tablet with at least one glass (120 ml) of plain water.
- The tablet must be swallowed whole. Do not suck or chew the tablet.
- Do not lie down for 30 minutes after taking your tablet.

Your doctor will tell you if you need calcium and vitamin supplements, if you are not taking enough from your diet.

If you take more Acrel GR than you should
If you or somebody else has accidentally taken more tablets than prescribed, drink one full glass of milk and seek medical attention.

If you forget to take Acrel GR
If you have forgotten to take your tablet on your chosen day, take it on the day you remember. Return to taking one tablet once a week on the day the tablet is normally taken. Do not take two tablets on the same day.

If you stop taking Acrel GR
If you stop treatment you may begin to lose bone mass. Please talk to your doctor before you consider stopping treatment.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Stop taking Acrel GR **and contact a doctor immediately** if you experience any of the following:
- Symptoms of a severe allergic reaction such as:
  - Swelling of face, tongue or throat
  - Difficulties in swallowing
  - Hives and difficulties in breathing

  The frequency of this side effect is not known (cannot be estimated from the available data).
- Severe skin reactions such as:
  - Blistering of the skin, mouth, eyes and other moist body surfaces (genitals) (Stevens Johnson syndrome)
  - Palpable red spots on the skin (leukocytoclastic vasculitis)
  - Red rash over many parts of the body and/or loss of the outer layer of the skin (toxic epidermal necrolysis).

  The frequency of this side effect is not known (cannot be estimated from the available data).

Tell your doctor promptly if you experience the following side effects:
- Eye inflammation, usually with pain, redness and light sensitivity. The frequency of this side effect is not known (cannot be estimated from the available data).

- Orbital inflammation – inflammation of the structures surrounding the eyeball. The symptoms may include: pain, swelling, redness, extrusion of the eye ball and vision disturbances. The frequency of this side effect is not known (cannot be estimated from the available data).
- Bone necrosis of the jaw (osteonecrosis) associated with delayed healing and infection, often following tooth extraction (see section 2, "Warnings and precautions"). The frequency of this side effect is not known (cannot be estimated from the available data).
- Symptoms from oesophagus such as pain when you swallow, difficulties in swallowing, chest pain or new or worsened heartburn. The frequency of this side effect is not known (cannot be estimated from the available data).

Unusual fracture of the thigh bone particularly in patients on long-term treatment for osteoporosis may occur rarely. Contact your doctor if you experience pain, weakness or discomfort in your thigh, hip or groin as this may be an early indication of a possible fracture of the thigh bone.

However in clinical studies the other side effects that were observed were usually mild and did not cause the patient to stop taking their tablets.

Other possible side effects:

Common side effects (may affect up to 1 in 10 people):
- Indigestion, feeling sick, stomach ache, stomach cramps or discomfort, constipation, feelings of fullness, bloating, diarrhoea, vomiting, abdominal pain
- Pain in your bones, muscles or joints
- Headache

Uncommon side effects (may affect up to 1 in 100 people):
- Flu
- Decreased number of white blood cells
- Depressed mood
- Dizziness, numbness tingling or burning sensation, decreased sensitivity
- Inflammation of the coloured part of the eye (iris) (red painful eyes with a possible change in vision), inflammation of the outermost layer of the eye and the inner surface of the eyelids (conjunctivitis), eye redness, vision blurred
- Hot flush, low blood pressure
- Coughing
- Inflammation or ulcer of the oesophagus (the tube that connects your mouth with your stomach) causing difficulty and pain in swallowing (see also section 2, "Warnings and precautions"), inflammation of the stomach and duodenum (bowel draining the stomach), reflux from oesophagus or from stomach, gastritis, increased acid in the stomach, stomach hernia, gut inflammation, gut distension, belching, wind, blood in the stool, bleeding from your bowels, heartburn, haemorrhoids, stool leakage
- Numbness of mouth, swollen tongue, swollen lips, dry mouth, gum inflammation, mouth sores
- Redness of the skin, rash, itching, purple spots on the skin, allergic dermatitis
- Muscle weakness/tiredness, muscle spasm, back pain, pain in extremity, pain in jaw, joint pain, neck pain
- Kidney stones
- Cyst in the ovary
- Tiredness, chills, flu like illness, pain in the chest, fever, swelling of face or body, pain, fatigue
- Increased activity of parathyroid gland
- Blood calcium and phosphate level decreased, blood calcium level increased, platelet count decreased, heart rate irregular, occult blood in the stools, urine analysis abnormal
- Allergic reactions

Rare side effects (may affect up to 1 in 1,000 people):
- Narrowing of the oesophagus (the tube that connects your mouth with your stomach), tongue

inflammation.
- Abnormal liver tests have been reported. These can only be diagnosed from a blood test.

Very rare side effects (may affect up to 1 in 10,000 people):
- Talk to your doctor if you have ear pain, discharge from the ear, and/or an ear infection. These could be signs of bone damage in the ear.

During post-marketing experience, the following have been reported (unknown frequency):
- Hair loss
- Liver disorders, some cases were severe

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly to ***the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.*** By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Acrel GR

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and blister after EXP. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Acrel GR contains
The active substance is risedronate sodium. Each tablet contains 35 mg risedronate sodium, equivalent to 32.5 mg risedronic acid.

The other ingredients are:
Tablet core:
Microcrystalline cellulose, silica (colloidal anhydrous), disodium edetate, sodium starch glycolate, stearic acid, magnesium stearate.

Enteric coating:
Methacrylic acid - ethyl acrylate copolymer (1:1), triethyl citrate, talc, iron oxide yellow E172, simeticone, polysorbate 80.

What Acrel GR looks like and contents of the pack
Acrel GR are oval, yellow tablets with “EC 35” engraved on one side. The dimensions of the tablet are as follows: width 13 mm, length 6 mm.

Blister packs of 1, 2, 4, 10, 12 or 16 tablets.
Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:
Theramex HQ UK Limited

5th Floor, 50 Broadway
London
SW1H 0BL
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Manufacturer:
Balkanpharma-Dupnitsa AD
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