

Package leaflet: Information for the patient

Optinate Septimum 35 mg film-coated 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 Optinate Septimum is and what it is used for
2. What you need to know before you take Optinate Septimum
3. How to take Optinate Septimum
4. Possible side effects
5. How to store Optinate Septimum
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1. What Optinate Septimum is and what it is used for

What Optinate Septimum is

Optinate Septimum 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 Optinate Septimum is used for

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

Treatment of osteoporosis in men at high risk of fractures.

2. What you need to know before you take Optinate Septimum

Do not take Optinate Septimum

- 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 Optinate Septimum:

- 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 been told by your doctor that you have an intolerance to some sugars (such as lactose).
- 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 Optinate Septimum.

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

Children and adolescents

Risedronate sodium is not recommended for use in children below 18 due to insufficient data on safety and efficacy.

Other medicines and Optinate Septimum

Medicines containing one of the following lessen the effect of Optinate Septimum if taken at the same time:

- calcium
- magnesium
- aluminium (for example some indigestion mixtures)
- iron.

Take these medicines at least 30 minutes after your Optinate Septimum tablet.

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Optinate Septimum with food and drink

It is very important that you do NOT take your Optinate Septimum tablet with food or drinks (other than plain water) so that it can work properly. In particular do not take this medicine at the same time as dairy products (such as milk) as they contain calcium (see section 2, "Other medicines and Optinate Septimum").

Take food and drinks (other than plain water) at least 30 minutes after your Optinate Septimum tablet.

Pregnancy and breast-feeding

Do NOT take Optinate Septimum if you may be pregnant, are pregnant or planning to become pregnant (see section 2, "Do not take Optinate Septimum"). The potential risk associated with the use of risedronate sodium (active substance in Optinate Septimum) in pregnant women is unknown.

Do NOT take Optinate Septimum if you are breast-feeding (see section 2, “Do not take Optinate Septimum”).

Optinate Septimum should only be used to treat postmenopausal women and men.

Driving and using machines

Optinate Septimum is not known to affect your ability to drive and use machines.

Optinate Septimum contains lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product (see section 2, “Warnings and precautions”).

Optinate Septimum contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per film-coated tablet, that is to say essentially ‘sodium-free’.

3. How to take Optinate Septimum

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 Optinate Septimum tablet (35 mg of risedronate sodium) once a week. Choose one day of the week that best fits your schedule. Every week, take the Optinate Septimum 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 the Optinate Septimum 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 Optinate Septimum tablet. Also, write in the dates you will take the tablet.

WHEN to take the Optinate Septimum tablet

Take your Optinate Septimum tablet at least 30 minutes before the first food, drink (other than plain water) or other medicine of the day.

HOW to take the Optinate Septimum tablet

- Take the tablet whilst you are in an upright position (you may sit or stand) to avoid heartburn.
- Swallow it with at least one glass (120 ml) of plain water.
- Swallow it whole. Do not suck or chew it.
- 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 Optinate Septimum than you should

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

If you forget to take Optinate Septimum

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 a double dose to make up for a forgotten tablet.

If you stop taking Optinate Septimum

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 Optinate Septimum 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 breathingThe frequency of this side effect is not known (cannot be estimated from the available data).
- Severe skin reactions that can include blistering of the skin. 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. This side effect is uncommon (may affect up to 1 in 100 people).

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.

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.
- Pain in your bones, muscles or joints.
- Headache.

Uncommon side effects (may affect up to 1 in 100 people)

- 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).
- Inflammation of the coloured part of the eye (iris) (red painful eyes with a possible change in vision).

Rare side effects (may affect up to 1 in 1,000 people)

- Inflammation of the tongue (red swollen, possibly painful), narrowing of the oesophagus (the tube that connects your mouth with your stomach).
- Abnormal liver tests have been reported. These can only be diagnosed from a blood test.

During post-marketing experience, the following have been reported

- Very rare: 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.
- Unknown frequency:
 - Hair loss
 - Liver disorders, some cases were severe

Rarely, at the beginning of treatment, a patient's blood calcium and phosphate levels may fall. These changes are usually small and cause no symptoms.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via [the national reporting system](#) listed in [Appendix V](#)*. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Optinate Septimum

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 Optinate Septimum 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: lactose monohydrate (see section 2), crospovidone A, magnesium stearate and cellulose microcrystalline.

Film coating: hypromellose, macrogol, hydroxypropylcellulose and colloidal anhydrous silica, titanium dioxide [E171], iron oxide yellow [E172], iron oxide red [E172].

What Optinate Septimum looks like and contents of the pack

Optinate Septimum 35 mg film-coated tablets are oval light-orange 11.7 x 5.8 mm tablets with the letters "RSN" on one side and "35 mg" on the other side. The tablets are supplied in 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:

[To be completed nationally]

Manufacturer:
Balkanpharma-Dupnitsa AD
3, Samokovsko Shosse Str.
2600 Dupnitsa
Bulgaria

This medicinal product is authorised in the Member States of the EEA under the following names:

Austria:	Actonel einmal wöchentlich 35 mg Filmtabletten
Belgium:	Actonel 35 mg Wekelijks filmomhulde tabletten Actonel 35 mg hebdomadaire comprimé pelliculé Actonel 35 mg Wöchentlich Filmtabletten
Cyprus:	Actonel OAW / "μία φορά την εβδομάδα"
Denmark:	Optinate Septimum filmovertrukne tabletter
Finland:	Optinate Septimum 35 mg kalvopäällysteiset tabletit
France:	Actonel 35 mg comprimé pelliculé
Germany:	Risedronat Theramex 35 mg Filmtabletten
Greece:	Actonel OAW / "μία φορά την εβδομάδα"
Hungary:	Actonel 35 mg filmtablettá
Iceland:	Optinate Septimum 35 mg filmuhúðaðar töflur
Italy:	Actonel 35 mg compresse rivestite con film
Luxembourg:	Actonel 35 mg hebdomadaire comprimé pelliculé
Malta:	Actonel "Once a Week" 35 mg film-coated tablet
The Netherlands:	Actonel Wekelijks 35 mg, filmomhulde tabletten
Portugal:	Actonel 35 mg comprimidos revestidos por película
Spain:	Actonel semanal 35 mg comprimidos recubiertos con película
Sweden:	Optinate Septimum 35 mg filmdragerade tabletter

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