170 mm

600 mm

Package leaflet: Information for the user

Sedropor
150 mg film-coated tablets
Ibandronic acid

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

1. What Sedropor is and what it is used for

Sedropor belongs to a group of medicines called bisphosphonates. It contains the active substance ibandronic acid. Sedropor may reverse bone loss by stopping more loss of bone and increasing bone mass in most women who take it, even though they won't be able to see or feel a difference. Sedropor may help lower the chances of breaking bones (fractures). This reduction in fractures was shown for the spine but not for the hip.

Sedropor is prescribed to you to treat postmenopausal osteoporosis because you have an increased risk of fractures.
Osteoporosis is a thinning and weakening of the bones, which is common in women after the menopause. At the menopause, a woman's ovaries stop producing the female hormone, oestrogen, which helps to keep her skeleton healthy.

The earlier a woman reaches the menopause, the greater her risk of fractures in osteoporosis.

Other things that can increase the risk of fractures include:
- not enough calcium and vitamin D in the diet
- smoking, or drinking too much alcohol
- not enough walking or other weight-bearing exercise
- a family history of osteoporosis

A healthy lifestyle will also help you to get the most benefit from your treatment. This includes
- eating a balanced diet rich in calcium and vitamin D
- walking or any other weight-bearing exercise
- not smoking; and not drinking too much alcohol.

2. What you need to know before you take Sedropor

Do not take Sedropor
- If you are allergic to ibandronic acid, or any of the other ingredients of this medicine (listed in section 6).
- If you have certain problems with your gullet/food pipe (oesophagus) such as narrowing or difficulty swallowing.
- If you can't stand or sit upright for at least one hour (60 minutes) at a time.
- **If you have, or had in the past, low blood calcium**. Please consult your doctor.

Warnings and precautions
Talk to your doctor or pharmacist before taking [Ibandronic acid].

A side effect called osteonecrosis of the jaw (ONJ) (bone damage in the jaw) has been reported very rarely in the post-marketing setting in patients receiving ibandronic acid for osteoporosis. ONJ can also occur after stopping treatment.

It is important to try and prevent ONJ developing as it is a painful condition that can be difficult to treat. In order to reduce the risk of developing osteonecrosis of the jaw, there are some precautions you should take.

Before receiving treatment, tell your doctor/nurse (healthcare professional) if:
- you have any problems with your mouth or teeth such as poor dental health, gum disease, or a planned tooth extraction.
- you do not receive routine dental care or have not had a dental check up for a long time.
- you are a smoker (as this may increase the risk of dental problems).
- you have previously been treated with a bisphosphonate (used to treat or prevent bone disorders).
- you are taking medicines called corticosteroids (such as prednisolone or dexamethasone).
- you have cancer.

Your doctor may ask you to undergo a dental examination before starting treatment with [Ibandronic acid].

While being treated, you should maintain good oral hygiene (including regular teeth brushing) and receive routine dental check-ups. If you wear dentures you should make sure these fit properly. If you are under dental treatment or will undergo dental surgery (e.g. tooth extractions), inform your doctor about your dental treatment and tell your dentist that you are being treated with [Ibandronic acid].

Contact your doctor and dentist immediately if you experience any problems with your mouth or teeth such as loose teeth, pain or swelling, or non-healing of sores or discharge, as these could be signs of osteonecrosis of the jaw.

Some people need to be especially careful while they are taking [Ibandronic acid]. Talk to your doctor before taking [Ibandronic acid]:
- If you have any disturbances of mineral metabolism (such as vitamin D deficiency).
- If your kidneys are not functioning normally.
- If you have any swallowing or digestive problems.

Irritation, inflammation or ulceration of the gullet/food pipe (oesophagus) often with symptoms of severe pain in the chest, severe pain after swallowing food and/or drink, severe nausea, or vomiting may occur, especially if you do not drink a full glass of water and/or if you lie down within an hour of taking [Ibandronic acid]. If you develop these symptoms, stop taking [Ibandronic acid] and tell your doctor straight away (see section 3).

Children and **adolescents**
Do not give Sedropor to children or adolescents below 18 years.

Other medicines and Sedropor
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. Especially:
- **Supplements containing calcium, magnesium, iron or aluminium**, as they could possibly influence the effects of Sedropor .
- Acetylsalicylic acid and other non-steroidal anti-inflammatory medicines (NSAIDs) and other non-steroidal anti-inflammatory medicines (NSAIDs) (including ibuprofen, diclofenac sodium and naproxen) may irritate the stomach and intestine. Sedropor may also do so. So be especially careful if you take painkillers or anti-inflammatories while you're taking Sedropor.

After swallowing your monthly Sedropor tablet, **wait for 1 hour before taking any other medication**, including indigestion tablets or medicine, calcium supplements, or vitamins.

Sedropor with food and drink
Do not take Sedropor with food. Sedropor is less effective if it's taken with food. **You can drink water but no other drinks**.

After you have taken Sedropor, please wait for 1 hour before you can have your first food and further drinks. (see 3. How to take Sedropor).

Pregnancy and breast-feeding
Sedropor is for use only by postmenopausal women and must not be taken by women who could still have a baby.
Do not take Sedropor if you are pregnant or breast feeding.
Ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines
You can drive and use machines as it's expected that Sedropor has no or negligible effect on your ability to drive and use machines.

Sedropor contains lactose.
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

Sedropor 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 Sedropor

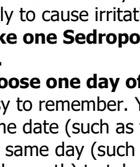
Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

The recommendeddose of Sedropor is one tablet once a month.

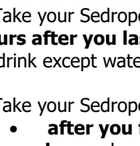
Taking your monthly tablet
It's important to follow these instructions carefully. They are designed to help your Sedropor tablet reach your stomach quickly, so it's less likely to cause irritation.
- **Take one Sedropor 150 mg tablet once a month.**
- **Choose one day of the month** that will be easy to remember. You can choose either the same date (such as the 1st of each month) or the same day (such as the first Sunday of each month) to take your Sedropor tablet. Choose the date that best fits your routine.
- Take your Sedropor tablet **at least 6 hours after you last had anything** to eat or drink except water.
- Take your Sedropor tablet
  - **after you first get up for the day**, and
  - **before you have anything else to eat or drink** (on an empty stomach)
- **Swallow your tablet with a full glass of water** (at least 180 ml).

Do not take your tablet with water with a high concentration of calcium, fruit juice or any other drinks. If there is a concern regarding potentially high levels of calcium in the tap water (hard water), it is advised to use bottled water with a low mineral content.

- **Swallow your tablet whole** — do not chew it, crush it or let it dissolve in your mouth.
- **For the next hour (60 minutes)** after you've taken your tablet
  - **do not lie down**; if you do not stay upright (standing or sitting), some of the medicine could leak back into your oesophagus



  - **do not eat anything**



  - d**o not drink** anything (except water if you need it)
  - do **not take any other medicines**
- After you've waited for an hour, you can have your first food and drink of the day. Once you've eaten, it's OK to lie down if you wish, and to take any other medication you need.

Continuing to take Sedropor
It's important to keep taking Sedropor every month, as long as your doctor prescribes it for you. After 5 years of using Sedropor, please consult with your doctor whether you should continue to take Sedropor.

If you take more Sedropor than you should
If you've taken more than one tablet by mistake, **drink a full glass of milk and talk to your doctor straight away**.

Do not make yourself vomit, and do not lie down — this could cause Sedropor to irritate your oesophagus.

If you forget to take Sedropor
- If you forget to take your tablet on the morning of your chosen day, **do not take a tablet later in the day**. Instead, consult your calendar and find out when your next scheduled dose is:
- **If you forgot to take your tablet on your chosen day and your next scheduled dose is only 1 to 7 days away…**

  Never take two Sedropor tablets within the same week. You should wait until your next scheduled dose is due and take it as normal. Then, continue taking one tablet once a month on the scheduled days you've marked on your calendar.
- **If you forgot to take your tablet on your chosen day and your next scheduled dose is more than 7 days away…**

You should take one tablet the next morning after the day you remember. Then, continue taking one tablet once a month on the scheduled days you've marked on your calendar.

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.

Talk to a nurse or a doctor straight away if you notice any of the following serious side effects - you may need urgent medical treatment:

Uncommon (may affect up to 1 in 100 people)
- severe pain in the chest, severe pain after swallowing food or drink, severe nausea, or vomiting, difficulty in swallowing. You may have a severe inflammation of your gullet/food pipe, possibly with sores or constriction of the gullet/food pipe

Rare (may affect up to 1 in 1000 people):
- itching, swelling of your face, lips, tongue and throat, with difficulty breathing.
- persistent eye pain and inflammation
- new pain, weakness or discomfort in your thigh, hip or groin. You may have early signs of a possible unusual fracture of the thigh bone

Very rare (may affect up to 1 in 10,000 people):
- pain or sore in your mouth or jaw, You may have early signs of severe jaw problems (necrosis (dead bone tissue) in the jaw bone)
- serious, potentially life-threatening allergic reaction
- 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.
- severe adverse skin reactions

Other possible side effects

Common (may affect less than 1 in 10 people)
- headache
- heartburn, discomfort in swallowing, stomach or tummy pain (may be due to an inflammation of the stomach), indigestion, nausea, havingdiarrhoea (loose bowels)
- muscle cramps, stiffness of your joints and limbs
- flu-like symptoms, including fever, shaking and shivering, feeling of discomfort, bone pain and aching muscles and joints. Talk to a nurse or doctor if any effects become troublesome or last more than a couple of days
- rash

Uncommon (may affect less than 1 in 100 people)
- dizziness
- flatulence (farting, feeling bloated)
- back pain
- feeling tired and exhausted
- asthma attacks

Rare (may affect less than 1 in 1000 people):
- inflammation of the duodenum (first section of the bowel) causing stomach pain
- hives

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 Sedropor

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

There are no special storage instructions.

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

Do not throw away any medicines via wastewater or household waste. Ask your doctor or 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 Sedropor contains
- The active substance is ibandronic acid. One tablet contains 150 mg of ibandronic acid(as sodium monohydrate).
- The other ingredients are:

tablet core: Povidone, cellulose microcrystalline, maize starch pregelatinised, crospovidone, silica colloidal anhydrous, Glycerol Dibehenate.
tablet coat: Opadry OY-LS-28908 (white II) consisting of: hypromellose, lactose monohydrate, titanium dioxide (E171), Macrogol 4000.

What Sedropor looks like and contents of the pack
Sedropor 150 mg film-coated tablets are white, round biconvex tablets.

Sedropor 150 mg film-coated tablets are supplied in a cardboard box containing the appropriate number (1 or 3 tablets) of PA/Aluminium/PVC- Aluminium foil blisters (alu-alu blister) containing 1 or 3 tablets.

THIS IS A MEDICAMENT
- A Medicament is a product, which affects your health, and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are the experts in medicines, their benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed.
- Do not repeat the same prescription, without consulting your doctor.

Keep all medicaments out of the reach of children.

Marketing Authorisation Holder:
Pharmathen S.A., Dervenakion 6, 15351 Pallini, Attiki, Greece

Responsible for exports:
Pharmathen S.A., Dervenakion 6, 15351 Pallini, Attiki, Greece

Manufacturer:
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