

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.

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor.

In this leaflet:

1. What Sedropor is and what it is used for
2. Before you take Sedropor
3. How to take Sedropor
4. Possible side effects
5. How to store Sedropor
6. Further information

1. WHAT SEDROPOR IS AND WHAT IT IS USED FOR

Sedropor belongs to a group of medicines called bisphosphonates (used in the treatment of osteoporosis). It contains ibandronic acid. It does not contain hormones. 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 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

Many people with osteoporosis have no symptoms. If you have no symptoms you may not know if you have the condition. However, osteoporosis makes you more likely to break bones if you fall or hurt yourself. A broken bone after the age of 50 may be a sign of osteoporosis. Osteoporosis can also cause back pain, height loss and a curved back.

Sedropor prevents loss of bone from osteoporosis, and helps to rebuild bone. Therefore Sedropor makes bone less likely to break.

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. BEFORE YOU TAKE SEDROPOR

Do not take Sedropor

- If you are allergic (hypersensitive) to ibandronic acid, or to any of the other ingredients of Sedropor (see section 6 for a list of the ingredients).
- If you have certain problems with your oesophagus (the tube connecting your mouth with your stomach) 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.

Do not give Sedropor to children or adolescents.

Take special care with Sedropor

Some people need to be especially careful while they're taking Sedropor. Check with your doctor:

- 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.
- If you are under dental treatment or will undergo dental surgery, tell your dentist that you are being treated with Sedropor.

Irritation, inflammation or ulceration of the oesophagus (the tube connecting your mouth with your stomach) 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 plain water and/or if you lie down within an hour of taking Sedropor. If you develop these symptoms, speak to your doctor straight away.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. Especially:

- supplements containing calcium, magnesium, iron or aluminium, as they could possibly influence the effects of Sedropor.
- Aspirin and other non-steroidal anti-inflammatory medicines (NSAIDs) (including ibuprofen, diclofenac sodium and naproxen) may irritate the stomach and intestine. Bisphosphonates (like 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.

Taking Sedropor with food and drink

Do not take Sedropor with food. Sedropor is less effective if it's taken with food. You can drink plain water but no other drinks (see 3. HOW TO TAKE SEDROPOR).

Pregnancy and breast-feeding

Do not take Sedropor if you're pregnant or breast feeding. If you're breast feeding, you may need to stop in order to take Sedropor.

Driving and using machines

You can drive and use machines as it's very unlikely that Sedropor will affect your ability to drive and use machines.

Important information about some of the ingredients of Sedropor

Sedropor contains an ingredient called 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.

3. HOW TO TAKE SEDROPOR

Always take Sedropor exactly as your doctor has told you. If you are not sure about anything, ask your doctor or pharmacist.

The usual dose 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 plain 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 plain water** (at least 180 ml). **Do not** take your tablet with mineral water, fruit juice or any other drinks.

- **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**

- do **not drink** anything (except plain 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.

Do not take your tablet at bedtime or before you get up for the day.

Continuing to take Sedropor

It's important to keep taking Sedropor every month, as long as your doctor prescribes it for you. Sedropor can treat osteoporosis only as long as you keep taking it.

If you take too much Sedropor

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 a dose

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 your next scheduled dose is only 1 to 7 days away...

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 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.

Never take two Sedropor tablets within the same week.

4. POSSIBLE SIDE EFFECTS

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

These side effects may occur with certain frequencies, which are defined as follows:

- very common: affects more than 1 user in 10
- common: affects 1 to 10 users in 100
- uncommon: affects 1 to 10 users in 1,000
- rare: affects 1 to 10 users in 10,000
- very rare: affects less than 1 user in 10,000
- not known: frequency cannot be estimated from the available data.

Common side effects are heartburn, indigestion, diarrhoea, stomach ache, and nausea. **Sedropor can also irritate the oesophagus, although you can usually avoid this by taking your dose as described in this leaflet. If you develop symptoms such as severe pain in the chest, severe pain after swallowing food or drink, severe nausea, or vomiting, stop taking Sedropor and tell your doctor straightaway.**

Other common side effects include rash, cramps in the muscles, pain in the muscles and joints, and headache. It also includes flulike symptoms (aches and pains, feeling of discomfort, fatigue) which are usually mild, are short-lasting and disappear soon after you have taken the first dose. So you should be able to carry on taking Sedropor. Talk to your doctor if any effects become troublesome or last a long time.

Uncommon side effects are dizziness, back pain and flatulence.

Rare side effects are swelling and itching of the face, lips and mouth.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE SEDROPOR

Keep out of the reach and sight of children.

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

This medicinal product does not require any special storage conditions.

Medicines should not be disposed of via wastewater or household waste. Ask your doctor or pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Sedropor contains

- The active substance is ibandronic acid. One tablet contains 150 mg of ibandronic acid (as ibandronate 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) with an instruction leaflet.

Marketing Authorisation Holder:

Pharmathen S.A., Dervenakion 6, 15351 Pallini, Attiki, Greece

Manufacturers:

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