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Bonefos 800mg Film-coated Tablets

Sodium clodronate

Package leaflet – information for the user

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 more 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 effectsnot listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Bonefos Tablets are and what they are used for

Bonefos Tablets contain sodium clodronate which belongs to a group of medicines called bisphosphonates. These medicines help prevent the loss of calcium from bones.

Bonefos Tablets are used to help manage bone diseases, particularly those associated with cancer. Bonefos Tablets also help maintain normal levels of calcium in your blood.

2. Before you take Bonefos Tablets

Do not take Bonefos Tablets if:

- you are **allergic** to the active ingredient (sodium clodronate), or to any of the other ingredients. The ingredients are listed in section 6
- you are **already taking another similar medicine**.

▪ **Tell your doctor** if any of these apply to you and **do not take Bonefos**.

The doctor will take special care if:

- you have **problems with your kidneys**
- you have (or have had) **pain, swelling or numbness of the jaw** or a “heavy jaw feeling” or loosening of a tooth.

▪ **Tell your doctor** before you take Bonefos Tablets, if any of these apply to you.

If you are having **dental treatment** or will undergo **dental surgery**, tell your dentist that you are being treated with a bisphosphonate. Certain types of dental treatment are not recommended while taking bisphosphonates.

This medicine contains 128 mg sodium per tablet, to be taken into consideration by patients on a controlled sodium (salt) diet.

Other medicines and Bonefos Tablets

Tell your doctor about any other medicines that you are taking, or have recently taken. This includes any products you bought without a prescription.

Tell your doctor if you are taking:

- non-steroidal anti-inflammatory drugs to relieve pain (e.g. **ibuprofen** or **diclofenac**)
- **antibiotics**
- **antacids** or **mineral supplements**
- a drug called **estramustine** which is used to treat cancer.

Do not take any **other medicines by mouth** for 2 hours before and 1 hour after each dose of Bonefos Tablets.

Food and drink with Bonefos Tablets

It is important that you take your tablets on an empty stomach (otherwise your body will not absorb the drug properly).

Except for plain water, do not eat or drink for 2 hours before and 1 hour after each dose. It is particularly important to **avoid drinking milk** in this period.

You can drink water whenever you like.

Pregnancy and breastfeeding

Bonefos Tablets are not normally given to people during pregnancy. If you think you might be pregnant or if you are planning a family, tell your doctor before taking Bonefos Tablets.

Do not breastfeed while you are taking Bonefos Tablets.

Driving and using machines

Bonefos Tablets have no known effect on your ability to drive or use machines.

3. How you take Bonefos Tablets

You need to take plenty of fluids (such as water) before, during and after your treatment.

You should take Bonefos Tablets exactly as prescribed by your doctor.

The tablets should be swallowed with plain water. Tablets may be divided into two halves to help with swallowing, but the two halves must be taken at the same time.

Do not crush or dissolve the tablets before you take them. **Never take them with milk** because it reduces the amount of drug that your body can absorb.

The daily adult dosage of Bonefos Tablets varies. In most cases the dose is between 1600 mg (2 tablets) and 3200 mg (4 tablets) per day. If you have problems with your kidneys then the daily dosage may be reduced.

If you have been prescribed a **single daily dose** of Bonefos Tablets, it should be taken (preferably in the morning) on an empty stomach with a glass of plain water. After using Bonefos Tablets, **you should not eat, drink (other than plain water) or take any other medicines by mouth for 1 hour.**

If you have been prescribed a **twice daily dose**, the first dose should be taken as recommended above. The second dose should be taken between meals, **more than 2 hours**

after and 1 hour before eating, drinking (other than plain water), or taking any other medicines by mouth.

Bonefos Tablets are not recommended for use in children.

If you take too many tablets

- **Get medical help immediately and drink plenty of water.** If possible, take your tablets with you to show the doctor. Your doctor may want to check the amount of calcium in your blood and how well your kidneys are working.

If you forget to take the tablets

Do not take the missed dose, just take your next dose at the usual time.

4. Possible side effects

Like all medicines, Bonefos Tablets can cause side effects, although not everybody gets them. The following side effects have been observed during treatment with Bonefos Tablets.

If you experience any of these serious side effects, **seek immediate medical attention:**

☐ difficulty breathing

☐ allergic skin reactions such as a rash, redness or itching

☐ numbness and tingling sensations around the mouth and/or in the fingers and toes, muscle cramps or spasms (in the back, hands and/or feet) or fits

☐ kidney problems which can be experienced as feeling generally unwell, a reduced appetite and you may observe foamy urine

☐ severe kidney damage which may include symptoms such as weakness or tiredness, change in frequency of urination and swelling of the face, arms, legs and abdomen. These problems are more common when taking some types of anti-inflammatory drug (most often diclofenac) at the same time as Bonefos Tablets

☐ pain, swelling or numbness of the jaw, a "heavy jaw feeling" or loosening of a tooth, especially if you who have been treated in the past with bisphosphonates such as zoledronate and pamidronate

☐ severe bone, joint and/or muscle pain that can start days to several months after starting treatment with Bonefos Tablets.

The following side effects are presented by how often they may occur:

Common side effects
(*These may affect up to 1 in 10 people*)

- low calcium levels in the blood without any symptoms (*asymptomatic hypocalcaemia*) or small increases in the levels of liver enzymes, which can be detected by blood tests
- diarrhoea
- feeling sick or being sick

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

- low calcium levels in the blood with symptoms (*symptomatic hypocalcaemia*) which may include numbness and tingling sensations around the mouth and/or in the fingers and toes, muscle cramps or spasms (in the back, hands and/or feet) or, less frequently, fits
- increased blood levels of a hormone (*parathyroid hormone*) or certain enzymes (*alkaline phosphatase)* which can be detected by blood tests
- allergic skin reaction such as rash, redness or itching

Other side effects (frequency unknown)

- breathing problems in patients with a condition called **aspirin – sensitive asthma**
- allergic reaction causing difficulty breathing - if you have any difficulty breathing **seek immediate medical attention**
- kidney problems which may include severe kidney damage and in rare cases fatal kidney failure have been reported. These problems are more common when taking some types of anti-inflammatory drug (most often **diclofenac**) at the same time as Bonefos Tablets
- dead tissue in the jaw bone (*osteonecrosis of the jaw*) which is mainly seen in patients who have been treated in the past with bisphosphonates such as **zoledronate** and **pamidronate**. Symptoms include pain, swelling or numbness of the jaw, a "heavy jaw feeling" or loosening of a tooth
- 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 (osteonecrosis of the external auditory canal) which could occur very rarely.
- severe bone, joint and/or muscle pain that can start days to several months after starting treatment with Bonefos Tablets. However, these symptoms may also be linked to the reason you are taking Bonefos Tablets
- 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.

Uveitis (swelling and irritation of the uvea, the middle layer of the eye) has been observed in patients taking Bonefos. Other ocular (visual) disturbances reported with bisphosphonate therapy include conjunctivitis (swelling or infection of the conjunctiva, the membrane lining the eyelids), episcleritis (swelling and irritation of the episclera, a thin layer of tissue covering the sclera, the white outer wall of the eye), and scleritis (swelling and irritation of the sclera). Conjunctivitis was only reported in one patient who received Bonefos and another bisphosphonate at the same time, but conjunctivitis has not yet been reported in patients taking Bonefos alone. So far, episcleritis and scleritis have not been reported in patients taking Bonefos. If you develop any eye symptoms, seek medical attention.

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 via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Bonefos Tablets

Keep out of the reach and sight of children.

Do not use after the expiry date which is marked on both the outer container and on each blister strip of tablets.

Do not store above 25ºC.

Do not dispose of medicines in waste water or household rubbish. Any unused tablets should be returned to a pharmacist (chemist) who will dispose of them properly. This helps protect the environment.

6. Further information

What Bonefos Tablets contain

The active substance is sodium clodronate.
Each film-coated tablet contains 800 mg sodium clodronate(as tetrahydrate).

The tablets also contain croscarmellose sodium, magnesium stearate, silicified microcrystalline cellulose and stearic acid.

The tablet coating is made from Opadry II white which contains polyvinyl alcohol (partially hydrolysed), talc, titanium dioxide [E171] and macrogol 3350.

What's in the pack

Bonefos Film-coated Tablets are available in packs of 60 tablets.

The white, oval tablets have a break-line and are marked 'L134' on one side.

Marketing Authorisation Holder

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