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Patient Information Leaflet:

CLASTEON 400MG CAPSULES

(Sodium clodronate)

Please read this leaflet carefully before taking Clasteon Capsules. Keep the leaflet in case you need to refer to it again. If you want to know more about Clasteon Capsules or have any questions, you should ask your doctor or pharmacist.

1. WHAT CLASTEON CAPSULES ARE AND WHAT THEY ARE USED FOR

Clasteon Capsules contain sodium clodronate, which is one of a group of medicines known as bisphosphonates.

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

2. WHAT YOU NEED TO KNOW BEFORE TAKING CLASTEON CAPSULES

You must NOT take Clasteon Capsules and should talk to your doctor if:

- you are allergic to sodium clodronate, similar medicines or any of the ingredients (listed in section 6)
- you have very poor kidney function
- you are already taking a similar medicine (containing bisphosphonates)

Tell your doctor if:

- you have kidney problems
- you have ever had pain or swelling of your jaw
- you are having or planning to have dental treatment or surgery. If you are having dental treatment tell your dentist that you are being treated with a bisphosphonate (Clasteon).

Other medicines and Clasteon

Tell your doctor or pharmacist if you are taking or have recently taken any other medicine including those obtained without a prescription. This is particularly important if you are taking any of the following:

- antibiotics
- non-steroidal anti-inflammatory medicines such as ibuprofen or diclofenac
- antacid indigestion tablets
- mineral supplements
- estamustine, used to treat prostate cancer.

Pregnancy and breastfeeding

Clasteon Capsules 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 this medicine.

Do not breastfeed while you are taking Clasteon Capsules.

Clasteon Capsules contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per capsule, that is to say essentially 'sodium-free'

3. HOW TO TAKE CLASTEON CAPSULES

Always take the capsules as your doctor tells you to.

Clasteon is for use in adults only.

The usual dose is 4 capsules daily taken as a single dose or, if more than 4 capsules, divided into two doses. Your doctor may tell you to take fewer than 4 capsules, but no more than 8 capsules daily.

- Swallow the capsules whole, with water (NOT milk - see below)
- **Single daily dose:** Take in the morning on an empty stomach, with a glass of water. Do not eat, drink (except water) or take any medicines for 1 hour after.
- **Twice daily dose:** Take the first dose as above. Take the second dose between meals, **more than 2 hours after and 1 hour before** eating, drinking (except water) or taking any other medicines.
- Make sure you drink a lot of fluid (water or diluted squash) during treatment with Clasteon.

Clasteon should not be taken with food or with drinks containing milk as it is harder for the medicine to be absorbed into the blood and so it does not work as well.

If you forget a dose take it as soon as possible. However, if it is nearly time for your next dose, skip the missed dose and carry on as before. Do not take a double dose.

If you take too many Clasteon Capsules or someone else accidentally takes your medicine, contact your doctor, pharmacist or nearest hospital immediately.

Symptoms of an overdose may be a feeling of sickness, or being sick (nausea or vomiting).

Continued overleaf.....

Your doctor has prescribed this medicine for you. Never give it to others as it may harm them, even if their symptoms are the same as yours.

4. POSSIBLE SIDE EFFECTS

As with all medicines Clasteon Capsules may cause side effects in some patients.

Stop taking the capsules and contact your doctor if any of the following occur:

- wheezing or difficulty in breathing
 - swelling of face, tongue or throat
 - itching, rash.
- These may be symptoms of an allergic (hypersensitivity) reaction.

Common side effects (occur in less than 1 in 10 patients):

- being sick, feeling sick (nausea) or diarrhoea. If this happens it may help if you take half the number of capsules in the morning and the rest in the evening

Rare side effects (occur in less than 1 in 1,000 patients)

- skin reactions
- difficulty breathing
- 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.
- low calcium levels in the blood or increased levels of some hormones or enzymes. These are unlikely to cause noticeable symptoms.

Very rare side effects (occur in less than 1 in 10,000 patients):

- 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.
- **Other side effects (frequency unknown):**
- kidney problems. This can happen if Clasteon is taken together with a non-steroidal anti-inflammatory drug (e.g. diclofenac). In these cases, your doctor may wish to check your kidneys from time to time.
- isolated cases of severe disease of the jaw bone (osteonecrosis - damage and death of the bone), mainly in patients treated with other bisphosphonates e.g. zoledronate and pamidronate. Symptoms may include pain, swelling or numbness of the jaw

- severe bone, joint or muscle pain
- inflammation of part of the eye, conjunctivitis.

Your doctor may test your blood from time to time, to check that Clasteon is working correctly.

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 Yellow Card Scheme at: www.mhra.gov.uk/yellowcard.

By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE THIS MEDICINE

Keep this medicine out of the sight and reach of children. Do not use this medicine after the expiry date printed on the pack.

If your doctor decides to stop the treatment, return any leftover capsules to the pharmacist. Only keep them if your doctor tells you to.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What is in this medicine:

Each capsule contains 400mg of the active ingredient sodium clodronate (as the tetrahydrate). The other ingredients are talc, maize starch, magnesium stearate and sodium starch glycolate. The capsule shell is made of gelatin and contains titanium dioxide (E171), indigotin (E132) and printing ink.

What this medicine looks like and contents of the pack:

Clasteon capsules are white and blue oblong shaped capsules, marked CLASTEON, available in packs of 30, 60 or 120 capsules.

Marketing authorisation holder: Beacon Pharmaceuticals Limited, The Bower, 4 Roundwood Avenue, Stockley Park, Heathrow, United Kingdom, UB11 1AF.

Manufacturer: Abiogen Pharma S.p.A., via Meucci 36, Ospedaletto - Pisa - Italy.

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Beacon Pharmaceuticals Limited, The Bower,
4 Roundwood Avenue, Stockley Park, Heathrow,
United Kingdom, UB11 1AF.

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