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Package leaflet: Information for the patient

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Loron® 520

520 mg film-coated tablets

Clodronate disodium

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 Loron® is and what it is used for

Loron® contains a medicine called clodronate disodium. This medicine is a non-amino-bisphosphonate.

Loron® is used to treat bone problems in people with certain types of cancer. These problems include:
- Loss of calcium (a mineral) from the bones and bone pain.
- High levels of calcium in the blood caused by loss of calcium from the bones.

Loron® works by binding to the bones. This helps to stop the bones from losing calcium which helps to keep the bones strong.

2. What you need to know before you take Loron®

Do not take Loron®:
- if you are allergic to clodronate disodium or any of the other ingredients of this medicine (listed in section 6).
- if you have pain or discomfort in your stomach or bowel that is severe.
- if you are pregnant, might become pregnant, or are breast-feeding (see the section on 'Pregnancy and breast-feeding').
- if you have problems with your kidneys (renal failure with creatinine clearance below 10 ml/min).
- if you are taking any other bisphosphonate medicines. These include amongst others alendronate sodium, ibandronic acid and risedronate sodium. For details see the section on 'Other medicines and Loron®'.

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Warnings and precautions
Talk to your doctor or pharmacist before taking Loron®.
- Loron® tablets should be taken with care if you have kidney problems (see section 3). During treatment with Loron® you must drink large amounts of liquid (water). This is particulary important if you have too much calcium in the blood (hypercalcaemia) or if your kidneys do not work adequately (renal insufficiency). Before and during therapy with Loron®, regular checks should be made on kidney function with serum creatinine, serum calcium and phosphate levels.
- Monitoring of liver enzymes is recommended.
- Osteonecrosis (death of bone tissue) of the jaw, generally associated with pulling teeth and/or local infection (including inflammation of the bone or bone marrow (osteomyelitis), has been reported when bisphosphonates were used intravenously or orally for the treatment of cancer. Many of these patients were also receiving chemotherapy and corticosteroids. Osteonecrosis of the jaw has also been reported in patients with osteoporosis receiving oral bisphosphonates. If you are planning to have dental treatment or dental surgery, talk to your doctor before you start taking Loron®. Your doctor may want you to have the dental treatment before you start taking this medicine. If you need to have dental treatment or dental surgery while you are taking Loron®, talk to your doctor and tell your dentist that you are taking this medicine.
- Orally administered, mainly nitrogen-containing, bisphosphonates may cause local irritation of the upper gastrointestinal mucosa. Thus, talk to your doctor if you have known gastrointestinal problems (e.g. Barrett's oesophagus, swallowing disorder, other oesophageal diseases, gastritis, duodenitis or ulcers). Stop taking Loron® and tell your doctor if you start to have difficulty or pain when swallowing, or you begin to get indigestion or heartburn, or your indigestion or heartburn gets worse.
- If you experience pain, weakness or discomfort in your thigh, hip or groin, consult your doctor, as this might be an early sign of a possible thighbone fracture.

Children
No data are available.

Other medicines and Loron®
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines that you buy without a prescription and herbal medicines. This is because Loron® can affect the way some medicines work. Also some other medicines can affect the way Loron® works:
- Other bisphosphonate medicines such as alendronate sodium, ibandronic acid or risedronate sodium. These are used to treat bone diseases including osteoporosis.
- Antibiotics called 'aminoglycosides'. These include e.g. streptomycin and gentamicin. If you have taken one of these antibiotics in the last month, you must tell your doctor or pharmacist. Aminoglycosides can enhance the calcium-lowering effect of clodronate, even if you have stopped taking them some weeks before. As a result, the amount of calcium and magnesium in your blood may be reduced.
- Medicines called 'non-steroidal anti-inflammatory drugs' (NSAIDs), most often diclofenac. There have been reports that clodronate may be associated with the onset of kidney disorder during concomitant taking of drugs against pain and inflammation.
- Antacids (used to treat indigestion) and mineral supplements. Uptake of the active substance within the gastrointestinal tract (absorption) and hence the effect of clodronate can be reduced by medicines with high levels of calcium, iron or magnesium. You should therefore allow a sufficient interval (about 2 hours) between taking such medicines and clodronate.
- Estramustine. An increase in the serum concentration of estramustine phosphate by up to 80% has been reported when estramustine phosphate and clodronate were used at the same time.

Loron® with food and drink
Tell your doctor or pharmacist if you are taking any food supplements that contain calcium. You may need to stop taking these while you are taking Loron®. Also calcium rich foods may impair absorption.

Pregnancy, breast-feeding and fertility
Do not take Loron® if you are pregnant, might become pregnant or are breast-feeding. This is because it may affect your baby. You should use effective contraception during treatment with Loron®.

Driving and using machines
Loron® is not likely to affect you being able to drive or use any tools or machines.

Loron® contains lactose and sodium
Loron® contains lactose, which is a type of sugar. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

This medicine contains 83.4 mg sodium (main component of cooking/table salt) in each film-coated tablet. This is equivalent to 4 % of the recommended maximum daily dietary intake of sodium for an adult.

3. How to take Loron®

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

After taking Loron® you should not lay down, but remain in an upright position to prevent upper abdominal pain.

Adults and elderly people
- The usual dose is 2 film-coated tablets **once** a day. (This is known as a **'single daily dose'**.)
- Your doctor may **change** this to 1 film-coated tablet **twice** a day (i.e. **'twice daily dose'**), if certain side effects happen.
- If your doctor thinks it is necessary, your dose may be increased to a maximum of 4 film-coated tablets a day.

People with kidney problems
- If you have problems with your kidneys (renal failure with creatinine clearance between 10 and 30 ml/min), your doctor may want you to take a daily dose that is half of the recommended adult dose.

If you have been prescribed a 'single daily dose'
The single daily dose (2 film-coated tablets) should be taken in the morning on an empty stomach one hour before eating, drinking or taking any other oral drugs.

If you have been prescribed a 'twice daily dose'
The first dose (i.e. the 1st film-coated tablet) should be taken in the morning on an empty stomach one hour before eating, drinking or taking any other oral drug. The second dose (i.e. the 2nd film-coated tablet) should be taken between meals, more than two hours after and one hour before eating, drinking or taking any other oral drugs.

Swallow the film-coated tablets with a glass of water (not milk).

Use in children
No data are available.

If you take more Loron® than you should
Contact a doctor immediately or go to a hospital straight away. Take the medicine pack with you. Drink plenty of water.
The following effects may happen: feeling or being sick, 'pins and needles' in your hands or feet, or cramps in your muscles which may be signs of hypocalcaemia (decrease in calcium in the blood). Nausea and vomiting may occur. Increases in serum creatinine and renal dysfunction have been reported with high intravenous doses of clodronate. One case of total kidney failure and liver damage has been reported after accidental ingestion of 20,000 mg (50x400 mg) of clodronate.

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If you forget to take Loron®
- If you forget to take a dose, take it as soon as you remember. However, if it is nearly time for the next dose, skip the missed dose.
- Do not take a double dose to make up for a forgotten dose.

If someone else takes your Loron® film-coated tablets by mistake, they should talk to a doctor or go to a hospital straight away.

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 everyone gets them.

The most common reported drug reaction is diarrhoea which is usually mild and occurs more commonly at higher doses.

The following is a list of side effects that have been associated with the use of Loron®.

Common (may affect up to 1 in 10 people):
- nausea, vomiting and diarrhoea, usually mild and at higher dosages
- hypocalcaemia (asymptomatic)
- increase of liver enzymes (transaminases) in blood, usually within normal range

Rare (may affect up to 1 in 1,000 people):
- allergic reaction
- hypersensitivity reactions manifesting as skin reaction
- hypocalcaemia (symptomatic)
- increased serum parathyroid hormone associated with serum calcium decreased
- increased serum alkaline phosphatase
- transaminases increased (exceeding twice the normal range without associated other hepatic function abnormality)
- unusual (atypical) fractures of the thighbone
- worsening kidney function

Very rare (may affect up to 1 in 10,000 people):
- decreased serum phosphate level
- increased serum lactate dehydrogenase (LDH)
- breathing problems, including shortness of breath and tightness in the chest
- 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.

Not known (cannot be estimated from the available data):
- pain in the mouth and/or jaw, mouth swelling or ulcers, numbness or heavy feeling in the jaw, or loose teeth or molars. This may indicate jawbone

damage (osteonecrosis), which is generally accompanied by infection and delayed recovery, often after extraction of a tooth or molar.
- eye disorders including uveitis (inflammation of the uvea, the vascular skin of the eye), conjunctivitis (pink eye), episcleritis (inflammation of the episclera, a thin layer of tissue covering the white part of the eye) and scleritis (inflammation of the white of the eye)
- airway-constricting reactions in patients with aspirin-sensitive asthma
- hypersensitivity reactions manifesting as respiratory disorder
- impairment of renal function (elevation of serum creatinine and proteinuria), severe renal damage especially after rapid intravenous infusion of high doses
- individual cases of renal failure, in rare cases with fatal outcome, have been reported especially when clodronate and certain pain and anti-inflammatory drugs (mainly diclofenac) were used at the same time
- severe bone, joint, and/or muscle pain. The onset of symptoms varied from days to several months after starting treatment.

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 the Yellow Card Scheme at:
www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.
By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Loron®

- Loron® 520 mg film-coated tablets do not need special storage conditions.
- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date which is stated after (EXP). The expiry date refers to the last day of that month.
- Do not throw away any medicines via wastewater. 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 Loron® contains
The active substance is clodronate disodium.
Each film-coated tablet contains 520 mg clodronate disodium.

The other ingredients are talc, maize starch, cellulose microcrystalline, magnesium stearate, sodium starch glycolate, hypromellose, polyacrylate dispersion 30%, macrogol 10000, lactose monohydrate, titanium dioxide (E171), polysorbate 80 and sodium citrate.

What Loron® looks like and contents of the pack
Loron® film-coated tablets are oblong white film-coated tablets with “E9” marked on one side. They are scored with a break line on both sides, so that they can easily be broken into equal halves.

Loron® film-coated tablets are supplied in blister packs containing 10 or 60 film-coated tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

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Hohenzollerndamm 150-151
14199 Berlin
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Manufacturer
CENEXI
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