Ostiban®

Ibandronate Sodium INN Film Coated Tablet

DESCRIPTION

Ostiban® is a tablet preparation of Ibandronic Acid (as Ibandronate Sodium). It is a highly potent bisphosphonate belonging to the nitrogen-containing group of bisphosphonates, which act selectively on bone tissue and specifically inhibit osteoclast activity without directly affecting bone formation. It does not interfere with osteoclast recruitment. Ibandronic Acid leads to progressive net gains in bone mass and a decreased incidence of fractures through the reduction of elevated bone turnover towards premenopausal levels in postmenopausal women.

INDICATIONS

- Treatment of osteoporosis in postmenopausal women at increased risk of fracture.
- A reduction in the risk of vertebral fractures has been demonstrated; efficacy on femoral neck fractures has not been established.

DOSAGE AND ADMINISTRATION

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure. The recommended dose is one tablet once a month. Taking your monthly tablet is important to follow these instructions carefully. They are designed to help your Ibandronic Acid tablet reach your stomach quickly, so it's less likely to cause irritation.

- **Take one Ibandronic Acid 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 Ibandronic Acid tablet. Choose the date that best fits your routine.
- **Ibandronic Acid Tablet should be taken after an overnight fast (at least 6 hours) and 1 hour before the first food or drink (other than water) of the day or any other medicinal products or supplementations (including Calcium)**
- **Take your Ibandronic Acid tablet**
  - after you first get up for the day, and
  - before you have anything 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 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.

  - 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 Ibandronic Acid tablets.** It's important to keep taking Ibandronic Acid tablets every month, as long as your doctor prescribes it for you. After 5 years of using Ibandronic Acid tablet, please consult with your doctor whether you should continue to take Ibandronic Acid tablet.
- **If you take more Ibandronic Acid tablets 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 Ibandronic Acid to irritate your oesophagus.
- **If you forget to take**
  - If you forgot 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 the 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 Ibandronic Acid tablets within the same week**
- **Dose adjustment not required for patients with renal and hepatic impairment.**
- **Never give Ibandronic Acid Tablet to children or adolescents below 18 years.**
- **Duration of bisphosphonate treatment should be re-evaluated periodically based on the benefits and potential risks of Ibandronic Acid on individual patient basis, particularly after 5 or more years of use.**

PHARMACOKINETIC PROPERTIES

- **Absorption:** The absorption of Ibandronic Acid in the upper gastrointestinal tract is rapid after oral administration. Absorption is impaired by any kind of food or drink other than plain water. Maximum plasma concentration was reached within 0.5 to 2 hours in the fasted state and absolute bioavailability was about 0.6%.
- **Volume of distribution:** 90 L
- **Protein binding:** 90.9 to 99.5% over an Ibandronic Acid concentration range of 2 to 10 ng/mL
- **Metabolism:** No evidence of Ibandronic Acid being metabolized in humans.
- **Route of elimination:** Ibandronic Acid is eliminated by renal excretion. Unabsorbed Ibandronic Acid is eliminated unchanged in the feces.
- **Half-life:** 10-60 hours.
- **Clearance:** 84 to 160 mL/min [IV administration]

CONTRAINDICATIONS

- Hypersensitivity to Ibandronic Acid
- Hypocalcaemia
- Abnormalities of the esophagus which delay oesophageal emptying such as stricture or achalasia
- Inability to stand or sit upright for at least 60 minutes
- Ibandronic Acid is not recommended for patients with creatinine clearance below 30mL/min

USE IN PREGNANCY AND LACTATION

There are no adequate data from the use of Ibandronic Acid in pregnant women. Studies in rats have shown some reproductive toxicity. The potential risk for humans is unknown. Ibandronic Acid should not be used during pregnancy. It is not known whether Ibandronic Acid is excreted in human milk. Studies in lactating rats have demonstrated the presence of low levels of Ibandronic Acid in the milk following intravenous administration. Ibandronic Acid should not be used during lactation.

WARNING AND PRECAUTION

Existing hypocalcaemia must be corrected before starting Ibandronic Acid therapy. Other disturbances of bone and mineral metabolism should also be effectively treated. Adequate intake of calcium and vitamin D is important in all patients. Orally administered bisphosphonates may cause local irritation of the upper gastrointestinal mucosa. Because of these possible irritant effects and a potential for worsening of the underlying disease, caution should be used when Ibandronic Acid is given to patients with active upper gastrointestinal problems.

SIDE EFFECTS

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)

- Rash, 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
- Severe adverse skin reactions
- 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 possible side effects

- **Common (may affect up to 1 in 10 people)**
  - Headache
  - Heartburn, stomach pain (such as “gastroenteritis” or “gastritis”), indigestion, nausea, having diarrhoea or constipation
  - Rash
  - Pain or stiffness in your muscles, joints, or back
  - Flu-like symptoms (including fever, shaking and shivering, feeling of discomfort, fatigue, bone pain and aching muscles and joints)
  - Fatigue
- **Uncommon (may affect up to 1 in 100 people)**
  - Back pain
  - Feeling weak
  - Dizziness
  - Flatulence
  - Asthma attacks

- **Rare (may affect up to 1 in 1000 people)**
  - Itching (hives)
  - Inflammation of the duodenum (first section of the bowel) causing stomach pain

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.

PHARMACEUTICAL PRECAUTIONS

- Do not store above 30 °C temperature.
- Keep away from light and wet place.
- Keep out of reach of children.

PACKAGING

Ostiban® tablet: Box containing 1 strip of 1 tablet. Each film coated tablet contains Ibandronate Sodium INN equivalent to Ibandronic Acid 150 mg.

SK+F
Manufactured by
ESKAYEF PHARMACEUTICALS LTD.
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