

Maxbon™ Kit

1 tablet of Ibandronic Acid 150 mg + 60 tablets of Calcium Orotate 400 mg

PLEASE READ THIS ENTIRE LEAFLET CAREFULLY BEFORE YOU START TAKING THIS MEDICINE:

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor.
- 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 get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor.

COMPOSITION

Maxbon™ Kit contains 1 tablet of ibandronic Acid 150 mg and 60 tablets of Calcium Orotate 400 mg.

DESCRIPTION

Ibandronic Acid is a group of medicine called bisphosphonates. It alters the cycle of bone formation and break down in the body. It slows bone loss while increasing bones mass, which may prevent bone fracture. Ibandronic Acid has an affinity for hydroxyapatite crystals in bone and acts as a hydroxyapatite agent. At the cellular level, Ibandronic Acid inhibits osteoclast. The osteoclasts adhere normally to the bone surface but show evidence of reduce active resorption.

Osteoporosis: Human body constantly breaking down old bone and making new bone tissue. If people have osteoporosis, their body breaks down more bones than it forms. So that gradually bone loss occurs and bones become thinner and fragile. This is especially common in women after the menopause. Many people with osteoporosis have no symptom and may not even know that they have it. However, osteoporosis makes them more likely to have fractures, especially in spine, hips and wrists.

INDICATION

Maxbon™ Kit is indicated for the:

- Treatment and prevention of postmenopausal osteoporosis in women.
- Treatment and prevention of osteoporosis in men.

DOSEAGE & ADMINISTRATION

One tablet of Ibandronic Acid 150 mg once monthly of the same date of each month is recommended. To maximize clinical benefit of Ibandronic acid, two tablets of Calcium Orotate 400 mg per day are usually recommended in divided dosage.

HOW TO TAKE Maxbon™ Kit TABLET

- To maximize absorption and clinical benefit, Ibandronic Acid tablet of **Maxbon™ Kit** should be taken at least 60 minutes before the first food or drink (other than water) of the day or before taking any oral medication or supplementation, including calcium, antacids, or vitamins.
- To facilitate delivery to the stomach and to reduce esophageal irritation, Ibandronic Acid tablet should be swallowed whole with a full glass of plain water (250 ml) while the patient is standing or sitting in an upright position. Patients should not lie down for 60 minutes after taking Ibandronic Acid tablet.
- Ibandronic Acid 150 mg tablet of **Maxbon™ Kit** should be taken on the same date of each month (i.e., the patients Ibandronic Acid day).
- If the once monthly dose is missed, and the patients next scheduled Ibandronic Acid day is more than 7 days away, the patient should be instructed to take one Ibandronic Acid 150 mg tablet in the morning following the date that it is remembered. The patient should then return to taking one Ibandronic Acid 150 mg tablet every month in the morning of their chosen day, according to their original schedule.
- If the once monthly dose is missed, and the patients next scheduled Ibandronic Acid day is only 1 to 7 days away, the patient must wait until the subsequent month's scheduled Ibandronic Acid day to take their tablet. The patient should then return to taking one Ibandronic Acid 150 mg tablet every month in the morning of their chosen day according to their original schedule.
- The Patient must not take two Ibandronic Acid 150 mg tablets within the same week.
- Start taking calcium Orotate tablets from the next day of Ibandronic Acid day (from day-2 and onwards)

SPECIAL INSTRUCTION

Take special care if you have-

Low blood circular level (hypocalcaemia); Cannot sit or stand up for 60 minutes; Have an allergy to Ibandronate Sodium; Are pregnant or may become pregnant; Are breast feeding or plan to breast feed; Adequate intake of Calcium and Vitamin D is important in all patients; Patients should follow the dosing instructions to minimize the risk of gastrointestinal side effects.

DRUG INTERACTIONS

Please tell your doctor if you are taking or have recently taken any other medicines, including medicine obtained without a prescription specially aspirin or other NSAIDs. Antacids, supplements or medicine that contains aluminiums, calcium, magnesium or other minerals can interfere with the absorption of Ibandronate sodium. If you use these other medicines, do not take these for at least 60 minutes after taking Ibandronic Acid tablet.

PREGNANCY, LACTATION AND PEDIATRIC USE

There are no adequate and well controlled studies in pregnant women for **Maxbon™ Kit**. **Maxbon™ Kit** should be used during pregnancy only if the potential benefit justifies the potential risk to the mother and fetus.

- It is not known whether **Maxbon™ Kit** is excreted in human milk. Caution should be exercised when **Maxbon™ Kit** is administered to a nursing woman.
- Safety and effectiveness in pediatric patients have not been established.

SPECIAL DOSE ADJUSTMENT

No dose adjustment is necessary for patients with mild or moderate renal impairment where creatinine clearance is equal to or greater than 30 ml/min. No dose adjustment is required for patients with hepatic impairment.

ADVERSE REACTIONS

The main adverse drug reactions are: mild or moderate fever, nausea, diarrhea, abdominal pain, myalgia, headache and constipation.

SIDE EFFECTS

Ibandronic Acid

Common side effects include Hypertension, Dyspepsia, Nausea, Diarrhea, Abdominal Pain, Arthralgia, Back Pain, Localized Osteoarthritis, Myalgia, Muscle Cramp, Influenza, Nasopharyngitis, Bronchitis, Urinary Tract Infection, Upper Respiratory Tract Infection, Headache, Dizziness, Skin Rash, Insomnia etc.

Calcium Orotate

Bloating and swelling in the abdomen are common side effects of Calcium Orotate. Loss of appetite, upset stomach, constipation, nausea, vomiting, unusual weight loss, mood changes, bone/muscle pain, headache, increased thirst/urination, weakness, unusual tiredness, formation of kidney stones may occur infrequently.

PRECAUTIONS

Ibandronic Acid of **Maxbon™ Kit** may cause local irritation of the upper gastrointestinal mucosa, • Adequate Intake of Calcium is important in all patient of hypocalcaemia, • Severe and occasionally incapacitating bone joint, and/or muscle pain has been reported in patients taking Ibandronic Acid, • Ibandronic Acid is not recommended for use in patients with severe renal impairment (Creatinine clearance of <30 ml/min).

Calcium Orotate

Before taking Calcium Orotate, precaution is needed if the patient is allergic to Calcium Orotate. Any calcium supplement taken without food may increase the risk of kidney stones. Therefore, it is advisable that calcium orotate be taken with food.

HOW TO STORE

Store in cool and dry place (below 30° c). Keep out of the reach of children.

HOW SUPPLIED

Maxbon™ Kit: Each box contains one kit. Each kit contains 1 film coated tablet of Ibandronate Sodium Monohydrate INN equivalent to Ibandronic Acid 150 mg and 60 film coated tablets of Calcium Orotate INN 400 mg in one calendar strip.

Manufactured by



SQUARE
PHARMACEUTICALS LTD.
BANGLADESH