This document has been approved by Saudi Food and Drug Authority (SFDA).

Physician's Guide

Zodric® (zoledronic acid)

A Physician's Guide to Zodric® for the Treatment of Osteoporosis

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This Physician Guide is designed to help you prescribe Zodric® (Zoledronic Acid 5mg) appropriately for patients with osteoporosis.
It is meant to be used as a guide only.

Please consult the Summary of Product Characteristics before prescribing zoledronic acid.

- Zoledronic acid 5 mg is approved for treating:
  - Osteoporosis in post-menopausal women and adult men at increased risk of fracture, including those with a recent low-trauma hip fracture.
  - For treatment of osteoporosis associated with long-term systemic glucocorticoid therapy in post-menopausal women and in adult men at increased risk of fracture.
  - For treatment of Paget's disease of the bone in adults.
- The use of zoledronic acid 5 mg in patients with severe renal impairment (CrCl< 35mL/min) is contraindicated due to an increased risk of renal failure in this population.
- The following precautions are recommended to minimize the risk of renal adverse reactions:
  - CrCl should be calculated based on actual body weight using the Cockcroft-Gault formula before each zoledronic acid 5 mg dose.
  - Transient increase in serum creatinine may be greater in patients with underlying impaired renal function.
  - Monitoring of serum creatinine should be considered in at-risk patients.
  - zoledronic acid 5 mg should be used with caution when concomitantly used with other drugs that could impact renal function.
  - Patients, especially, those at an advanced age and those receiving diuretic therapy, should be appropriately hydrated prior to administration of zoledronic acid 5 mg.
  - A single dose of zoledronic acid should not exceed 5 mg and the duration of infusion should be at least 15 minutes.
- zoledronic acid 5 mg is given once a year as a single intravenous infusion.
- The optimal duration of bisphosphonate treatment for osteoporosis has not been established.
- The need for continued treatment should be re-evaluated periodically based on the benefits and potential risks of zoledronic acid 5 mg on an individual patient basis, particularly after 5 or more years of use.
- Pre-existing hypocalcaemia must be treated by adequate intake of calcium and vitamin D before initiating therapy with zoledronic acid 5 mg.

- Other disturbances of mineral metabolism must also be effectively treated (e.g. diminished parathyroid reserve, intestinal calcium malabsorption). Physicians should consider clinical monitoring for these patients.
- It is recommended that patients should receive adequate calcium and vitamin D supplementation. For patients with a recent low-trauma hip fracture, a loading dose of 50.000 to 125.000 IU of vitamin D given orally or via intramuscular route is recommended prior to the first zoledronic acid 5 mg infusion.
- Zoledronic acid 5 mg is contraindicated during pregnancy and breast-feeding, due to potential teratogenicity.
- Zoledronic acid 5 mg is not recommended in women of childbearing potential.
- A healthy lifestyle plays an important part in maintaining strong bones. Patients should be reminded that there are things which they can do to help in keeping their bones as strong as possible.
- A healthy diet is very important in maintaining strong bones. Patients should be advised on the benefits of a good diet. Calcium and vitamin D supplementation are recommended in conjunction with zoledronic acid 5 mg.
- Vitamin D is important in the absorption of calcium from the diet. Sunlight helps the body to make vitamin D. As little as 15 minutes of natural light can have a beneficial effect.
- Physical activity, especially weight bearing exercise such as walking, are important in keeping the bones and surrounding muscles strong and healthy.
- Smoking and alcohol intake can impact on bone status. Stopping smoking and moderating alcohol intake can have a beneficial effect on bone health.
- The majority of side effects with zoledronic acid 5 mg are mild to moderate and occur within the first three days of administration, Patients should be advised about the post-dose symptoms which are commonly seen following administration of an intravenous bisphosphonate. These include flu-like symptoms such as fever, myalgia, flu-like illness, headache, and arthralgia. These can be managed with mild pain relievers such as paracetamol and ibuprofen.
- Atypical subtrochanteric and diaphyseal femur fractures have been reported with bisphosphonate therapy, primarily in patients receiving long-term treatment for osteoporosis. These fractures occur after minimal or no trauma and some patients experience thigh or groin pain, often associated with imaging features of stress fractures, weeks to months before presenting with a completed femur fracture.
- Discontinuation of bisphosphonate therapy in patients suspected to have an atypical femur fracture should be considered pending evaluation of the patient, based on an individual benefit risk assessment.

- A side effect called osteonecrosis of the jaw (ONJ) (severe bone damage in the jaw) have been reported predominantly in cancer patients treated with bisphosphonates.
- It is important to try and prevent ONJ developing as it is a painful condition that can be difficult to treat. In order to reduce the risk of developing ONJ, some precautions should be taken:
    - A dental examination with appropriate preventive dentistry should be considered prior to treatment with bisphosphonates in patients with concomitant risk factors (e.g. cancer, chemotherapy, anti-angiogenic drugs.
    - During the treatment with zoledronic acid 5 mg, it is prudent to maintain good oral hygiene, undergo routine dental check-ups, and immediately report any oral symptoms.
    - While treatment, these patients should avoid invasive dental procedures if possible. For patients who develop osteonecrosis of the jaw while on bisphosphonate therapy, dental surgery may exacerbate the condition.
    - For patients requiring dental procedures, there are no data available to suggest weather discontinuation of bisphosphonate treatment reduces the risk of osteonecrosis of the jaw.
    - The clinical judgment of the treating physician should guide the management plan of each patient bases on individual benefit/risk assessment.

Call for reporting:

Reporting suspected adverse reactions is important. It allows continued monitoring of the benefit/risk balance of the medicinal product.
All patients should be provided with educational material and be counselled about key signs and symptoms of serious adverse reactions and when to seek attention from a healthcare provider. Healthcare professionals are asked to report any suspected adverse reactions directly by contacting:

- **Pharmacovigilance Department at MS Pharma:**
    - **Email:** pharmacovigilance@mspharma.com
    - **Website:** www.mspharma.com
    - **Phone No:** + 966112790122 Ext. 6013

- **The National Pharmacovigilance Center (NPC): (Saudi food and drug authority)**
    - **Email:** npc.drug@sfda.gov.sa
    - **Call Center:** 19999
    - **Website:** https://ade.sfda.gov.sa/
    - **QR Code:**