**OSTADIL®**
zoledronic acid

# Physician's Guide
## OSTADIL® (zoledronic acid) for the treatment of osteoporosis

This reminder card is designed to help you prescribe OSTADIL® (zoledronic acid 4 mg) appropriately for patients with osteoporosis.
It is meant to be used as a guide only.
Please refer to the Summary of Product Characteristics (SPC) before prescribing OSTADIL®.

- **OSTADIL® is approved for:**
  - Prevention of skeletal related events (pathological fractures, spinal compression, radiation or surgery to bone, or tumour-induced hypercalcaemia) in adult patients with advanced malignancies involving bone
  - Treatment of adult patients with tumour-induced hypercalcaemia (TIH).
- **The use of OSTADIL® 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:**
  - Creatinine clearance should be calculated based on actual body weight using the Cockcroft-Gault formula before each OSTADIL® 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.
  - OSTADIL® 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 OSTADIL®.
  - OSTADIL® 4 mg concentrate for solution for infusion, further diluted in 100 ml, should be given as a single intravenous infusion in no less than 15 minutes.
- **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 OSTADIL® on an individual patient basis, particularly after 5 or more years of use.**
- **Pre-existing hypocalcemia and other mineral metabolism disturbances must be treated with adequate intake of calcium and vitamin D before initiating therapy with OSTADIL®. 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 OSTADIL® infusion.**
- **OSTADIL® is contraindicated during pregnancy and breast-feeding, due to potential teratogenicity.**
- **OSTADIL® 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.**
  1. 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 OSTADIL®.

2. 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.
3. Physical activity, especially weight bearing exercise such as walking, are important in keeping the bones and surrounding muscles strong and healthy.
4. Smoking and alcohol intake can impact on bone status. Stopping smoking and alcohol intake can have a beneficial effect on bone health.

- **The majority of side effects with OSTADIL® 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:**
  - o 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.
  - o During the treatment with zoledronic acid, it is prudent to maintain good oral hygiene, undergo routine dental check-ups, and immediately report any oral symptoms.
  - o While on 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.
  - o For patients requiring dental procedures, there are no data available to suggest whether 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 based on individual benefit/risk assessment.


**You can report any problem or adverse events through:**

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