

A Physician's Guide to Zoledronic Acid SPC

This reminder card is designed to help you prescribe Zoledronic Acid SPC (zoledronic acid) Appropriately for patients with osteoporosis. It is meant to be used as a guide only.

Please refer to the summary of the product characteristics before prescribing Zoledronic Acid SPC

- Zoledronic Acid SPC is approved for treating osteoporosis in postmenopausal women and men at increased risk of fracture, including those with a recent low-trauma hip fracture and for the treatment of osteoporosis associated with long-term systemic glucocorticoid therapy in postmenopausal women and in men at increased risk of fracture. Zoledronic Acid is also indicated for the treatment of Paget's disease of the bone in adults.
- Osteonecrosis of the jaw has been reported predominantly in patients with cancer receiving treatment regimens including bisphosphonates, including zoledronic acid. Many of these patients were also receiving chemotherapy and corticosteroids. The majority of reported cases have been associated with dental procedures such as tooth extraction. 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, corticosteroids, poor oral hygiene). While on treatment, these patients should avoid invasive dental procedures if possible.
- 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 SPC
 - 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.
- Pre-existing hypocalcemia and other mineral metabolism disturbances must be treated with adequate intake of calcium and vitamin D before initiating therapy with Zoledronic Acid SPC. 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 SPC infusion.
- Zoledronic Acid SPC is contraindicated during pregnancy and breast-feeding, due to potential teratogenicity. Zoledronic Acid SPC is not recommended in women of childbearing potential.
- The majority of side effects with Zoledronic Acid SPC 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.
- A typical sub trochanteric 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.
- The use of Zoledronic Acid SPC in patients with severe renal impairment (Creatinine Clearance <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 Zoledronic Acid SPC 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 SPC 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 SPC.
 - A single dose of Zoledronic Acid SPC should not exceed 5 mg and the duration of infusion should be at least 15 minutes.
- Zoledronic Acid SPC 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 SPC on an individual patient basis, particularly after 5 or more years of use.

You can report side effects directly via www.sudairpharma.com

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