**Zoledronic Acid Hospira 5 mg/100 ml solution for infusion**

**Physician reminder card**

This document aims to help you prescribe Zoledronic Acid Hospira 5 mg/100 ml for patients with osteoporosis. This document should be used only as a guide. Please see the Summary of Product Characteristics before prescribing Zoledronic Acid Hospira 5 mg/100 ml.

Zoledronic Acid Hospira 5 mg/100 ml is approved for the following therapeutic indications:

* Treatment of osteoporosis in post-menopausal women and in men at increased risk of fracture, including those with a recent low-trauma hip fracture.
* Treatment of osteoporosis associated with long-term systemic glucocorticoid therapy in post-menopausal women and in men at increased risk of fracture.

The administration of Zoledronic Acid may compromise renal function, especially in patients with pre-existing renal dysfunction or other risks, including advanced age, concomitant use of nephrotoxic drugs, diuretic therapy, or dehydration that occurs after administration of Zoledronic Acid.

For this reason the following precautions are recommended in order to minimize the risk of adverse reactions:

* Zoledronic Acid Hospira 5 mg/100 ml should not be used in patients with creatinine clearance <35 ml/min.
* Confirm each patient’s serum creatinine before each treatment with Zoledronic Acid Hospira 5 mg/100 ml to ensure the creatinine clearance is >35 ml/min.
* Instruct patients to drink fluids, such as water, within a few hours prior to treatment to ensure adequate hydration. This is especially important in the elderly and for patients receiving diuretic therapy.
* Zoledronic Acid Hospira 5 mg/100 ml should be used with caution when concomitantly used with other medicinal products that could impact renal function.
* Zoledronic Acid Hospira 5 mg/100 ml should be infused slowly and at a constant rate over a period of no less than 15 minutes.
* Zoledronic Acid Hospira 5 mg/100 ml is contraindicated in pregnancy and during breast-feeding.

There are no adequate data on the use of zoledronic acid in pregnant women. Studies in animals with zoledronic acid have shown reproductive toxicological effects including malformations. The potential risk for humans is unknown. It is not known whether zoledronic acid is excreted into human breast milk.

* Zoledronic Acid Hospira 5 mg/100 ml is administered as a single intravenous infusion once a year for the treatment of post-menopausal osteoporosis, osteoporosis in men and the treatment of osteoporosis associated with long-term systemic glucocorticoid therapy.
* Patients must receive adequate calcium and vitamin D intake in association with Zoledronic Acid Hospira 5 mg/100 ml administration.
* Patients should be instructed on the importance of appropriate diet and lifestyle, including a well balanced diet with adequate calcium-rich foods, regular weight-bearing exercise, avoidance of smoking and keeping alcohol consumption within recommended limits.

For further information please consult the Summary of Product Characteristics (SmPC) or European Public Assessment Report (EPAR) at <http://www.ema.europa.eu/ema/>

**Adverse events should be reported. Reporting forms and information can be found at** <http://medicinesauthority.gov.mt/file.aspx?f=440>**. Adverse events should also be reported to Hospira’s Malta representative – Drugsales Ltd. Telephone: +356 21 419 070/1/2 or Email:** [**abusuttil@drugsalesltd.com**](mailto:abusuttil@drugsalesltd.com)