OSTADIL®
zoledronic acid

Patient reminder card regarding Osteonecrosis of the jaw

This reminder card contains important safety information that you need to be aware of before and during treatment with OSTADIL® (zoledronic acid).
Your doctor has recommended that you receive OSTADIL® (zoledronic acid), which is used to prevent bone complications, e.g. fractures, in adult patients with bone metastases (spread of cancer from primary site to the bone) and to reduce the amount of calcium in the blood in adult patients where it is too high due to the presence of a tumour. Tumours can accelerate normal bone change in such a way that the release of calcium from bone is increased. This condition is known as tumour-induced hypercalcaemia (TIH).
A side effect called osteonecrosis of the jaw (ONJ) (severe bone damage in the jaw) has been reported very rarely in patients receiving zoledronic acid for osteoporosis. ONJ can also occur after stopping treatment.
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, there are some precautions you should take:

Before starting treatment:
Tell your doctor/nurse (health care professional) if you have any problems with your mouth or teeth. Your doctor may ask you to undergo a dental examination if you:

- Were previously treated with another medication being a bisphosphonate and taking medicines called corticosteroids (such as Prednisolone or Dexamethasone).
- Are smoker.
- Have cancer.
- Have not had a dental check up for a long time.
- Have problems with your mouth or teeth.

While being treated:

- You should maintain good oral hygiene, brush your teeth regularly and receive routine dental check-ups. If you wear dentures you should make sure these fit properly.
- If you are under dental treatment or will undergo dental surgery (e.g. tooth extractions), inform your doctor and tell your dentist that you are being treated with zoledronic acid.
- Contact your doctor and dentist immediately if you experience any problems with your mouth or teeth such as loose teeth, pain or swelling, or non-healing of sores or discharge, as these could be signs of osteonecrosis of the jaw.

Please read the package leaflet that comes with your medicine for further information
You can report any problem through:

You can report any problem or adverse events through:
Pharmacovigilance department in Tabuk Pharmaceuticals:
P.O. Box 28170, Riyadh 11437, Kingdom of Saudi Arabia
Tel: +966 11 47 749 46
Email: pv.info@tabukpharmacuticals.com
Fax: +966 11 47 826 86
The National Pharmacovigilance and Drug Safety Center (NPC):
By email: npc.drug@sfda.gov.sa
Or by fax: +966 11 2057662
Or by online: https://ade.sfda.gov.sa/
Toll free phone: 19999

أوستاديل
زوليدرونيك أسيد

بطاقة إرشادية للمريض فيما يخص تلف الفك العظمي (النخر العظمي):

تحتوي هذه البطاقة الإرشادية على معلومات احترازية هامة تحتاجها قبل وأثناء العلاج بأوستاديل (زوليدرونيك أسيد)

لقد أوصى طبيبك بأن تُعطى أوستاديل (زوليدرونيك أسيد) والذي يستعمل للوقاية من حدوث مضاعفات في العظم، مثل الكسور، عند المرضى البالغين الذين يعانون من النقائل العظمية (انتشار الخلايا السرطانية وهجرتها من منشأها الأصلي في جسم الإنسان إلى خلايا العظام). ويستخدم أوستاديل لتقليل كمية الكالسيوم في الدم عند المرضى البالغين حيث تكون مرتفعة جدا نتيجة لوجود ورم.

يوجد عرض جانبي نادر جداً قد أُبلغ عنه يسمى النخر العظمي في الفك (ONJ) (تلف شديد في عظم الفك) مع المرضى الذين يتلقون علاج أوستاديل (زوليدرونيك أسيد) لهشاشة العظام.

قد يظهر (ONJ) بعد إيقاف العلاج. (ONJ) حالة مؤلمة وقد يصعب علاجها لذا فمن المهم جداً محاولة منع حدوثه.

هناك بعض التعليمات التي يجب عليك اتباعها من أجل التقليل من خطر الاصابة بـ (ONJ):

قبل البدء بالعلاج:

أخبر طبيبك/الممرض (مقدم الرعاية الصحية) إن كانت لديك أي مشاكل في الفم أو الأسنان.

قد يطلب منك طبيبك أن تخضع لفحص الأسنان في الحالات التالية:

- قد تم علاجك مسبقاً بأي دواء من مجموعة بيسفوسفونيت.
- تتناول أدوية تسمى الكورتيكوستيرويد (مثل: البريدنيزولون أو الديكساميثازون).
- إذا كنت مدخناً.
- تعاني من مرض السرطان.
- لم تخضع لفحص الأسنان منذ مدة طويلة.
- لديك مشاكل في الفم أو الأسنان.

أثناء العلاج:

يجب عليك المحافظة على صحة الفم، قم بتنظيف أسنانك بانتظام، والقيام بالفحص الدوري إذا كنت تستخدم طقم الأسنان، يجب عليك التأكد من أنها تتوافق بشكل صحيح.

إذا كنت تتلقى علاجاً للأسنان، أو إذا كنت ستجري جراحة في الأسنان (مثلاً خلع أحد الأسنان) أخبر طبيبك وطبيب الأسنان أنك تستعمل أوستاديل.

أبلغ طبيبك مباشرة عن أي أعراض في الفم مثل تخلخل لأحد الأسنان، أو ألم، أو تورم، أو عدم إلتئام الجروح أو الإفرازات (قيح أو نزيف) فقد تكون تلك أعراض نخر عظام الفك.

شركة تبوك للصناعات الدوائية:

البريد الإلكتروني: pv.info@tabukpharmaceuticals.com

فاكس: ٠٩٦٦١١٤٧٨٢٨٦

المركز الوطني للتيقظ والسلامة الدوائية (الهيئة العامة للغذاء والدواء):

الرقم الموحد: ١٩٩٩٩

البريد الإلكتروني: npc.drug@sfda.gov.sa

فاكس: ٠٩٦٦١١٢٠٥٧٦٦٢

الموقع الإلكتروني: https://ade.sfda.gov.sa

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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P.O. Box 28170, Riyadh 11437, Kingdom of Saudi Arabia

Tel: +966 11 47 749 46

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