Ostira™

contains the active ingredient zoledronic acid

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Ostira™.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you using Ostira™ against the benefits they expect it will have for you.

If you have any concerns about using this medicine, ask your doctor or pharmacist.

Keep this leaflet.
You may need to read it again.

What Ostira™ is used for

Ostira™ contains the active ingredient zoledronic acid. It belongs to a group of medicines called bisphosphonates.

Ostira™ is used

- to treat osteoporosis in postmenopausal women to reduce incidence of bone fractures.
- To strengthen bones in men who have osteoporosis
- to treat osteoporosis in men and women over 50 years of age, to prevent additional fractures in those who have had a hip fracture,
- to treat or prevent osteoporosis in men and women caused by treatment with steroid medicines such as prednisone
- to treat Paget's disease of bone.

Osteoporosis is a disease which causes bones to become less dense, gradually making them weaker, more brittle and likely to break..

Paget's disease is a chronic disorder in which the bone material breaks down more quickly than usual, and new bone material grows more quickly than usual and in a disordered way. The new bone that is formed may be thicker but weaker than normal, which can cause pain and may lead to fractures.

.Your doctor may have prescribed Ostira™ for another purpose.

Ask your doctor if you have any questions regarding why Ostira™ has been prescribed for you.
Ostira™ is not addictive.

This medicine is available only with a doctor's prescription.

Before you are given Ostira™

When you must not have it

Do not take or receive Ostira™ if:

you have had an allergic reaction to:

- zoledronic acid or any of the ingredients listed at the end of this leaflet
- any other bisphosphonate medicine

Some of the symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.

If you are not sure whether you are allergic to other bisphosphonate medicines, talk to your doctor.

you have kidney problems
If you are unsure, check with your doctor first

you have uveitis
An inflammatory problem in the eye. If you are unsure, check with your doctor.

you are pregnant
There is no information on the use of this medicine in pregnancy and therefore should not be used during pregnancy.

you are breast feeding
It is not known whether the active ingredient, zoledronic acid, passes into the breast milk and could affect your baby and therefore breast feeding should be discontinued before you are given Ostira™.

you have low levels of calcium in your blood

the package is torn or shows signs of tampering

the expiry date (EXP) printed on the pack has passed.
If you take this medicine after the expiry date has passed, it may not work as well.

If you are not sure if you should be receiving Ostira™, talk to your doctor.

Before you start to take or receive it

Tell your doctor if:

you have any other health problems, especially if:

- you have a kidney or liver problem
- you have a heart condition
- you have asthma and are also allergic to aspirin
- you are allergic to any other medicines, foods, dyes or preservatives
- you have had surgery on your thyroid or parathyroid gland
- you have a calcium deficiency or a vitamin D deficiency
- you have or have had uveitis or iritis (inflammatory conditions of the eye).
- you had or have pain in the teeth, gums or jaw, swelling or numbness of the jaw or a 'heavy jaw feeling' or loosening of a tooth

It is advisable to have a dental check-up before starting on Ostira™. Tell your dentist you may be receiving Ostira™.

Tell your doctor if you need to have any dental treatment or dental surgery.
A dental condition called jaw osteonecrosis has been reported in some patients being treated with zoledronic acid or with other drugs in the same class as Ostira™. You may need to have dental treatments completed before starting it.

If you have not told your doctor about any of the above, tell them before you start receiving Ostira™.

Your doctor may want to take special precautions if you have any of the above conditions.

Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you have bought without a prescription from a pharmacy, supermarket or healthfood shop. Also tell your doctor if you are being treated with other medicines which may contain zoledronic acid.

Some medicines may interfere with Ostira™. These medicines include:

- medicines that may have side effects on your kidneys (e.g. Diuretics or 'water' tablets)
- aminoglycoside medicines, used to treat severe infections. The combination of an aminoglycoside and bisphosphonate medicine may cause the level of calcium in the blood to become too low.

These medicines may be affected by Ostira™, or may affect how well it works. You may need to receive different amounts of your medicine, or you may need to take different medicines. Your doctor will advise you.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while receiving Ostira™.

Ask your doctor or pharmacist if you are not sure about this list of medicines.

How Ostira™ is given

Ostira™ is administered by a healthcare professional in a hospital setting. It is given as a 'drip' into a vein, usually over a period of 15 minutes. It is given once per year.

Make sure you drink enough fluids before and after the treatment as directed by your doctor. Two glasses of fluid (such as water) before and after the infusion are usually enough. This will help to prevent dehydration.

Ostira™ is given as a single infusion over a period of at least 15 minutes. Each dose lasts at least one year. Your doctor will decide if you need additional doses.

Your doctor may also prescribe a daily calcium supplement and a multiple vitamin containing Vitamin D.

If you receive too much

As Ostira™ is given to you under the supervision of your doctor, it is very unlikely that you will receive too much.

Tell your doctor if you have any of the following symptoms. This may mean that the level of calcium in your blood is too low

- unusual light headedness, dizziness or faintness
- numbness or tingling
- muscle cramps

Your doctor may give you extra calcium supplements, should your calcium level become too low.

While you are having Ostira™

Things you must do

Make sure you follow your doctor's instructions carefully and keep all appointments.

If you get a headache, fever or other flu-like symptoms in the first three days after you are given Ostira™, take paracetamol if your doctor has told you to. Some people get short-lasting flu-like symptoms after having Ostira™. Paracetamol can provide some relief.

Take calcium and vitamin D supplements if your doctor has told you to.
Most people with osteoporosis do not get enough calcium and vitamin D in their diet and supplements are needed to help strengthen your bones.

If you are being treated with Ostira™ for Paget's disease, your doctor should advise corrective treatment for a vitamin D deficiency and that you take calcium and vitamin D supplements for at least the first ten days after you have Ostira™ to reduce the risk of low calcium levels in your blood.

Tell all doctors, dentists and pharmacists who are treating you that you are receiving Ostira™.

Tell your doctor if you become pregnant while receiving Ostira™.

Practice good dental hygeine. Be sure to brush and floss your teeth daily, and have regular dental check-ups.

If you develop pain in your mouth, teeth or jaw, or have bleeding gums, or have an unusual feeling in your teeth or gums, tell your doctor and dentist immediately.
A dental condition called jaw osteonecrosis has been reported in some patients being treated with zoledronic acid or other drugs in the same class.

Things to be careful of

Be careful driving or operating machinery until you know how Ostira™ affects you.
The effect of Ostira™ on the ability to drive or use machinery has not been studied. Be careful driving or operating machinery until you know how Ostira™ affects you.

Side effects

Tell your doctor or nurse as soon as possible if you do not feel well after you have been given Ostira™.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or nurse if you notice any of the following and they worry you:

- short-lasting fever, sometimes with flu-like symptoms such as chills, tiredness, weakness and aches and pains
- redness, swelling or pain where the needle for the infusion was inserted
- upset stomach, abdominal pain, loss of appetite
- nausea (feeling sick) or vomiting
- dry or sore mouth
- constipation or diarrhoea
- swollen aching joints or muscles, pain in the bones
- Muscle weakness
- swelling of fingers or lower legs due to fluid build up
- anxiety, confusion, difficulty sleeping
- headache, facial pain
- irritated eyes, blurred vision, eye pain, sensitivity to light, runny, itchy or swollen eyes
- changes in taste sensation
- cough
- slow heart beat
- increased sweating
- palpitations or irregular heart beat which may be accompanied by dizziness and breathlessness
- difficulty breathing with wheezing or coughing

Tell your doctor or dentist immediately or go to Accident and Emergency at your nearest hospital if you notice any of the following

- signs of allergy such as rash, itching or hives on the skin; swelling of the face, lips, tongue or other part of the body; shortness of breath, wheezing or troubled breathing
- signs that the level of calcium in your blood may have fallen too far, such as unusual lightheadedness, dizziness or faintness, numbness or tingling sensation, muscle cramps
- constant "flu-like" symptoms (chills, fever, sore throat, sores in mouth, swollen glands, tiredness or lack of energy) that could be a sign of blood problems
- chest pain
- passing less urine than normal, blood in the urine
- pain in the mouth, teeth or jaw, swelling or sores inside the mouth, numbness or a "heavy jaw feeling" or loosening of a tooth. These symptoms could be a sign of a jaw-bone problem known as jaw osteonecrosis.
- Any thigh, hip or groin pain

Some of the above side effects may be serious. You may need urgent medical attention.

This is not a complete list of all possible side effects. Others may occur in some people and there may be some side effects not yet known.

Tell your doctor if you notice anything else that is making you feel unwell, even if it is not on this list.

Ask your doctor or pharmacist if you don't understand anything in this list.

Do not be alarmed by this list of possible side effects.
You may not experience any of them.

After having Ostira™

Storage

If you are keeping a supply of Ostira™ at home:

Store the medicine in a cool dry place below 30 degrees C.

Do not store Ostira™ or any other medicine in the bathroom or near a sink.

Do not leave it in the car on hot days.

Keep the medicine where young children cannot reach it. A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If you no longer need Ostira™ or the expiry date has passed, return any unused medicine to your pharmacist.

Product description

What Ostira™ looks like

Ostira™ is a clear, colourless liquid packaged in plastic infusion bags.

Ingredients

Ostira™

Active ingredient – Zoledronic acid

Inactive ingredients

- mannitol
- sodium citrate dihydrate
- water for injections

Ostira™ does not contain sucrose, gluten, tartrazine or any other azo dyes.

Distributor

Ostira™ is distributed by:

Pfizer Australia Pty Ltd
ABN 50 008 422 348
38-42 Wharf Road
West Ryde NSW 2114
Australia
Toll Free number:
1800 675 229

Please check with your pharmacist for the latest Consumer Medicine Information

Australian Registration Numbers

- 5 mg/100 mL infusion AUST R – 188019

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