

DIDRONEL[®]

Etidronate Disodium

Consumer Medicine Information

What is in this leaflet

Please read this leaflet carefully before you start taking Didronel.

This leaflet answers some common questions about Didronel. It does not contain all the available information and 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 taking Didronel against the expected benefits it will have for you.

Use Didronel as instructed and follow the advice given in this leaflet.

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

Keep this leaflet with the medicine.

You may need to read it again.

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

Use Didronel only as directed by your doctor.

What Didronel is used for

Didronel contains the active ingredient etidronate disodium. It belongs to a group of medicines called bisphosphonates.

Didronel is used to:

- treat osteoporosis in both women and men, a condition where there is a thinning and weakening of the bones, which may lead to fractures. It is taken in combination with calcium tablets.
- treat symptoms such as bone pain and abnormal bone formation in Paget's disease, a condition where there is increased bone turnover.
- to prevent and treat abnormal deposits of calcium forming in soft tissue or muscle, which may occur after spinal cord injury or total hip replacement.

Ask your doctor if you have any questions about why Didronel has been prescribed for you.

Your doctor may have prescribed Didronel for another reason.

Do not give Didronel to children.

The safety and effectiveness of Didronel in children has not been established.

Before you start taking Didronel

When you must not take it

Do not take Didronel if:

- you suffer from severe softening or weakening of the bones called osteomalacia (your doctor will treat this condition before you start Didronel)

- you have allergies to any of the ingredients of Didronel which are listed under the heading, "Product Description", at the end of this leaflet
- the product has passed its expiry date (EXP) printed on the bottle label
- the package is not intact or if the packaging shows any signs of tampering
- there is a noticeable change to the appearance of the product
- it has not been prescribed for you by your doctor.

Before you start to take it

See your doctor for a check up before you start to use Didronel.

Tell your doctor if:

- you are pregnant or trying to become pregnant
- you are breastfeeding
- you suffer from inflammatory bowel disease
- you suffer from any kidney disorders, particularly if you are elderly
- you suffer from high blood calcium or high urine calcium
- you have cancer
- you have dental problems or had previous dental surgery such as a tooth extraction or dental implant.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and Didronel may interfere with each other. These medicines may be affected by Didronel or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

These include:

- any other bisphosphonates
- warfarin, a medicine used to prevent blood clots
- calcium supplements
- vitamin and mineral supplements, and antacids for indigestion containing calcium, iron, magnesium or aluminium.

You can still take the medicines containing calcium while you are taking Didronel. However, you must take Didronel at least two hours before or two hours after taking any of these calcium medicines to make sure there is no problem with absorption.

Your doctor and pharmacist have more information on medicines to be careful with or to avoid while taking Didronel.

How to take Didronel

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the bottle, ask your doctor or pharmacist for help.

How much to take

Your doctor will decide the dose of Didronel.

When to take it

Swallow the tablets as a single, oral dose at bedtime with a glass of water and preferably on an empty stomach. However, if you feel any stomach pain, please consult your doctor for advice.

To avoid problems with absorption, take Didronel at least two hours before or two hours after:

- eating foods high in calcium (eg. milk, cheese, yoghurt, tinned fish)
- taking vitamin and mineral supplements or antacids containing calcium, iron, magnesium or aluminium.

How long to take it

For osteoporosis, Didronel is taken in repeated 90 day cycles with calcium tablets. However, Didronel and the calcium tablets are to be taken separately on different days. Your doctor will advise you of the specific instructions and duration of treatment.

For Paget's disease, the usual treatment time is up to six months, followed by a break for 3 months before starting treatment again.

For spinal cord injury, the total treatment period is 12 weeks.

For total hip replacement, Didronel treatment is usually started one month before the operation and continues for three months after the operation.

Please ask your doctor or pharmacist if you have any questions.

If you forget to take Didronel

If it is almost time for your next dose, skip the dose you have missed and take your next dose when you are meant to.

Otherwise, take it as soon as you remember and then go back to taking your medicine as you would normally.

Do not take a double dose to make up for the dose that you missed.

This may increase the chance of you getting an unwanted side effect.

If you are taking Didronel for osteoporosis, do not take it on the same day as the calcium tablets.

If you have trouble remembering when to take your medicine, ask your pharmacist for some hints.

In case of overdose

Immediately telephone your doctor or the New Zealand National Poisons Information Centre (telephone 0800 POISON or 0800 764 766) for advice, or go to Accident and Emergency at your nearest hospital, if you think that you or anyone else may have taken too much Didronel.

Do this even if there are no signs of discomfort or poisoning.

If you take too many Didronel tablets, you may start vomiting and may need urgent medical attention.

Have the Didronel pack or this leaflet available to give details if needed.

While you are using Didronel

If you are about to have any tests, tell your doctor that you are taking this medicine.

It may interfere with the results of some bone scans.

Tell any other doctors, dentists, and pharmacists who treat you that you are taking Didronel.

Inform your dentist that you are taking Didronel or have taken Didronel in the past. Also let your dentist know of any existing medical conditions.

Having dental surgery while you are taking Didronel can increase the risk of damage to the teeth and jawbone.

Keep all of your doctor's appointments so that your progress can be checked.

You may need regular blood and urine tests.

Side Effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Didronel.

Didronel helps most people with bone problems, but it may have unwanted side effects in some people. All medicines can have side effects. Sometimes they are serious, most of the time they are not.

You may need medical attention if you get some of the side effects.

Do not be alarmed by the following lists of side effects.

You may not experience any of them.

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

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

- nausea (feeling sick)
- diarrhoea
- painful joints
- skin rashes, itchiness or itchy rash
- loss of hair.

These are the more common and milder side effects of Didronel.

Mild side effects such as headache, stomach pain, leg cramps were also reported in people taking Didronel for osteoporosis.

Tell your doctor immediately, or go to accident and emergency at your nearest hospital if you notice any of the following:

- aggravation of asthma
- memory loss, confusion changes in mood; seeing or hearing things that are not there
- numbness or tingling sensations
- burning on tongue or swollen, red, sore tongue
- signs of frequent infections such as fever, severe chills, sore throat or mouth ulcers – these symptoms may be caused by a reduction in the number of white blood cells
- headaches, shortness of breath when exercising, dizziness, looking pale – signs of anaemia (low number of red blood cells)
- bleeding or bruising more easily than usual
- blood in urine or bowel motions, black tarry bowel motions, black vomit – signs

of internal bleeding or other bleeding disorders

- toothache, jaw pain, or swelling and numbness of the jaw area.

These may be serious side effects of Didronel. You may need urgent medical attention. Serious side effects are rare.

New bone pain, increased or recurring bone pain were also reported in people taking Didronel for Paget's disease.

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

Other side effects not listed above may also occur in some people.

After using Didronel

Storage

Store Didronel in a cool place where the temperature stays below 25°C.

Do not use it past the expiry date (EXP) printed on the bottle label.

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

Heat and dampness can destroy some medicines.

Do not leave your tablets in the car on hot days or on window sills.

Keep your Didronel tablets out of reach of children.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

Return any unused tablets to your pharmacist for disposal.

Never give Didronel to someone else.

This medicine is for you only.

Product Description

What Didronel tablets look like

Didronel is a rectangular white tablet engraved with 'P&G' on one side and '402' on the other. It is packed in bottles of 60 tablets.

Ingredients

Each tablet contains 200 mg etidronate disodium. It also contains:

- magnesium stearate
- microcrystalline cellulose
- pregelatinised maize starch.

Supplier

Pfizer New Zealand Ltd
P O Box 3998
Auckland, New Zealand

Toll Free Number: 0800 736 363

This leaflet was revised on 27
January 2009.

© Pfizer New Zealand Ltd

® Registered Trademark