

ARROW - ETIDRONATE

Disodium etidronate 200 mg Tablets

WHAT IS IN THIS LEAFLET

This leaflet answers some common questions about ARROW - ETIDRONATE.

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

All medicines have benefits and risks. Your doctor has weighed the risks of you taking ARROW - ETIDRONATE against the benefits they expect it will have for you.

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

Keep this leaflet with your medicine. You may need to read it again.

WHAT ARROW - ETIDRONATE IS USED FOR

Disodium etidronate, the active ingredient in ARROW - ETIDRONATE Tablets, belongs to a group of medicines called bisphosphonates. Bisphosphonates can be used to help bone diseases such as osteoporosis and Paget's disease.

Your doctor may prescribe ARROW - ETIDRONATE to prevent and treat abnormal deposition of calcium in the bone. This condition may happen following spinal cord injury or total hip replacement.

As part of the treatment, your doctor will give you calcium to take after completing the course of ARROW - ETIDRONATE.

Your doctor may have prescribed ARROW - ETIDRONATE for another reason. Ask your doctor if you have any questions about why ARROW - ETIDRONATE has been prescribed for you.

ARROW - ETIDRONATE should not be given to children.

There is no experience with the use of ARROW - ETIDRONATE in children.

There is no evidence that ARROW - ETIDRONATE Tablets is addictive.

ARROW - ETIDRONATE is available only with a doctor's prescription.

BEFORE YOU TAKE ARROW - ETIDRONATE

When you must not take it

Do not take ARROW - ETIDRONATE if you are allergic to medicines containing etidronate, bisphosphonates or any of the ingredients listed at the end of this leaflet.

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.

Do not take ARROW - ETIDRONATE if the expiry date (Exp.) printed on the pack has passed.

It may not work well if you do.

Do not take ARROW - ETIDRONATE if the packaging is torn or shows signs of tampering.

Before you start to take it

Tell your doctor if you are allergic to any other medicines, foods, dyes or preservatives.

Tell your doctor if your dietary intake of vitamin D and calcium is low (foods rich in these include dairy products).

Tell your doctor if you have the following medical problems:

- kidney disease
- inflammatory bowel disease
- severe lack of calcium in bones called osteomalacia, which should be treated first before taking ARROW - ETIDRONATE
- high blood calcium or high urine calcium.

Tell your doctor if you are pregnant or intend to become pregnant.

Tell your doctor if you are breastfeeding or intend to breastfeed.

Taking other medicines

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

Some medicines may be affected by ARROW - ETIDRONATE, or may affect how well it works. These include:

- other bisphosphonates
- calcitonin
- calcium and vitamin supplements.

Your doctor can tell you what to do if you are taking any of these medicines. If you are not sure whether you are taking any of these medicines, check with your doctor or pharmacist.

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

If you have not told your doctor about any of the above, tell them before you start taking ARROW - ETIDRONATE.

HOW TO TAKE ARROW - ETIDRONATE

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

These directions may differ from the information contained in this leaflet. If you do not understand the instructions provided with this medicine, ask your doctor or pharmacist for help.

How much to take

Your doctor will decide the dose of ARROW - ETIDRONATE.

For osteoporosis, your doctor would prescribe calcium tablets with ARROW - ETIDRONATE, which give you a full 90-day course of treatment. Take all your ARROW - ETIDRONATE tablets before starting calcium tablets.

Day 1 - Day 14: usual dose is two ARROW - ETIDRONATE Tablets every day;

Day 15 - Day 90: calcium tablet(s) daily.

During the last week of treatment, you should see your doctor or pharmacist about your next prescription. You would need to repeat the course over again from Day 1 for another 90 days, depending on your doctor's instructions.

How to take it

Swallow the tablet only with a glass of water.

When to take it

Take ARROW - ETIDRONATE as a single, oral dose at bedtime, preferably on an empty stomach. However, if you feel any stomach pain, please consult your doctor for advice.

Certain foods and medicines may stop ARROW - ETIDRONATE from working properly. So, you must always follow these directions:

1. Take ARROW - ETIDRONATE with water **not** milk.
2. Do **not** take ARROW - ETIDRONATE at the same time as your calcium supplement.
3. Do **not** take ARROW - ETIDRONATE with food.

4. Do **not** eat or drink the following products for **2 hours before or after** taking ARROW - ETIDRONATE:

- dairy products or foods high in calcium (e.g. milk, cheese, yoghurt, tinned fish)
- antacids (heartburn remedies)
- vitamins
- mineral supplements like iron, calcium
- laxatives containing magnesium.

Take the tablet at about the same time of each day.

Taking your tablet at the same time each day will have the best effect on your condition. It will also help you to remember when to take it.

How long to take it

The length of your treatment will depend on your medical condition and other factors, such as your weight, and how well you respond to treatment:

- osteoporosis - up to three years
- Paget's disease - up to six months and then have a break for three months before starting treatment again
- spinal cord injury - 12 weeks (total treatment period)
- total hip replacement - usually started one month before the operation and three months after the operation.

If you forget to take it

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

Otherwise, take the missed dose as soon as you remember, and then go back to taking your tablets as you would normally.

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

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

If you are not sure what to do, ask your doctor or pharmacist.

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

If you take too much (overdose)

Immediately telephone your doctor, or the National Poisons Information Centre (0800 POISON or 0800 764 766), or go to the Accident and Emergency department at your nearest hospital, if you think that you or anyone else may have taken too many ARROW - ETIDRONATE Tablets.

Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Keep the telephone numbers for these places handy.

If you take too many ARROW - ETIDRONATE Tablets, you may start vomiting.

WHILE YOU ARE TAKING ARROW - ETIDRONATE

Things you must do

Before starting any new medicine, tell your doctor or pharmacist that you are taking ARROW - ETIDRONATE.

Tell all the doctors, dentists and pharmacists who are treating you that you are taking ARROW - ETIDRONATE.

Tell your doctor if you become pregnant while taking ARROW - ETIDRONATE.

Tell your doctor if, for any reason, you have not taken your medicine exactly as directed.

Otherwise, your doctor may think that it is not working and change your treatment unnecessarily.

Things you must not do

Do not use ARROW - ETIDRONATE to treat any other conditions unless your doctor tells you to.

Do not change the dose of your ARROW - ETIDRONATE without checking with your doctor.

Do not give ARROW - ETIDRONATE to anyone else, even if they have the same condition as you.

SIDE EFFECTS

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

Like other medicines, ARROW - ETIDRONATE Tablets can cause some 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.

Do not be alarmed by this list of possible 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 and they worry you:

- nausea (feeling sick)

- diarrhoea
- painful joints
- skin rashes, itchiness or itchy rash
- loss of hair.

These are the more common side effects of ARROW - ETIDRONATE, and they are usually mild and short-lived.

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

- allergic reactions such as swelling of the face, lips, mouth, tongue or throat that may cause difficulty in swallowing or breathing; asthma-like symptoms or aggravation of asthma; pinkish or itchy swellings on the skin (hives or nettle rash)
- changes in mood, confusion or memory loss
- 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. This may be caused by a reduction in the number of red and white blood cells.

These side effects are rare but serious. You may need urgent medical attention.

This is not a complete list of all possible side effects. Other side effects not listed above may also occur in some patients. Tell your doctor if you notice anything that is making you feel unwell.

AFTER TAKING ARROW - ETIDRONATE

Storage

Keep ARROW - ETIDRONATE where children cannot reach it.

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

Keep ARROW - ETIDRONATE in a cool, dry place where the temperature stays below 25°C.

Keep your tablets in the blister packs until it is time to take them.

If you take the tablets out of the blister pack, they may not keep well.

Do not store ARROW - ETIDRONATE or other medicines in the bathroom or near a sink. Do not leave the tablets in the car or on window sills.

Heat, light and dampness can destroy some medicines.

Disposal

If your doctor tells you to stop taking ARROW - ETIDRONATE, or your tablets have passed their expiry date, ask your pharmacist what to do with any tablets that are left over.

PRODUCT DESCRIPTION

What ARROW - ETIDRONATE looks like

ARROW - ETIDRONATE Tablets are off-white, rectangular tablet marked "ED 2" on one side and ">" on the other side. It is available in both bottles and blister packs of 100 tablets.

Ingredients

The active ingredient in ARROW - ETIDRONATE is disodium etidronate. Each ARROW - ETIDRONATE Tablets contains 200 mg of disodium etidronate.

The tablets also contain

- maize starch
- microcrystalline cellulose
- pregelatinised maize starch
- magnesium stearate
- purified water.

The tablets do not contain gluten, lactose, sucrose, tartrazine or any azo dyes.

Supplier

ARROW - ETIDRONATE is distributed in New Zealand by:

Teva Pharma (New Zealand) Limited
PO Box 128 244
Remuera
Auckland 1541
Telephone: 0800 800 097

Date of preparation

4 May 2017

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