

## PATIENT INFORMATION LEAFLET

### SCHEDULING STATUS

**S3**

### FEMAX 70 (Tablet)

The active substance is alendronic acid as alendronic sodium trihydrate.  
Each FEMAX 70 tablet contains 70 mg alendronic acid as alendronic sodium trihydrate.

### Read all of this leaflet carefully before you start taking FEMAX 70

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- FEMAX has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

### What is in this leaflet

1. What FEMAX 70 is and what it is used for.
2. What you need to know before you take FEMAX 70.
3. How to take FEMAX 70.
4. Possible side effects.
5. How to store FEMAX 70.
6. Contents of the pack and other information.

#### 1. What FEMAX is and what it is used for

FEMAX belongs to a group of medicines called bisphosphonates.

It is prescribed by your doctor to treat symptoms of post menopausal osteoporosis (a bone disease which causes bones to become thin and weak, making them prone to fractures). It can also be prescribed for the treatment of primary hypogonadal osteoporosis in men (a condition where the male hormone levels are very low resulting in bones becoming weak).

## **2. What you need to know before you take FEMAX 70**

### **Do not take FEMAX 70:**

- if you are hypersensitive (allergic) to alendronic sodium trihydrate or any of the other ingredients of FEMAX 70. Check the list of ingredients given in the section of this leaflet
- if you have a disorder of the oesophagus (the tube that connects your mouth to your stomach)
- if you are unable to stand or sit upright for at least 30 minutes after taking the tablet
- if you have kidney problems
- if you have low blood calcium
- if you are pregnant or think you may be pregnant
- if you are breastfeeding
- These tablets should not be given to children.
- Make certain your health care professional knows if you are on any special diet, such as a low-sodium or low-sugar diet. Your doctor may recommend that you eat a balanced diet with an adequate amount of calcium and vitamin D (found in milk or other dairy products)

### **Warnings and precautions**

#### **Take special care with FEMAX**

If you experience or suffer from any of the following, inform your doctor:

- have or have had medical or dental problems, any allergies and if you are or have been a smoker
- if you have swallowing or digestive problems
- if you have/have had stomach operations
- if you have mouth sores
- if you develop chest pain
- if you have heart burn
- if you suffer from chest pain
- if you are lactose intolerant (inability to digest milk or milk products);
- if you have kidney problems

#### **Other medicines and FEMAX**

If you are taking other medicines on a regular basis, including complementary or traditional medicine, the use of **FEMAX** with these medicines may cause undesirable reactions. Please consult your doctor, pharmacist or other health care professional for advice.

Tell all doctors and health care professionals who are treating you that you are taking **FEMAX** before you start taking any new medicines .

Calcium supplements, iron or magnesium, including antacids and mineral supplements and certain laxatives, will interfere with FEMAX. You must wait at least 30 minutes after taking **FEMAX** before taking any other medication.

### **FEMAX 70 with food and drink and alcohol**

FEMAX must be taken at least 30 minutes before eating or drinking or taking any other medication. Follow your doctor's instructions.

### **Pregnancy and breastfeeding and fertility**

You should not take FEMAX if you are pregnant or breast feeding.

### **Driving and using machinery**

There is no data to indicate FEMAX may cause you to become drowsy or reduce your ability to drive or use machines .

### **FEMAX 70 contains lactose**

Contains lactose monohydrate. Patients with the rare hereditary conditions of lactose/fructose or galactose intolerance should not take FEMAX.

**FEMAX** contains lactose monohydrate and should not be taken if you are unable to digest milk or milk products.

## **3. How to take FEMAX**

Do not share medicines prescribed for you with any other person.

Always take FEMAX exactly as your doctor has told you. You should check with your doctor or pharmacist if you are unsure.

The usual dose is:

FEMAX must be taken on an empty stomach.

Swallow the tablets whole with plain tap water. Do not lie down for at least 30 minutes after taking FEMAX or having your first meal. Do not take FEMAX at bedtime or before getting up. Do not suck or chew the tablet.

For the treatment of post menopausal osteoporosis and osteoporosis in men: 70mg (one tablet) once weekly.

There is no need to adjust the dose if you are an elderly person or if you have mild kidney problems. If you have any concerns, talk to your doctor or health care professional for advice.

Your doctor will tell you how long your treatment with FEMAX will last.

If you have the impression that the effect of FEMAX is too strong or too weak, talk to your doctor or pharmacist.

### **If you take more FEMAX than you should**

Drink a full glass of milk and contact your doctor or pharmacist immediately. If neither is available, seek help at the nearest hospital or poison control centre even if there are no signs or discomfort.

Do not induce vomiting. Do not lie down.

The most common signs of an overdose is an upset stomach, heartburn, gastritis (inflammation of the stomach lining) and ulcers.

### **If you forget to take FEMAX**

It is important to try to take your dose at the same time each day. If you miss a dose by a few hours, take the dose when you remember. If most of the day has passed, wait for the next scheduled dose. Do not take a double dose to make up for the forgotten individual doses.

## **4. Possible side effects**

FEMAX can have side effects.

Not all side effects reported for FEMAX are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking FEMAX, please consult your healthcare professional for advice.

**If any of the following happens, stop taking FEMAX and tell your doctor immediately or go to the casualty department at your nearest hospital:**

- Swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing;
- rash or itching;
- fainting.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to FEMAX. You may need urgent medical attention or hospitalisation.

**Tell your doctor if you notice any of the following:**

The following side effects have been reported frequently:

- stomach pain
- constipation
- diarrhoea
- feeling bloated
- dyspepsia (indigestion)
- flatulence (feeling windy)
- throat ulcer
- difficulty swallowing
- bone, muscle or joint pain
- headache

The following side effects have been reported less frequently:

- dizziness
- nausea
- mouth ulcers
- stomach ulcer
- swelling of joints
- rash or other skin reactions
- low blood calcium
- allergic reactions like swelling beneath the skin
- blurred vision
- liver condition called hepatitis

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

## **5. How to store FEMAX**

- Store all medicines out of reach and sight of children.
- Store at or below 25 °C and store in a dry place.
- Store in the original container until required for use.
- Do not store in a bathroom
- Do not use after the expiry date stated on the label / carton / bottle
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

## **6. Contents of the pack and other information**

### **What FEMAX contains:**

- The active substance is alendronic acid as alendronic sodium trihydrate.
- The other ingredients are croscarmellose sodium, lactose monohydrate, magnesium stearate, microcrystalline cellulose.

### **What FEMAX looks like and contents of the pack**

A white to off-white capsule shaped tablet embossed "AN 70" on one side and "> " (Arrow logo) on the other side.

Blister packs of 4 tablets each in a carton.

### **Holder of Certificate of Registration and Manufacturer**

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### **Access to the corresponding Professional Information**

Can be obtained on the SAHPRA website