Clean copy of Amended Patient Information Leaflet

Information for the Patient about

OSTEOBON-70

SCHEDULING STATUS:

S3

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM:

OSTEOBON-70 (Tablets) containing **alendronic acid (alendronate)** 70 mg.

Read all of this leaflet carefully before you start taking OSTEOBON-70:

- **Keep this leaflet; you may need to read it again.**
- **If you have further questions please ask your doctor or your pharmacist.**
- **OSTEOBON-70 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 OSTEOBON-70 CONTAINS:

The active substance in **OSTEOBON-70** is alendronate sodium trihydrate equivalent to 70 mg alendronic acid (alendronate).

The other inactive ingredients are magnesium stearate, maize starch, mannitol, microcrystalline cellulose and sodium starch glycollate.

OSTEOBON-70 is available as a 70 mg tablet.

WHAT OSTEOBON-70 IS USED FOR:

OSTEOBON-70 belongs to a class of medicines called aminobisphosphonates. **OSTEOBON-70** is not a hormone.

OSTEOBON-70 has been prescribed by your doctor to treat a condition known as osteoporosis. When used for the treatment of osteoporosis, **OSTEOBON-70** rebuilds bone and reduces the risk of developing fractures.

BEFORE YOU TAKE OSTEOBON-70:

Do not take OSTEOBON-70 if you:

- Are hypersensitive (allergic) to alendronate or any of the other ingredients of **OSTEOBON-70**.
- Have severe kidney problems.
- Have stomach, intestinal or digestive problems associated with dyspepsia or heartburn, including inflammation of the stomach lining and/or ulcers.
- Have disorders of the oesophagus (the tube that connects your mouth with your stomach), including difficulty in swallowing, narrowing of the oesophagus and ulcers.
- Have been told by your doctor that you have low blood calcium or vitamin D deficiency.
- If you are not able to sit or stand upright for at least 30 minutes after taking **OSTEOBON-70.**

The safety and efficacy of **OSTEOBON-70** in children have not been established.

Take special care with OSTEOBON-70:

- If you require a serious dental procedure or invasive dental surgery. Should you have cancer or are on cancer treatment, or on steroids, or have poor oral hygiene, pre-existing dental disease, low red blood cell counts, blood clotting abnormalities or infection, you should avoid serious dental procedures whilst on **OSTEOBON-70**. Before any dental procedure you should advise your dentist to contact your doctor about your **OSTEOBON-70** treatment.
- You should stop taking **OSTEOBON-70** and consult your doctor if you develop chest pain, difficulty with swallowing or painful swallowing, or worsening heartburn.
- If you experience pain in the thigh as this may be due to a so-called stress fracture of your thigh bone (femur). These fractures may occur with minimal or no trauma. Sometimes stress fractures develop on both sides. Please discuss the long-term use of **OSTEOBON-70** with your treating doctor.
- If you have been told that your blood calcium levels are too low or that you have a vitamin D deficiency. These conditions need to be corrected before you start treatment with **OSTEOBON-70**. You may have to go for blood tests to monitor your blood calcium levels while receiving treatment with **OSTEOBON-70**.

- If you experience bone, joint, and/or muscle pain while taking **OSTEOBON-70**. You may experience such symptoms from day one of taking **OSTEOBON-70**, or only after several months. The symptoms usually go away if treatment with **OSTEOBON-70** is stopped. Please report any such symptoms to your doctor, since he/she may decide that you require alternative treatment.

Use in children:

OSTEOBON-70 is not indicated for children.

Use in elderly:

OSTEOBON-70 is as effective and just as well tolerated by older and younger patients.

Taking OSTEOBON-70 with food and drink:

See **"HOW TO TAKE OSTEOBON-70"**.

Pregnancy and breastfeeding:

Do not take **OSTEOBON-70** whilst you are pregnant or breastfeeding.

If you are pregnant or breastfeeding your baby while taking OSTEOBON-70, please consult your doctor, pharmacist or other healthcare professional for advice.

Driving and using machinery:

OSTEOBON-70 should not affect your ability to operate machinery or drive.

Taking other medicines with OSTEOBON-70:

See **"HOW TO TAKE OSTEOBON-70"**.

Oral medicines, including calcium supplements and antacids, will interfere with the absorption (and affect the effectiveness) of **OSTEOBON-70**. Wait at least 30 minutes after **OSTEOBON-70** before taking any other oral medicines.

If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of OSTEOBON-70 with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other healthcare professional, for advice.

HOW TO TAKE OSTEOBON-70:

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

Always take OSTEOBON-70 exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

These are the important things you must do to help make sure you will benefit from **OSTEOBON-70**.

STEP 1 As **OSTEOBON-70** is only taken once weekly, you must pick a day of the week that suits your schedule best. Take one **OSTEOBON-70** tablet on your chosen day every week immediately after you get up. Do not take **OSTEOBON-70** at bedtime or before arising for the day.

STEP 2 After getting up in the morning, swallow one **OSTEOBON-70** tablet with a full glass (200 – 240 ml) of **plain water**, on an empty stomach. Do not suck or chew the **OSTEOBON-70** tablet.

STEP 3 Do not take the tablet with coffee or tea, mineral water, juice or any beverage other than plain water, since these decrease the amount of **OSTEOBON-70** absorbed by the body.

STEP 4 Do not lie down after swallowing your **OSTEOBON-70** tablet. Remain upright (sitting, standing or walking) for at least 30 minutes and until you have eaten your first food of the day.

STEP 5 Wait at least 30 minutes after swallowing your **OSTEOBON-70** tablet before taking your first beverage, food or other medicines of the day. It is important to take **OSTEOBON-70** on an empty stomach.

By following steps 1 – 5 you will ensure maximum absorption of your **OSTEOBON-70** tablet, and help avoid irritation of your oesophagus.

Other important points to remember while taking OSTEOBON-70:

- Should you develop chest pain, new or worsening heartburn, or difficult or painful swallowing, stop taking **OSTEOBON-70** and contact your doctor.
- For full benefit of this medicine it is important that you take **OSTEOBON-70** for as long as your doctor prescribes it. You can only treat your osteoporosis if you continue to take **OSTEOBON-70**.
- It is important to tell your doctor about all medicines that you are taking or plan to take, including those medicines obtained without a prescription.

If you have the impression that the effect of **OSTEOBON-70** is too strong or too weak, tell your doctor or pharmacist.

If you take more OSTEOBON-70 than you should:

In the event of overdosage (if you take too many tablets), drink a full glass of milk. Do not induce vomiting. Do not lie down.

In the event of overdosage, contact your doctor or pharmacist immediately. If neither is available, seek help at the nearest hospital or poison control centre.

If you forget to take OSTEOBON-70:

Do not take the missed dose later in the day. Resume the usual routine the next morning. Never take two tablets on the same day. Return to taking one tablet once a week on the day that you originally chose according to your schedule.

POSSIBLE SIDE-EFFECTS:

OSTEOBON-70 can have side-effects. Not all side-effects reported for OSTEOBON-70 are included in this leaflet. Should your general health worsen while taking OSTEOBON-70, please consult your doctor, pharmacist or other healthcare professional for advice.

Serious side-effects that you, or a family member, should report to your doctor immediately include:

- Severe allergic reactions characterised by skin rash, fever, swelling of the lips, tongue, face or whole body, hives and itching, difficulty breathing or shortness of breath.
- Any skin rash with blister formation or any skin rash which involves the mouth, eyes or genitalia as this may indicate the development of toxic epidermal necrolysis or Stevens-Johnson syndrome.
- Severe stomach pain or painful swallowing.
- Black or bloody stools as these may be signs of an ulcer.
- Vomiting blood, as this may be a sign of a stomach or duodenal ulcer.
- Thigh pain, weakness or discomfort as these symptoms may be due to a stress fracture of the thigh bone (femur) (see **"Take special care with OSTEOBON-70"**).
- Jaw pain or delayed healing and infection, sometimes following tooth extraction (see **"Take special care with OSTEOBON-70"**).
- Pins and needles around the mouth or lips or in the hands or feet, pin-point red spots on the skin, or muscle cramps, as these symptoms may be due to low blood calcium levels.
- Inflammation of the eye, presenting with blurred vision, eye pain or redness of the eye.

Other side-effects that you should report to your doctor as soon as possible include:

- Hives or any skin rash other than those mentioned above, including rash which is worsened by sunlight.

- Bone, muscle or joint pain (see **"Take special care with OSTEOBON-70"**).
- Swelling of the joints.
- Swelling of the hands or legs.
- Difficulty swallowing.
- Mild stomach pain, runny stomach, nausea and/or vomiting, or heartburn.

Please report the following side-effects to your doctor if they continue or become bothersome:

- Headache, dizziness, sensation of spinning, or taste disturbances.
- Hair loss or itching.
- Weakness or generally feeling unwell.
- Flu-like symptoms, including fever and muscle pain.
- Ulcers of the mouth and throat (which occur especially when tablets are chewed or dissolved in the mouth).
- Flatulence, constipation, poor digestion, feeling bloated.

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

STORAGE AND DISPOSING OF OSTEOBON-70:

KEEP ALL MEDICINES OUT OF THE REACH AND SIGHT OF CHILDREN.

Store **OSTEOBON-70** in a dry place at or below 25 °C.

Do not use **OSTEOBON-70** after the month and year following the expiry date stated on the packaging material.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems, for example toilets.

Keep the blisters in the outer carton until required for use.

PRESENTATION OF OSTEOBON-70:

OSTEOBON-70 tablets are supplied in a PVC/PVDC coated clear transparent film and aluminium foil blister strip of 4 tablets.

IDENTIFICATION OF OSTEOBON-70:

White, capsule-shaped, biconvex tablets plain on one side and '3173' debossed on the other side.

REGISTRATION NUMBER:

A39/3.2/0396

NAME AND ADDRESS OF REGISTRATION HOLDER:

CIPLA MEDPRO (PTY) LTD

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RSA

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