Product Name: ALENDRONATE UNICORN 70
Applicant Name: Unicorn Pharmaceuticals (Pty) Ltd.
Product strength and dosage form: 70 mg Trihydrate monosodium alendronate equivalent to alendronic acid/tablet

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S3

ALENDRONATE UNICORN 70 tablets

70 mg Trihydrate monosodium alendronate equivalent to alendronic

acid Sugar free

Read all of this leaflet carefully before you start taking **ALENDRONATE UNICORN 70.**

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

If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.

ALENDRONATE UNICORN 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 is in this leaflet

1. What **ALENDRONATE UNICORN 70** is and what it is used for
2. What you need to know before you take **ALENDRONATE UNICORN 70**
3. How to take **ALENDRONATE UNICORN 70**
4. Possible side effects
5. How to store **ALENDRONATE UNICORN 70**

6. Contents of the pack and other information

What ALENDRONATE UNICORN 70 is and what it is used for

ALENDRONATE UNICORN 70 is a tablet containing the active substance alendronic acid (commonly called alendronate) and belongs to a group of non-hormonal medicines called bisphosphonates. **ALENDRONATE UNICORN 70** prevents the loss of bone that occurs in women after they have been through the menopause and helps to rebuild bone. It reduces the risk of spine and hip fractures.

ALENDRONATE UNICORN 70 is prescribed to treat osteoporosis (thinning of the bone) after menopause in women and also to treat osteoporosis in men.

2. What you need to know before you take ALENDRONATE

UNICORN 70 Do not take ALENDRONATE UNICORN 70

- If you are hypersensitive (allergic) to alendronate or any of the other ingredients of **ALENDRONATE UNICORN 70** (see section 6).
- If you are suffering from any medical problems especially a history of problems with your esophagus (the tube that connects your mouth with your stomach) and digestive tract disorders associated with dyspepsia or heartburn, including inflammation of the stomach lining and/or ulcers, and severe kidney problems.
- If you have been told by your doctor that you have low blood calcium or a vitamin D deficiency.
- If you have disorders of the esophagus (the tube that connects your mouth with your stomach), including difficulty in swallowing, narrowing of the esophagus and ulcers.

- If you are not able to stay in an upright position for at least 30 minutes after taking **ALENDRONATE UNICORN 70**.
- Children and adolescents.

Warnings and precautions

Take special care with **ALENDRONATE UNICORN 70:**

- If you suffer from (mild to moderate) kidney problems. Speak to your doctor if you are unsure.
- Stop taking **ALENDRONATE UNICORN 70** tablets immediately and consult your doctor if you develop the following symptoms of problems with your esophagus (the tube that connects your mouth with your stomach):
  - Difficulty or pain swallowing;
  - Chest pain or new or worsening heartburn.
- The risk of developing the above side effects can be reduced if you swallow **ALENDRONATE UNICORN 70** with a full glass of water and/or if you do not lie down for at least 30 minutes. These side effects may worsen if you continue to take **ALENDRONATE UNICORN 70** after developing these symptoms.
- 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 dental hygiene, pre- existing dental disease, low red blood cell counts, blood clotting abnormalities or infection, you should avoid dental procedures whilst on **ALENDRONATE UNICORN 70**. Before any dental procedure, you should advise your dentist to contact your doctor about your **ALENDRONATE UNICORN 70** treatment.

- 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 **ALENDRONATE UNICORN 70** with your doctor.
- Your doctor has told you that you have Barrett's esophagus (a condition associated with changes in the cells that line the lower esophagus)
- You have been told you have trouble absorbing minerals in your stomach or intestines (malabsorption syndrome),
- You have been told you have low blood calcium or that you have a
- vitamin D deficiency. These conditions need to be corrected before you start treatment with **ALENDRONATE UNICORN 70**. You may
- have to go for blood tests to monitor your blood calcium levels while receiving treatment with **ALENDRONATE UNICORN 70**.
- If you experience bone, joint, and/or muscle pain while taking **ALENDRONATE UNICORN 70**. You may experience such symptoms from day one of taking **ALENDRONATE UNICORN 70** or only after several months. The symptoms usually go away if treatment with **ALENDRONATE UNICORN 70** is stopped. Please report any such symptoms to your doctor, since he/she may decide that you, require alternative treatment.
- Your doctor may require you to visit your dentist before starting treatment, especially if you have other medical conditions such as cancer, you are undergoing chemotherapy or radiotherapy, you are taking corticosteroids (such as prednisone or dexamethasone), you are taking angiogenesis inhibitors (such as bevacizumab, or thalidomide), you are or have been a smoker, you have anaemia or clotting disorder, diabetes, you are overweight, you

are suffering from an infection.

- You have poor dental health, gum disease, a planned dental extraction or you do not receive routine dental care.
- You should avoid dental procedures or surgery while taking **ALENDRONATE UNICORN 70.**
- Do not suck or chew the tablet as it may cause burning in the mouth and throat.

You may be advised to have a dental check-up before starting treatment with **ALENDRONATE UNICORN 70**

It is important to maintain good oral hygiene when being treated with **ALENDRONATE UNICORN 70**. You should have routine dental check-ups throughout your treatment and you should contact your doctor or dentist if you experience any problems with your mouth or teeth such as loose teeth, pain or swelling.

Children and adolescents

Not Applicable

Other medicines and ALENDRONATE UNICORN 70

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines.)

- Do not take any, mineral supplements or antacids, containing aluminium, magnesium, iron or calcium with **ALENDRONATE UNICORN 70** as it will decrease the absorption of alendronate from the stomach. If your daily multivitamin supplement contains calcium, aluminium, magnesium or iron, you should wait 30 minutes after taking **ALENDRONATE UNICORN 70** before taking these medicines/supplements.

- Certain medicines called non-steroidal anti-inflammatory drugs (NSAIDs), such as ibuprofen, may interfere with how **ALENDRONATE UNICORN 70** works and cause digestive problems. Caution should therefore be used if you take **ALENDRONATE UNICORN 70** and NSAIDs at the same time.

ALENDRONATE UNICORN 70 with food and drink

It is important to take **ALENDRONATE UNICORN 70** with a full glass of water only (not mineral water) in the morning at least 2 hours before taking any other food, beverages or any other medicines.

It is likely that food and beverages (including mineral water and milk) will make **ALENDRONATE UNICORN 70** less effective if taken at the same time.

Pregnancy and breastfeeding and fertility

ALENDRONATE UNICORN 70 should not be used during pregnancy and breast-feeding.

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby please consult your doctor, pharmacist or other healthcare provider for advice before taking **ALENDRONATE UNICORN 70**.

Driving and using machines

ALENDRONATE UNICORN 70 will most likely not make you drowsy or impair your ability to drive and use machinery but take care if you feel dizzy, tired, have blurred vision and severe

bone, muscle or joint pain while using **ALENDRONATE UNICORN 70**.

3. How to take ALENDRONATE UNICORN 70

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

Always take **ALENDRONATE UNICORN 70** exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The usual dose is one **ALENDRONATE UNICORN 70** tablet once a week, swallowed with a full glass of plain water (not less than 200 ml) on an empty stomach. The tablet should be taken in the morning as soon as you get out of bed and at least 2 hours before any food, beverage or any other medication. It is important to take **ALENDRONATE UNICORN 70** on an empty stomach.

Do not take **ALENDRONATE UNICORN 70** at bedtime or before arising for the day.

Do not take the tablet with coffee or tea, mineral water, juice or any beverage other than plain water, since these drinks decrease the amount of **ALENDRONATE UNICORN 70** absorbed by your body.

Do not suck or chew the tablet.

Do not lie down for at least 30 minutes after you have taken **ALENDRONATE UNICORN 70** tablets. Remain upright (sitting, standing, or walking) for at least 30 minutes and until you have eaten your first food of the day.

It is important to follow the above instructions to reduce the risk of side effects related to the esophagus (the tube that connects your mouth with your stomach) (e.g. irritation, inflammation or ulceration).

If you have trouble remembering when to use your medicine, ask your pharmacist for

information.

Your doctor will tell you how long your treatment with **ALENDRONATE UNICORN 70** will last. Do not stop treatment early. If you have the impression that the effect of **ALENDRONATE UNICORN 70** is too strong or too weak, tell your doctor or pharmacist.

If you take more ALENDRONATE UNICORN 70 than you should

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

The following may occur if you take more **ALENDRONATE UNICORN 70** than you should:

- Upset stomach, heartburn, throat or digestive problems,

ulcers Taking milk or antacids may help relieve the symptoms.

Do not make yourself vomit, as it may cause irritation or pain on the throat. Do not lie down.

If you forget to take ALENDRONATE UNICORN 70

If you forget to take **ALENDRONATE UNICORN 70**, take the missed dose on the morning after you remember. Do not take a double dose to make up for forgotten individual doses. You should then return to taking one tablet once a week on the same day as originally scheduled.

4. Possible side effects

ALENDRONATE UNICORN 70 can have side effects.

Not all side effects reported for **ALENDRONATE UNICORN 70** are included in this leaflet. Should your general health worsen, or if you experience any untoward effects

while taking **ALENDRONATE UNICORN 70**, please consult your doctor, or pharmacist

or other healthcare

provider for advice.

If any of the following happens, stop taking **ALENDRONATE UNICORN 70** and tell your doctor immediately or go to the casualty department at your nearest hospital:

• hives, swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing

• heartburn**,**

• skin rash or itching

• fainting

These are all very serious events. If you have them, you may have had a serious allergic reaction to **ALENDRONATE UNICORN 70**. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

• changes in the way your heart beats, for example, if you notice it is beating faster

• esophagus (the tube that connects your mouth with your stomach) problems, such as difficulty with swallowing, ulceration which can cause chest pain, heartburn or difficulty or pain upon swallowing, sore esophagus, bleeding in the mouth and esophagus, constant cough or changes in your voice. These side effects, if serious, may be a sign of cancer of the esophagus.

• stomach pain and stomach or peptic ulcers (sometimes severe or with bleeding)

• kidney failure: you may experience less urine than is normal for you, swelling of legs, ankles or feet, nausea or extreme tiredness

• Stevens-Johnson syndrome or other serious skin disorder (begins with flu-like symptoms,

followed by a painful red or purplish rash that spreads and blisters).

These are all serious side effects. You may need urgent medical attention. Tell your doctor if you notice any of the following:

• you look pale and feel tired and breathless (you may have anaemia where you have less haemoglobin in your blood than is normal)

• bleeding from the gums, nose or mouth, any bleeding that will not stop, reddish or pink urine, unexpected bruising (you may have less platelets in your blood than is normal)

• mouth ulcers

• signs of infections such as fever/chills or a sore throat (you may have less white blood cells than is normal)

• hallucinations (hearing things that aren't there)

• headaches, vertigo (the feeling of moving or spinning while you aren't moving), changes in your sense of taste or dizziness

• inflammation of the eye, redness or pain of the eye, abnormal or blurred vision

• abdominal pain, indigestion, bloated or swollen stomach, nausea, vomiting, constipation, diarrhoea, wind, acid regurgitation from the stomach, black or tar-like stools, sore throat or difficulty swallowing, chest pain

• liver problems, such as yellowing of skin and eyeballs (jaundice), pain in your upper right abdomen, abdominal swelling or generally feel unwell

• rash (occasionally due to sunlight), redness and itchiness of skin, hair loss

• bone, muscle and/or joint pain which is sometimes severe, joint swelling, redness or warmth, pain in the mouth or jaw, usually due to delayed healing and infection, often following tooth extraction, unusual fractures of the thigh bone or hip, thigh pain, vague

discomfort, or weakness

• temporary flu-like symptoms (muscle/joint pain, generally feeling unwell and in rare cases fever) usually at the start of treatment

• symptoms of low blood calcium levels including muscle cramps or spasms and/or tingling sensation in the fingers or around the mouth

• temporary decreases of phosphate levels in your blood which may be detected in a blood test

• ear pain, discharge from the ear, and/or an ear infection. These could be signs of bone damage in the ear

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

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on the SAHPRA website.

By reporting side effects, you can help provide more information on the safety of **ALENDRONATE UNICORN 70.**

Side effects must also be reported to Unicorn Pharmaceuticals (Pty) Ltd to vigilance@unicornpharma.co.za.

5. How to store ALENDRONATE UNICORN 70

Store at or below 25 □C.

Protect from light and moisture.

Keep blisters in outer carton until required for use.

STORE ALL MEDICINES OUT OF REACH OF

CHILDREN.

Do not use after the expiry date stated on the

carton. 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 ALENDRONATE

UNICORN 70 contains

The active substance is alendronate monosodium trihydrate.

Each **ALENDRONATE UNICORN 70** tablet contains 70 mg alendronate monosodium trihydrate. The other ingredients are cellulose microcrystalline, crospovidone, magnesium stearate.

ALENDRONATE UNICORN 70 is sugar free.

What ALENDRONATE UNICORN 70 looks like and contents of the pack

ALENDRONATE UNICORN 70 tablets are white oval, smooth, flat and marked in one face with "70".

ALENDRONATE UNICORN 70 tablets are packed in an aluminium and PVC/PVDC or polyamide, aluminium, PVC blister pack containing 4 tablets in an outer carton.

Holder of Certificate of Registration

Unicorn Pharmaceuticals (Pty) Ltd

4th Floor Offices, Block A, The District Building

41 Sir Lowry Road

Woodstock, Cape Town, 7925

Republic of South Africa

enquiries@unicornpharma.co.za

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