**PROPOSED PATIENT INFORMATION LEAFLET**

## SCHEDULING STATUS

S3

**ACTAMAX 35 mg** film coated tablet

Risedronate sodium

**ACTAMAX 35 mg** contains sugar (lactose monohydrate 2 mg per tablet).

## Read all of this leaflet carefully before you start taking ACTAMAX 35 mg

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- ACTAMAX 35 mg 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 ACTAMAX 35 mg is and what it is used for

ACTAMAX 35 mg belongs to a group of medicines called bisphosphonates which are used to treat osteoporosis.

ACTAMAX 35 mg is prescribed by medical practitioners to treat osteoporosis (thinning of the bone) in woman after menopause, in combination with calcium 500 – 1 000 mg per day. Your doctor will advise you, if in addition, you require vitamin D supplementation.

ACTAMAX 35 mg is also used for the treatment of primary osteoporosis in men.

## 2. What you need to know before you take ACTAMAX 35 mg

**Do not take ACTAMAX 35 mg:**

- if you are hypersensitive (allergic) to risedronate, or to any of the ingredients of ACTAMAX 35 mg (see section 6)
- if you have been diagnosed with a condition called hypocalcaemia (deficiency of calcium in the blood)
- if you are suffering from severe kidney disease
- if you are pregnant or breastfeeding your baby (see Pregnancy and breastfeeding).

**Warnings and precautions**

**Take special care with ACTAMAX 35 mg:**

- ACTAMAX 35 mg will be prescribed to you if you have osteoporosis with low bone mineral density and/or a fracture
- if you are a very elderly patient (over the age of 80)
- if you have or have previously had problems with your throat, for instance you may have or have had pain or difficulty in swallowing food
- if you have a history of stomach ulcers or indigestion
- immediately stop taking ACTAMAX 35 mg tablets if you develop symptoms of oesophageal disease (such as difficulty or pain upon swallowing, retrosternal pain (pain behind the breastbone) or new or worsening heartburn) and consult your doctor
- if you have abnormal bone and mineral metabolism (for example lack of vitamin D, parathyroid hormone abnormalities, both leading to a low blood calcium level) as you may need to take additional calcium and vitamin D during treatment with ACTAMAX 35 mg
- if you are unable to stay in an upright position (sitting or standing) for at least 30 minutes
- if you had problems in the past with your oesophagus including pain or difficulty in swallowing food or you have previously been told that you have Barrett's oesophagus (a condition associated with changes in the cells that line the lower oesophagus)

- pay careful attention to the dosing instructions in HOW TO TAKE ACTAMAX 35 mg below. Tell your doctor if you develop difficulty or pain on swallowing, new or worsening heartburn while taking ACTAMAX 35 mg
- if you take any food, drinks or medicines containing calcium, magnesium, iron and aluminium (such as antacids for heartburn, nutritional supplements) as these may interfere with how ACTAMAX 35 mg works. These products should not be taken at the same time as ACTAMAX 35 mg (see Other medicines and ACTAMAX 35 mg)
- ACTAMAX 35 mg should be taken first thing in the morning at least 30 minutes before any food, drink or any other medicine other than water. Failing this, ACTAMAX 35 mg should be taken two hours either before or after intake of any medicine, food or liquid
- If you have abnormal bone and mineral metabolism. Your doctor will treat this condition first before starting treatment with ACTAMAX 35 mg. Your doctor may prescribe calcium and vitamin D as supplements.
- If you have severe problems with your kidneys (see Do not take ACTAMAX 35 mg)
- ACTAMAX 35 mg may cause jaw-bone problems in some people. Jaw-bone problems may include infection, and delayed healing after teeth are pulled out or other work that involves drilling into the jaw. If you develop a toothache, jaw pain, painful exposed bone or swelling, especially following dental work, tell your doctor or dentist immediately

- if you have had or have pain, swelling or numbness of the jaw or a “heavy jaw feeling” or loosening of a tooth as your dentist will need to correct any of these problems before you start treatment with ACTAMAX 35 mg
- if you are under dental treatment or need to undergo dental surgery, tell your dentist that you are being treated with ACTAMAX 35 mg. Invasive dental procedures should be avoided where possible
- if you are being treated for chronic ear conditions or have an ear injury
- unusual fracture of the thigh bone may occur particularly if you are on long-term treatment for osteoporosis. Contact your doctor if you experience pain, weakness or discomfort in your thigh, hip or groin as this may be an early indication of a possible fracture of the thigh bone.

Your doctor may request tests to monitor your condition before and/or during treatment.

**Other medicines and ACTAMAX 35 mg**

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

Medicines containing calcium, magnesium, iron and aluminium, including antacids, mineral supplements and certain laxatives may interfere with the absorption of ACTAMAX 35 mg and should not be taken at the same time (see Take special care with ACTAMAX 35 mg).

**ACTAMAX 35 mg with food and drink**

ACTAMAX 35 mg tablets must always be taken at least 30 minutes before the first food, drink or any other medicine of the day, other than water. If this is not possible, ACTAMAX 35 mg should be taken at least two hours before or after the intake of food or drink during the course of the day.

**Pregnancy and breastfeeding**

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking ACTAMAX 35 mg.

DO NOT take ACTAMAX 35 mg if you are pregnant, suspect you are pregnant or you are planning to become pregnant (see Do not take ACTAMAX 35 mg).
DO NOT take ACTAMAX 35 g if you are breastfeeding your baby (see Do not take ACTAMAX 35 mg).

**Driving and using machines**

ACTAMAX 35 mg should not have any effect on your ability to drive and use machinery. It is not always possible to predict to what extent ACTAMAX 35 mg may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which ACTAMAX 35 mg affects them.

**ACTAMAX 35 mg contains lactose**

ACTAMAX 35 mg contains lactose. Patients with the rare hereditary conditions of lactose or galactose intolerance should not take ACTAMAX 35 mg.

ACTAMAX 35 mg contains lactose which may have an effect on the control of your blood sugar if you have diabetes mellitus.

## 3. How to take ACTAMAX 35 mg

Do not share medicines prescribed for you with any other person. Always use ACTAMAX 35 mg exactly as your doctor has instructed. You should check with your doctor or pharmacist if you are unsure.

The dosage and dosage interval will be determined by your condition.

ACTAMAX 35 mg:

The usual dose is one tablet once a week on the same day of the week.

ACTAMAX 35 mg must always be taken at least 30 minutes before the first food, liquid or any other medicine of the day other than water, at least two hours before or after food or liquid at any other time of the day and at least 30 minutes before going to bed.

ACTAMAX 35 mg should not be taken at bedtime or before getting up in the morning.

The tablets must be swallowed whole and not sucked or chewed. Food, beverages and medicines containing calcium, magnesium, iron and aluminium may interfere with the absorption of ACTAMAX 35 mg and should not be taken at the same time.

You should take ACTAMAX 35 mg while in an upright position with a glass of plain water (≥ 120 ml) to aid delivery to the stomach. You should not lie down for 30 minutes after taking the tablet (see Take special care with ACTAMAX 35 mg).

Take ACTAMAX 35 mg preferably on arising in the morning.

Your doctor will tell you how long your treatment with ACTAMAX 35 mg will last. Do not stop treatment early because may begin to lose bone mass.

If you have the impression that the effect of ACTAMAX 35 mg is too strong or too weak, tell your doctor or pharmacist.

**If you take more ACTAMAX 35 mg 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.

**If you forget to take ACTAMAX 35 mg**

If a dose is missed, one ACTAMAX 35 mg tablet should be taken on the day that the tablet is remembered.

Patients should then return to taking one tablet once a week on the day the tablet is normally taken.

Do not take a double dose to make up for forgotten individual doses.

**If you stop taking ACTAMAX 35 mg**

It is important that you continue the course of treatment. Do not stop taking ACTAMAX 35 mg unless your doctor tells you to do so.

## 4. Possible side effects

ACTAMAX 35 mg can have side effects.

Not all side effects reported for ACTAMAX 35 mg are included in this leaflet. Should your general health worsen, or if you experience any untoward effects while using ACTAMAX 35 mg, please consult your healthcare provider for advice.

If any of the following happens, stop using ACTAMAX 35 mg 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

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to ACTAMAX 35 mg. 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:

- bruising easily (thrombocytopenia)

- weakness, fatigue, weight loss, headache (symptoms of a condition called vasculitis)
- Stevens-Johnson syndrome (a life threatening skin disorder with symptoms such as a red-purplish rash and blisters)
- severe bone, joint or muscle pain
- thigh or groin pain (which may be a side effect of a bone fracture)
- swelling in any part of the body.

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

Tell your doctor if you notice any of the following:

Frequent side effects:

- headache
- dry eyes, eye pain and inflammation, conjunctivitis (pink eye)
- indigestion, nausea, vomiting, abdominal pain, diarrhoea, constipation, abdominal pain, gastritis
- abnormal liver function test results
- pain in your bones, muscles or joints
- pain.

Less frequent side effects:

- anaemia, abnormal blood test results
- swelling or irritation of the eye, blurred vision, abnormal vision, vision disturbances

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- inflammation (swelling), narrowing or ulcer of the oesophagus (tube that goes to the stomach with symptoms such as difficulty or pain when swallowing), swelling of the tongue
- pain, swelling, redness, or other signs of infection in the gums or sockets that don't heal after dental work
- skin rashes or other skin conditions, such as flushing, hives, itching, dry skin, and hair-loss to serious skin conditions causing blisters and peeling, tissue damage
- thigh bone fractures
- osteonecrosis (bone death because of poor blood supply) in the jaw and ear canal
- fever, chills, fatigue, general feeling of discomfort or being unwell
- cancer of the oesophagus (the tube that takes food from the mouth to the stomach).

The following side effects have been reported but the frequency for them to occur is not known:

- increase in some white blood cells (eosinophilia), lack of white blood cells, resulting in frequent infections such as fever, severe chills, sore throat or mouth ulcers (neutropenia)
- difficulty in sleeping (insomnia), sleepiness (somnolence)
- flatulence (excessive gas in the stomach or bowel), bleeding from the stomach wall, burping, painful swallowing

- serious liver disorders
- excessive sweating
- decreased libido
- acute mountain sickness with symptoms of headache, nausea, and fatigue
- decreased blood calcium and phosphate levels.

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. This includes any possible side effects not listed in this leaflet. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of ACTAMAX 35 mg.

## 5. How to store ACTAMAX 35 mg

Store all medicines out of reach of children.

Store at or below 25 °C

Do not remove from the outer carton until required for use.

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 ACTAMAX 35 mg contains

Each film coated tablet contains risedronate sodium hemipentahydrate equivalent to 35 mg risedronate sodium.

### The other ingredients are

***Tablet cores***

Crospovidone, magnesium stearate, microcrystalline cellulose, pregelatinised starch.

***Film coating (Opadry white)***

Hypromellose, lactose monohydrate, macrogol/PEG 4000, titanium dioxide.

### What ACTAMAX 35 mg looks like and contents of the pack

White, round, biconvex film coated tablets, embossed with “35” on one side, 11,2 ± 0,1 mm in diameter and 5,0 mm ± 0,2 mm in thickness.

Tablets are packed in white opaque PVC/PE/PVDC and silver aluminium blister strips of 1 x 4 tablets each inside a printed outer carton.

### Holder of Certificate of Registration

**PROPOSED PATIENT INFORMATION LEAFLET**

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