FINAL PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S3

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

BONTELVIA 35 mg (film-coated tablet)

Read all of this leaflet carefully before you start taking **BONTELVIA 35 mg.**

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- **BONTELVIA 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 BONTELVIA 35 mg CONTAIN

The active substance is risedronate sodium.

Each film-coated tablet contains 35 mg of risedronate sodium. Contains lactose.

The other ingredients are: microcrystalline cellulose, crospovidone and magnesium stearate.

The coating ingredients contain: hypermellose, hydroxy propyl cellulose, polyethylene glycol, colloidal silicon dioxide, titanium dioxide (C.I. No: 77891), iron oxide yellow (C.I. No: 77492) and iron oxide red (C.I. No: 77491).

WHAT BONTELVIA 35 mg ARE USED FOR

BONTELVIA 35 mg belongs to a group of non-hormonal medicines called biphosphonates which are used to treat bone disease. It works directly on your bones to make them stronger and therefore less likely to break. **BONTELVIA 35 mg** is used in the treatment of osteoporosis in postmenopausal women to reduce the risk of spinal and hip fractures as well as osteoporosis in men.

BEFORE YOU TAKE BONTELVIA 35 mg

Do not take BONTELVIA 35 mg:

- If you are hypersensitive (allergic) to risedronate sodium, or any of the other ingredients of **BONTELVIA 35 mg**.
- If you have a condition called hypocalcaemia (a low blood calcium level).
- If you have kidney problems.
- If you are pregnant or breastfeeding your baby.

Take special care with BONTELVIA 35 mg:

- **BONTELVIA 35 mg** will be prescribed to you if you have osteoporosis with low bone mineral density and/or a fracture.
- If you are elderly (> 80 years).
- **BONTELVIA 35 mg** may cause irritation or ulceration of the food pipe (oesophagus). Inform your doctor:
    - 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 BONTELVIA 35 mg** below. Tell your doctor if you develop difficulty or pain on swallowing, new or worsening heartburn while taking **BONTELVIA 35 mg**.
- If you have abnormal bone and mineral metabolism. Your doctor will treat this condition first before starting treatment with **BONTELVIA 35 mg**. Your doctor may prescribe calcium and vitamin D as supplements.
- If you have had or have pain, swelling or numbness of the lower jaw or loosening of a tooth.

- If you are under dental treatment or will undergo dental surgery, tell your dentist that you are being treated with **BONTELVIA 35 mg**. Invasive dental procedures should be avoided where possible.
- **BONTELVIA 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.
- Speak to your doctor and dentist about good oral hygiene and regular dental check-ups while you are using **BONTELVIA 35 mg**.
- Tell your doctor if you have ear pain, discharge from the ear, and/or an ear infection. These could be signs of bone damage in the ear.
- 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 will advise you on what to do when taking **BONTELVIA 35 mg** if you have any of the above.

Taking BONTELVIA 35 mg with food and drink:

It is very important that you do NOT take **BONTELVIA 35 mg** with food or drinks (other than plain water) so that it can work properly. In particular do not take **BONTELVIA 35 mg** at the same time as dairy products (such as milk) as they contain calcium (see “Taking other medicines”).Take food and drinks (other than plain water) at least 30 minutes after **BONTELVIA 35 mg**.

Pregnancy and breastfeeding:

- You must not take **BONTELVIA 35 mg** during pregnancy.
- Do not breastfeed during treatment with **BONTELVIA 35 mg**.

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

Driving and the use of machinery:

BONTELVIA 35 mg is not known to affect your ability to drive and use machines.

Important information about some of the ingredients of BONTELVIA 35 mg:

BONTELVIA 35 mg contains lactose. Patients with the rare hereditary conditions of lactose/fructose or galactose intolerance should not take **BONTELVIA 35 mg**.

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

Taking other medicines with BONTELVIA 35 mg:

Always tell your healthcare professional if you are taking any other medicine.

(This includes complementary or traditional medicines.)

Medicines containing one of the following lessen the effect of **BONTELVIA 35 mg** if taken at the same time:

- calcium
- magnesium
- aluminium
- iron.

Take these medicines at least 30 minutes after taking **BONTELVIA 35 mg.**

HOW TO TAKE BONTELVIA 35 mg

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

Always take BONTELVIA 35 mg exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure. If you have the impression that the effect of BONTELVIA 35 mg is too strong or too weak, talk to your doctor or

pharmacist.

Take ONE **BONTELVIA 35 mg** once a week.

Choose one day of the week that best fits your schedule. Every week, take **BONTELVIA 35 mg** on your chosen day.

Take **BONTELVIA 35 mg** at least 30 minutes before the first food, drink (other than plain water) or other medicine of the day.

Take the tablet whilst you are in an upright position (you may sit or stand) to avoid heartburn. Swallow it with at least one glass (120 ml) of plain water. Swallow it whole. Do not suck or chew it.

Do not lie down for 30 minutes after taking your tablet.

Your doctor will tell you if you need calcium and vitamin supplements, if you are not taking enough from your diet.

If you take more BONTELVIA 35 mg than you should:

Seek emergency medical attention if you think you have used too much of **BONTELVIA 35 mg**.

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 BONTELVIA 35 mg:

If you have forgotten to take your tablet on your chosen day, take it on the day you remember. Return to taking one tablet once a week on the day the tablet is normally taken. Do NOT take two tablets in one day to make up for the tablet you missed.

Effects when treatment with BONTELVIA 35 mg is stopped:

Your doctor will tell you how long your treatment with **BONTELVIA 35 mg** will last. Do not stop treatment early because if you stop treatment you may begin to lose bone mass. Please talk to your doctor before you consider stopping treatment.

POSSIBLE SIDE EFFECTS

BONTELVIA 35 mg can have side effects.

Not all side effects reported for **BONTELVIA 35 mg** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking **BONTELVIA 35 mg**, please consult your doctor, pharmacist or other healthcare professional for advice.

Stop taking BONTELVIA 35 mg and contact a doctor immediately if you experience any of the following:

- Symptoms of a severe allergic reaction such as:

  – Swelling of face, tongue or throat

  – Difficulties in swallowing

  – Hives and difficulties in breathing.
- Severe skin reactions that can include blistering of the skin.

Tell your doctor promptly if you experience the following side effects:

- Eye inflammation, usually with pain, redness and light sensitivity.
- Problems with your jaw or teeth, associated with delayed healing and/or infection following a tooth extraction or after invasive dental work.
- Symptoms from oesophagus such as pain when you swallow, difficulties in swallowing, chest pain or new or worsened heartburn.
- Unusual fracture of the thigh bone 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.
- Ear pain, discharge from the ear, and/or an ear infection. These could be signs of bone damage in the ear.

Frequent side effects:

- Indigestion, feeling sick, stomach ache, stomach cramps or discomfort, constipation, feelings of fullness, bloating, diarrhoea.
- Pain in your bones, muscles or joints.

- Headache.

Less frequent side effects:

- Inflammation or ulcer of the oesophagus causing difficulty and pain in swallowing, inflammation of the stomach and duodenum (bowel draining the stomach), stomach pain, inflammation of the tongue (red swollen, possibly painful), narrowing of the oesophagus.
- Inflammation of the coloured part of the eye (iris) (red painful eyes with a possible change in vision).

Frequency not known:

- Flatulence (excessive gas in the stomach or bowel), bleeding from the stomach wall, burping, painful swallowing.
- Abnormal liver tests have been reported. These can only be diagnosed from a blood test.
- Hair loss.
- Increased sweating.
- Skin rash or redness of the skin, sometimes made worse by sunlight.
- 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).
- Decreased libido.
- Difficulty in sleeping.
- Sleepiness.
- Liver disorders.
- Acute mountain sickness with symptoms of headache, nausea, and fatigue.
- Fever.
- Fatigue.
- A patient’s blood calcium and phosphate levels may fall.

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

STORING AND DISPOSING OF BONTELVIA 35 mg

Store at or below 25 °C (room temperature). Protect from light. Keep the blisters in the carton until required for use.

Keep HDPE containers well closed.

KEEP ALL MEDICINES OUT OF REACH OF CHILDREN.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

PRESENTATION OF BONTELVIA 35 mg

1) Blister Pack:

Tablets are packed in Triplex 250/25/90 clear PVC/PE/PVdC as the forming material and 25 μ aluminium foil with 6-8 gsm heat seal lacquer as the lidding material. Each blister contains 4 tablets packed in a pre-printed unit carton.

Pack size: 4's – Each carton contains 1 blister of 4 tablets each.

2) HDPE Container Pack:

Tablets are packed in white, round 40 ml HDPE container with 33 mm neck finish closed with 33 mm white closure with wad having induction sealing liner. Each container contains 30 tablets packed in a pre-printed unit carton.

Pack size: 30's - One HDPE container contains 30 tablets.

IDENTIFICATION OF BONTELVIA 35 mg

Orange colour, circular, biconvex, film coated tablet debossed with "CL 92" on one side and plain on other side.

REGISTRATION NUMBER/REFERENCE NUMBER

46/3.2/0904

NAME AND ADDRESS OF REGISTRATION HOLDER

Macleods Pharmaceuticals SA (Pty) Ltd

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