Front Side

420 mm

335 mm

SCHEDULING STATUS: S3

PROPRIETARY NAME AND DOSAGE FORM:

BONTELVIA 35 mg (film-coated tablet)

COMPOSITION:
Each film-coated tablet contains risedronate sodium 35 mg. Contains lactose.
Excipients: crospovidone, magnesium stearate and microcrystalline cellulose.
The coating ingredients contain: colloidal silicon dioxide, hydroxy propyl cellulose, hypermellose, iron oxide red (C.I. No: 77491), iron oxide yellow (C.I. No: 77492), polyethylene glycol and titanium dioxide (C.I. No: 77891).

PHARMACOLOGICAL CLASSIFICATION:

A.3.2 Connective Tissue medicines, Non-hormonal preparations.

PHARMACOLOGICAL ACTION:

Pharmacodynamic properties:
Risedronate sodium is a pyridinyl bisphosphonate that binds to bone hydroxyapatite and inhibits osteoclast-mediated bone resorption, while bone formation is preserved. In preclinical studies risedronate sodium demonstrated potent anti-osteolytic and antiresorptive activity, dose dependently. The activity of risedronate sodium was confirmed by bone marker measurements.

Pharmacokinetic properties:
Absorption: Absorption after an oral dose is relatively rapid (t_{max} ~ 1 hour) and occurs through out the upper gastrointestinal tract. Absorption is independent of dose over the range studied (single dose study, 2.5 to 30 mg; multiple dose studies, 2.5 to 5 mg daily and up to 50 mg dosed weekly). Mean oral bioavailability of the tablet is 0.63 % and is decreased significantly when risedronate sodium is administered with food.

Distribution:
Preclinical studies in rats and dogs dosed intravenously with single doses of ^{14}C-risedronate sodium indicate that approximately 60 % of the dose is distributed to bone. The remainder of the dose is excreted in the urine. The mean steady state volume of distribution is 6,3 l/kg in humans. Human plasma protein binding is about 24 %.

Metabolism: There is no evidence of systemic metabolism of risedronate sodium.

Elimination:
Approximately half of the absorbed dose is excreted in urine within 24 hours, and 85 % of an intravenous dose is recovered in the urine over 28 days. Mean renal clearance is 105 ml/min and mean total clearance is 122 ml/min, with the difference primarily reflecting non-renal clearance or clearance due to adsorption to bone. The renal clearance is not concentration dependent, and there is a linear relationship between renal clearance and creatinine clearance.
Unabsorbed risedronate sodium is eliminated unchanged in faeces. Once risedronate sodium is absorbed, the serum concentration-time profile is multiphasic with an initial half life of about 1,5 hours and a terminal exponential half-life of 480 hours.

Special populations:
Elderly and patients with renal impairment (See dosage and directions for use).

INDICATIONS:

Treatment of osteoporosis in postmenopausal women in combination with calcium 500 to 1000 mg per day. Additional administration of vitamin D should be considered when deficiency might be expected.
Treatment of primary osteoporosis in males.

CONTRA – INDICATIONS:

Known hypersensitivity to risedronate and any other ingredients of **BONTELVIA 35 mg.**
Hypocalcaemia (see WARNINGS AND SPECIAL PRECAUTIONS).
Advanced renal impairment: creatinine clearance < 30 ml/min.
Pregnancy and lactation.

WARNINGS AND SPECIAL PRECAUTIONS:

Efficacy of bisphosphonates including **BONTELVIA 35 mg** in the treatment of osteoporosis is related to the presence of low bone mineral density and/or prevalent fracture.

High age or clinical risk factors for fracture alone are not sufficient reasons to initiate treatment of osteoporosis with a bisphosphonate such as **BONTELVIA 35 mg.**

The evidence to support efficacy of bisphosphonates including **BONTELVIA 35 mg** in the very elderly (>80 years) is limited.

Bisphosphonates, including **BONTELVIA 35 mg**, have been associated with oesophagitis, gastritis, oesophageal ulcerations and gastroduodenal ulcerations. Thus, caution should be used:

- in patients who have a history of oesophageal disorders which delay oesophageal transit or emptying e.g. stricture or achalasia.
- in patients who are unable to stay in the upright position for at least 30 minutes after taking the tablet.
- if **BONTELVIA 35 mg** is given to patients with active or recent oesophageal or upper gastrointestinal problems (including known Barrett's oesophagus).

Medical practitioners should emphasise to patients the importance of paying attention to the dosing instructions and be alert to any signs and symptoms of possible oesophageal reaction. The patients should be instructed to seek timely medical attention if they develop symptoms of oesophageal irritation such as dysphagia, pain on swallowing, retrosternal pain or new/worsened heartburn.

In order to facilitate delivery to the stomach and minimise the possibility of gastrointestinal adverse effects, patients should take **BONTELVIA 35 mg** while in an upright position (sitting or standing) with a full glass of plain water and should avoid lying down for 30 minutes after taking **BONTELVIA 35 mg.**

Foods, drinks (other than plain water) and medicinal products containing polyvalent cations (such as calcium, magnesium, iron and aluminium) interfere with the absorption of **BONTELVIA 35 mg** and should not be taken at the same time. Therefore to achieve the benefits of **BONTELVIA 35 mg**, patients should take the tablet either at least 30 minutes before the first food, medicine or drink (other than plain water) of the day or at least 2 hours away from food or drink at any time of the day.

Hypocalcaemia and other disturbances of bone and mineral metabolism should be effectively treated before starting **BONTELVIA 35 mg.** Asymptomatic small decreases in serum calcium and phosphorus levels have been observed in some patients. Adequate intake of calcium and vitamin D is important. Patients should receive supplemental calcium and vitamin D if dietary intake is inadequate.

BONTELVIA 35 mg is contraindicated in patients with severe renal impairment (creatinine clearance less than 30 ml/min) (see CONTRA-INDICATIONS).

Osteonecrosis of the jaw, frequently associated with tooth extraction and/or local infection (including osteomyelitis) has been reported. Osteonecrosis of the jaw has also been reported in patients with osteoporosis receiving oral bisphosphonates such as **BONTELVIA 35 mg.**

A dental examination with appropriate preventive dentistry should be considered prior to treatment with **BONTELVIA 35 mg** in patients with concomitant risk factors (e.g. cancer, chemotherapy, radiotherapy, corticosteroids, poor oral hygiene).
While on treatment, these patients should avoid invasive dental procedures if possible. For patients who develop osteonecrosis of the jaw while on **BONTELVIA 35 mg** therapy, dental surgery may exacerbate the condition. For patients requiring dental procedures, there are no data available to suggest whether discontinuation of bisphosphonate (such as in **BONTELVIA 35 mg**) treatment reduces the risk of osteonecrosis of the jaw. Clinical judgment of the treating medical practitioner should guide the management plan of each patient based on individual benefit/risk assessment.

Osteonecrosis of the external auditory canal has been reported with bisphosphonates including **BONTELVIA 35 mg**, mainly in association with long-term therapy. Possible risk factors for osteonecrosis of the external auditory canal include steroid use and chemotherapy and/or local risk factors such as infection or trauma. The possibility of osteonecrosis of the external auditory canal should be considered in patients receiving **BONTELVIA 35 mg** who present with ear symptoms including chronic ear infections.

Atypical fractures of the femur:
Atypical subtrochanteric and diaphyseal femoral fractures have been reported with **BONTELVIA 35 mg**, primarily in patients receiving long-term treatment for osteoporosis. These transverse or short oblique fractures can occur anywhere along the femur from just below the lesser trochanter to just above the supracondylar flare. These fractures occur after minimal or no trauma and some patients experience thigh or groin pain, often associated with imaging features of stress fractures, weeks to months before presenting with a completed femoral fracture. Fractures are often bilateral; therefore the contralateral femur should be examined in **BONTELVIA 35 mg**-treated patients who have sustained a femoral shaft fracture. Poor healing of these fractures has also been reported. Discontinuation of **BONTELVIA 35 mg** therapy in patients suspected to have an atypical femur fracture should be considered pending evaluation of the patient, based on an individual benefit/risk assessment.
During **BONTELVIA 35 mg** treatment patients should be advised to report any thigh, hip or groin pain and any patient presenting with such symptoms should be evaluated for an incomplete femur fracture.

Effect on the ability to drive and use machines:
BONTELVIA 35 mg has no or negligible influence on the ability to drive and use machines.

Lactose warning:
BONTELVIA 35 mg contains lactose. Patients with the rare hereditary conditions of galactose intolerance e.g. galactosaemia, Lapp lactase deficiency, glucose-galactose malabsorption or fructose intolerance should not take **BONTELVIA 35 mg.**
BONTELVIA 35 mg contains lactose which may have an effect on the glycaemic control of patients with diabetes mellitus.

INTERACTIONS:

BONTELVIA 35 mg has been used with aspirin and NSAIDs.
BONTELVIA 35 mg may be used concomitantly with hormone replacement therapy.
Concomitant ingestion of medicines containing polyvalent cations (e.g. calcium, magnesium, iron and aluminium) will interfere with the absorption of **BONTELVIA 35 mg.**
BONTELVIA 35 mg is not systemically metabolised, does not induce cytochrome P450 enzymes and has low protein binding.

PREGNANCY AND LACTATION:

BONTELVIA 35 mg is contraindicated in pregnant and breastfeeding women (see CONTRA-INDICATIONS).

DOSAGE AND DIRECTIONS FOR USE:

The recommended dose is one 35 mg tablet orally once a week. The tablet should be taken on the same day each week. Foods, drinks (other than plain water) and medicinal products containing polyvalent cations (such as calcium, magnesium, iron and aluminium) may interfere with absorption of **BONTELVIA 35 mg** and should not be taken at same time. Therefore **BONTELVIA 35 mg** should be taken either at least 30 minutes before the first food, or other medicine or drink (other than plain water) of the day or at least 2 hours away from food or drink at any other time of the day and at least 30 minutes before going to bed.

Patients should be instructed that if a dose is missed, one **BONTELVIA 35 mg** 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. Two tablets should not be taken on the same day.

The tablet must be swallowed whole and not sucked or chewed. Patients should take **BONTELVIA 35 mg** while in an upright (standing or sitting) position with a glass of plain water (≥ 120 ml) to aid delivery to the stomach. Patients should not lie down for 30 minutes after taking the tablet (see Warnings and Special Precautions).

Elderly:
No dosage adjustment is necessary since bioavailability, and disposition were similar in elderly (>60 years of age) compared to younger patients.

Renal impairment:
No dosage adjustment is necessary in patients with creatinine clearance ≥ 30 ml/min. There is no clinical data in patients with severe renal impairment. (Creatinine clearance less than 30 ml/min) (see CONTRA-INDICATIONS).

Children:
Safety and efficacy of **BONTELVIA 35 mg** have not been established in children and growing adolescents.

SIDE EFFECTS

Immune system disorders:
Frequency not known: anaphylactic reaction, hypersensitivity and skin reactions including angioedema.
Eye disorders:
Less frequent: iritis.
Frequency not known: uveitis.
Gastrointestinal disorders:
Frequent: dyspepsia, nausea, constipation, diarrhoea, gastrointestinal disorders.
Less frequent: oesophagitis, oesophageal ulcer, gastritis, dysphagia, duodenitis, oesophageal stricture, abdominal pain, glossitis.
Frequency not known: flatulence, gastric haemorrhage, eructation, odynophagia.
Psychiatric disorders:
Frequency not known: insomnia, somnolence.
Nervous system disorders:
Frequent: headache.
Hepato-biliary disorders:
Less frequent: abnormal liver function tests.
Frequency not known: serious hepatic disorders.
Musculoskeletal and connective tissues disorders:
Frequent: musculoskeletal pain, arthralgia, bone pain.
Less frequent: osteonecrosis of the external auditory canal.
Frequency not known: osteonecrosis of the jaw, atypical subtrochanteric and diaphyseal femoral fractures.
Skin and subcutaneous disorders:
Frequency not known: generalised rash and bullous skin reactions, some severe including Stevens-Johnson syndrome toxic epidermal necrolysis, hyperhidrosis, hair loss, leukocytoclastic vasculitis.
Blood and lymphatic system disorders:
Frequency not known: eosinophilia, neutropenia.
Reproductive system and breast disorders:
Frequency not known: decreased libido.
General disorders:
Frequent: pain.
Frequency not known: fatigue, acute mountain sickness, pyrexia.
Investigations:
Frequency not known: Decreases in serum calcium and phosphate levels.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:

Decreases in serum calcium following overdose may be expected in some patients. Signs and symptoms of hypocalcaemia may all re occur in some of these patients.
Milk or antacids containing magnesium, calcium or aluminium should be given to bind risedronate and reduce absorption of **BONTELVIA 35 mg.**

IDENTIFICATION:

Orange colour, circular, biconvex, film-coated tablet debossed with "CL92" on one side and plain on other side.

PRESENTATION:

BONTELVIA 35 mg
1) Blister Pack:
Tablets are packed in Triplex 250/25/50 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.

STORAGE INSTRUCTIONS:

Store at or below 25 °C. Protect from light.
Keep the blisters in the carton until required for use.
Keep HDPE containers well closed.

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER:
46/3.2/0904

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:
Macleods Pharmaceuticals SA (Pty) Ltd
Ground Floor, Block 1, Bessonia Estate Office Park (East)
1 Cessonia Drive, Bassonia Rock, Ext 12, Alberton, Gauteng

DATE OF PUBLICATION OF THIS PACKAGE INSERT:
13 December 2019

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 bisphosphonates which are used to treat bone diseases. 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 (> 50 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 sitting 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.**

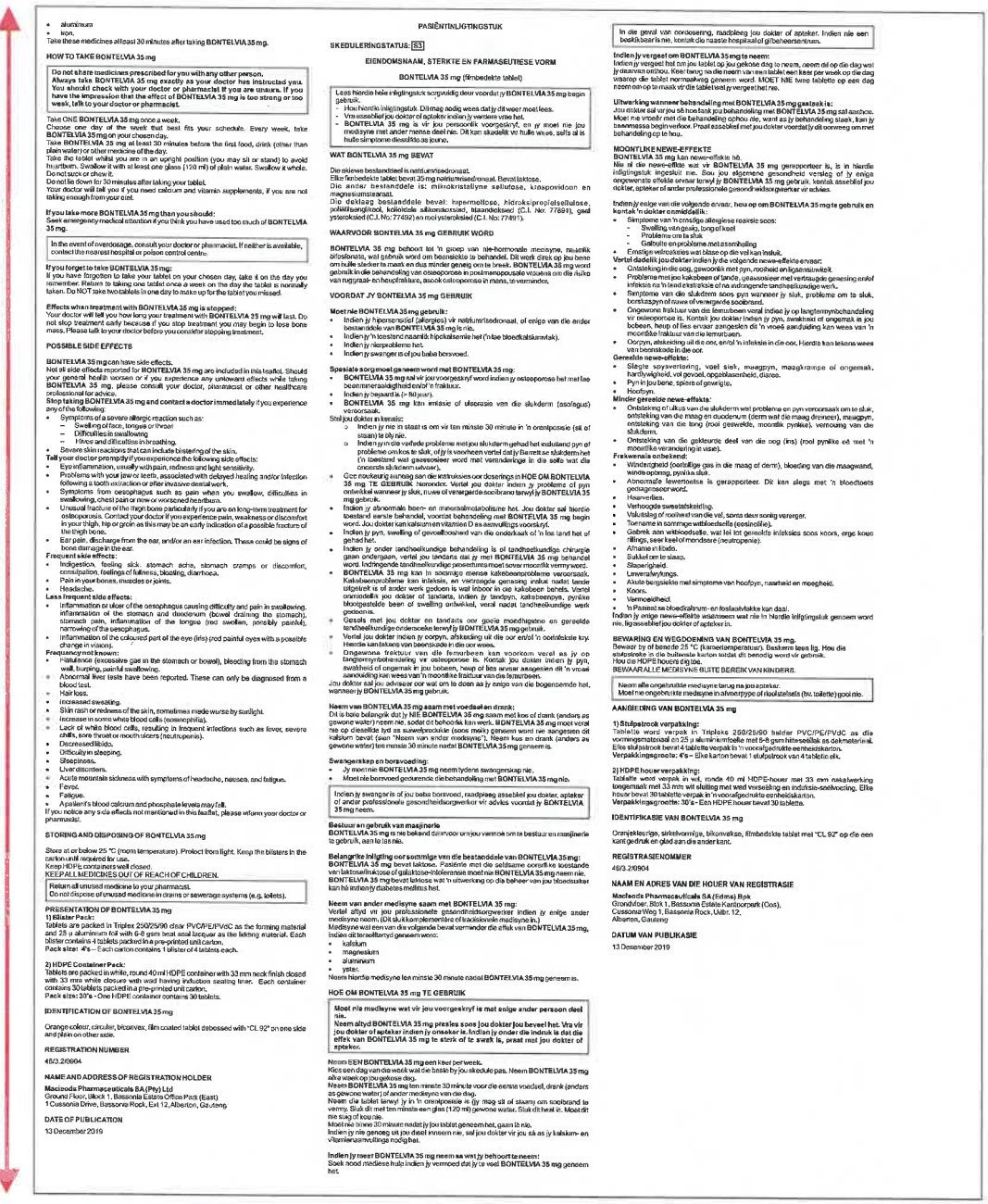
Driving and the use of machinery:
BONTELVIA 35 mg is not known to affect your ability to drive and use machines.

Important information about some of the ingredients of BONTELVIA 35 mg:
BONTELVIA 35 mg contains lactose. Patients with the rare hereditary conditions of lactose intolerance 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

BONTELVIA 35 mg (film-coated tablet)
PM03841301

Back Side



- 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 unknown 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 u 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

46/3.2/0694

NAME AND ADDRESS OF REGISTRATION HOLDER

Macleods Pharmaceuticals SA (Pty) Ltd
Ground Floor, Block 1, Bassonia Estate Office Park (East)
1 Cussonia Drive, Bassonia Rock, Ext 12, Alberton, Gauteng

DATE OF PUBLICATION

13 December 2019

PASIËNTINLIGTINGSTUK

SKEDULERINGSTATUS: S3

EIENDOMSNAAM, STERKTE EN FARMASEUTIESE VORM

BONTELVIA 35 mg (filmbedekte tablet)

Lees hierdie hele inligtingstuk sorgvuldig deur voordat jy **BONTELVIA 35 mg** begin gebruik.
- Hou hierdie inligtingstuk. Dit mag nodig wees dat jy dit weer moet lees.
- Vra asseblief jou dokter of apteker indien jy verdere vrae het.
- **BONTELVIA 35 mg** is vir jou persoonlik voorgeskryf, en jy moet nie jou medisyne met ander mense deel nie. Dit kan skadelik vir hulle wees, selfs al is hulle simptome dieselfde as joune.

WAT BONTELVIA 35 mg BEVAT

Die aktiewe bestanddeel is natriumrisedronaat.
Elke filmbedekte tablet bevat 35 mg natriumrisedronaat. Bevat laktose.
Die ander bestanddele is: mikrokristalliyne sellulose, krospovidoon en magnesiumstearaat.
Die deklaag bestanddele bevat: hipromellose, hidroksipropielsellulose, polielilenglikol, kolloïdale silikonsdioksied, titaandioksied (C.I. No: 77891), geel ysteroksied (C.I. No: 77492) en rooi ysteroksied (C.I. No: 77491).

WAARVOOR BONTELVIA 35 mg GEBRUIK WORD

BONTELVIA 35 mg behoort tot 'n groep van nie-hormonale medisyne, naamlik bifosfonate, wat gebruik word om beensiekte te behandel. Dit werk direk op jou bene om hulle sterker te maak en dus minder geneig om te breek. **BONTELVIA 35 mg** word gebruik in die behandeling van osteoporose in postmenopousale vrouens om die risiko van ruggraat- en heupfrakture, asook osteoporose in mans, te verminder.

VOORDAT JY BONTELVIA 35 mg GEBRUIK

Moet nie BONTELVIA 35 mg gebruik:
- Indien jy hipersensitief (allergies) vir natriumrisedronaat, of enige van die ander bestanddele van **BONTELVIA 35 mg** is nie.
- Indien jy 'n toestand naamlik hipokalsemie het (n lae bloedkalsiumvlak).
- Indien jy nierprobleme het.
- Indien jy swanger is of jou baba borsvoed.

Spesiale sorgmoet ge neem word met BONTELVIA 35 mg:
- **BONTELVIA 35 mg** sal vir jou voorgeskryf word indien jy osteoporose het met lae beenmineraaldigtheid en/of 'n fraktuur.
- Indien jy hepatiet B (~ 5d jaar).
- **BONTELVIA 35 mg** kan irritasie of uitsaksie van die slukderm (esofagus) veroorsaak.

Stel jou dokter in kennis:
- Indien jy nie in staat is om vir ten minste 30 minute in 'n omnipossie (sit of staan) te bly nie.
- Indien jy nie die verlede probleme met jou slukderm gehad het insluitend pyn of probleme om kos te sluk, of jy is voorheen vertel dat jy Barrett se slukderm het (n toestand wat geassosieer word met veranderinge in die selle wat die onderste slukderm uitvoer).

Gee raadpleeg asseblief aan die instruksies oor doserings in **HOE OM BONTELVIA 35 mg TE GEBRUIK** hieronder. Vertel jou dokter indien jy probleme of pyn ontwikkel wanneer jy sluk, nuwe of verergerde sooibrand terwyl jy **BONTELVIA 35 mg** gebruik.
- Indien jy abnormale been- en mineraalmetabolisme het. Jou dokter sal hierdie toestand eerste behandel, voordat behandeling met **BONTELVIA 35 mg** begin word. Jou dokter kan kalsium en vitamien D as aanvullings voorskryf.
- Indien jy pyn, swelling of gevoelloosheid van die onderkaak of 'n los tand het of gehad het.
- Indien jy onder tandheelkundige behandeling is of tandheelkundige chirurgie gaan ondergaan, vertel jou tandarts dat jy met **BONTELVIA 35 mg** behandel word. Indringende tandheelkundige prosedures moet sover moontlik vermy word.
- **BONTELVIA 35 mg** kan in seldsame gevalle kaakbeenprobleme veroorsaak. Kaakbeenprobleme kan infeksie, en vertraagde genesing insluit nadat tande uitgetrek is of ander werk gedoen is wat lesers in die kakebeen behels. Vertel onmiddellik jou dokter of tandarts, indien jy tandpyn, kakebeenpyn, pynlike bloedgestelde been of swelling ontwikkel, veral nadat tandheelkundige werk gedoen is.
- Gesels met jou dokter en tandarts oor goeie mondhygiene en gereelde tandheelkundige ondersoeke terwyl jy **BONTELVIA 35 mg** gebruik.
- Vertel jou dokter indien jy corpyn, afsteking uit die oor en/of 'n oorinfeksie kry. Hierdie kan tekens van beensiekte in die oor wees.
- Ongewone fraktuur van die femurbeen kan voorkom veral as jy op langtermyn-behandeling vir osteoporose is. Kontak jou dokter indien jy pyn, swakheid of ongemak in jou been, heup of lies ervaar aangesien dit 'n vroeë aanduiding kan wees van 'n moontlike fraktuur van die femurbeen.

Jou dokter sal jou adviseer oor wat om te doen as jy enige van die bogenoemde het, wanneer jy **BONTELVIA 35 mg** gebruik.

Neem van BONTELVIA 35 mg saam met voedsel en drank:
Dit is baie belangrik dat jy **NIE BONTELVIA 35 mg** saam met kos of drank (anders as gewone water) neem nie, sodat dit behoorlik kan werk. **BONTELVIA 35 mg** moet veral nie op dieselfde tyd as suiwelprodukte (soos melk) geneem word nie aangesien dit kalsium bevat (sien "Neem van ander medisyne"). Neem kos en drank (anders as gewone water) ten minste 30 minute nadat **BONTELVIA 35 mg** geneem is.

Swangerskap en borsvoeding:
- Jy moet nie **BONTELVIA 35 mg** neem tydens swangerskap nie.
- Moet nie borsvoed gedurende die behandeling met **BONTELVIA 35 mg** nie.

Indien jy swanger is of jou baba borsvoed, raadpleeg asseblief jou dokter, apteker of ander professionele gesondheidswerker vir advies voordat jy **BONTELVIA 35 mg** neem.

Bestuur en gebruik van masjinerie
BONTELVIA 35 mg is nie bekend daarvoor om jou vermoë om te bestuur en masjinerie te gebruik, aan te laat nie.

Belangrike inligting oor sommige van die bestanddele van BONTELVIA 35 mg:
BONTELVIA 35 mg bevat laktose. Pasiënte met die seldsame oorerflike toestande van laktose-intoleransie of galaktose-intoleransie moet nie **BONTELVIA 35 mg** neem nie. **BONTELVIA 35 mg** bevat laktose wat 'n uitwerking op die beheer van jou bloedsuiker kan hê indien jy diabetes mellitus het.

Neem van ander medisyne saam met BONTELVIA 35 mg:
Vertel altyd vir jou professionele gesondheidsorgwerker indien jy enige ander medisyne neem. (Dit sluit kommersiële of tradisionele medisyne in.)
Medisyne wat een van die volgende bevat verminder die effek van **BONTELVIA 35 mg**, indien dit terselfdertyd geneem word:
- kalsium
- magnesium
- aluminium
- ysters.

Neem hierdie medisyne ten minste 30 minute nadat **BONTELVIA 35 mg** geneem is.

HOE OM BONTELVIA 35 mg TE GEBRUIK

Moet nie medisyne wat vir jou voorgeskryf is met enige ander persoon deel nie.
Neem altyd BONTELVIA 35 mg presies soos jou dokter jou bevoel het. Vra vir jou dokter of apteker indien jy onseker is. Indien jy onder die indruk is dat die effek van BONTELVIA 35 mg te sterk of te swak is, praat met jou dokter of apteker.

Neem EEN **BONTELVIA 35 mg** een keer per week.
Kies een dag van die week wat die beste by jou skedule pas. Neem **BONTELVIA 35 mg** elke week op jou gekose dag.
Neem **BONTELVIA 35 mg** ten minste 30 minute voor die eerste voedsel, drank (anders as gewone water) of ander medisyne van die dag.
Neem die tablet terwyl jy in 'n oreinposisie is (jy mag sit of staan) om sooibrand te vermy. Sluk dit met ten minste een glas (120 ml) gewone water. Sluk dit heel in. Moet dit nie stuk of kou nie.
Moet nie binne 30 minute nadat jy jou tablet geneem het, gaan lê nie.
Indien jy nie geneig is om jou dwel innieem nie, sal jou dokter vir jou aanvullings kalsium- en vitamiensamevullings nodig het.

Indien jy meer BONTELVIA 35 mg neem as wat jy behoort te neem:
Soek nood mediese hulp indien jy vermoed dat jy te veel **BONTELVIA 35 mg** geneem het.

In die geval van oordosering, raadpleeg jou dokter of apteker. Indien nie een beskikbaar is nie, kontak die naaste hospitaal of gifbeheersentrum.

Indien jy vergeet om BONTELVIA 35 mg te neem:
Indien jy vergeet het om jou tablet op jou gekose dag te neem, neem dit op die dag wat jy daarvan onthou. Keer terug na die neem van een tablet een keer per week op die dag waarop die tablet normaalweg geneem word. **MOET NIE** twee tablette op een dag neem om op te maak vir die tablet wat jy vergeet het nie.

Uitwerking wanneer behandeling met BONTELVIA 35 mg gestaak is:
Jou dokter sal vir jou sê hoe lank jou behandeling met **BONTELVIA 35 mg** sal aanhou. Moet nie vroeër met die behandeling ophou nie, want as jy behandeling staak, kan jy toenemende been verlies. Praat asseblief met jou dokter voordat jy dit oorweeg om met behandeling op te hou.

MOONTLIKE NEWE-EFFEKTE
BONTELVIA 35 mg kan newe-effekte hê.
Nie al die newe-effekte wat vir **BONTELVIA 35 mg** gerapporteer is, is in hierdie inligtingstuk ingesluit nie. Sou jou algemene gesondheid verslag of jy enige ongewenste effekte ervaar terwyl jy **BONTELVIA 35 mg** gebruik, kontak asseblief jou dokter, apteker of ander professionele gesondheidsorgwerker vir advies.

Indien jy enige van die volgende ervaar, hou op om BONTELVIA 35 mg te gebruik en kontak 'n dokter onmiddellik:
- Simptome van 'n ernstige allergiese reaksie soos:
  - Swelling van gesig, tong of keel
  - Probleme om te sluk
  - Galbulte en probleme met asemhaling
- Ernstige velreaksies wat blase op die vel kan insluit.

Vertel dadelik jou dokter indien jy die volgende newe-effekte ervaar:
- Ontsteking in die oog, gewoonlik met pyn, rooiheid en ligsensitiwiteit.
- Probleme met jou kakebeen of tande, gekoppel aan vertraagde genesing en/of infeksie na 'n tand ekstraksie of na indringende tandheelkundige werk.
- Simptome van die slukderm soos pyn wanneer jy sluk, probleme om te sluk, borstaszyn of nuwe of vererigde sooibrand.
- Ongewone fraktuur van die femurbeen veral indien jy op langtermynbehandeling vir osteoporose is. Kontak jou dokter indien jy pyn, swakheid of ongemak in jou bobeen, heup of lies ervaar aangesien dit 'n vroeë aanduiding kan wees van 'n moontlike fraktuur van die femurbeen.
- Oorpyn, afskeiding uit die oor, en/of 'n infeksie in die oor. Hierdie kan tekens wees van beensiekte in die oor.

Gereelde newe-effekte:
- Slegte spysvertering, voel siek, maagpyn, maagkrampe of ongemak, hardlywigheid, vol gevoel, opgeblasenheid, diaree.
- Pyn in jou bene, spiere of gewrigte.
- Hoofpyn.

Minder gereelde newe-effekte:
- Ontsteking of uitsaksie van die slukderm wat probleme en pyn veroorsaak om te sluk, ontsteking van die maag en duodenum (derm wat die maag dreineer), maagpyn, ontsteking van die tong (rooi geswelde, moontlik pynlike), vernouing van die slukderm.
- Ontsteking van die gekleurde deel van die oog (iris) (rooi pynlike oë met 'n moontlike verandering in visie).

Fraiwenaisie anbekend:
- Windigheid (oortollige gas in die maag of derm), bloeding van die maagwand, winde-opkoms, pynlike sluk.
- Abnormale lewertoetse is gerapporteer. Dit kan slegs met 'n bloedtoets gediagnoseer word.
- Haarverlies.
- Verhoogde sweetafskeiding.
- Veluitslag of rooiheid van die vel, soms deur sonlig vererger.
- Toename in sommige witbloedselle (eosinofilie).
- Gebrek aan witbloedselle, wat lei tot gereelde infeksies soos koors, erge koue rillings, seer keel of mondsere (neutropenie).
- Afname in libido.
- Sukkel om te slaap.
- Slaperigheid.
- Leweraandwykings.
- Akute bergsiekte met simptome van hoofpyn, naarheid en moegheid.
- Koors.
- Vermoeidheid.
- 'n Pasiënt se bloedkalsium- en fosfaatvlakke kan daal.

Indien jy enige newe-effekte waarneem wat nie in hierdie inligtingstuk gemeem word nie, lig asseblief jou dokter of apteker in.

BEWARING EN WEGDOENING VAN BONTELVIA 35 mg.
Bewaar by of benede 25 °C (kamertemperatuur). Beskerm teen lig. Hou die blisterstrate in die buitenste karton totdat dit benodig word vir gebruik.
Hou die HDPE houers digtie.
BEWAAR ALLE MEDISYNE BUITE BEREIK VAN KINDERS.

Neem alle ongebruikte medisyne terug na jou apteker.
Moet nie ongebruikte medisyne in afvoerpype of rioolstelsels (bv. toilette) gooi nie.

AANBIEDING VAN BONTELVIA 35 mg

1) Stulpstrook verpakking:
Tablette word verpak in Triplex 250/25/90 helder PVC/PE/PVdC as die vormingsmateriaal en 25 µ aluminiumfoelie met 6-8 gsm hitteseallak as deklmateriaal. Elke stulpstrook bevat 4 tablette verpak in 'n voorafgedrukte eenheidskarton.
Verpakkingsgrootte: 4's – Elke karton bevat 1 stulpstrook van 4 tablette elk.

2) HDPE houer verpakking:
Tablette word verpak in wit, ronde 40 ml HDPE-houer met 33 mm nekafwerking toegemaak met 33 mm wit sluiting met wad wat verseëling en indukse-seëlvoering. Elke houer bevat 30 tablette verpak in 'n voorafgedrukte eenheidskarton.
Verpakkingsgrootte: 30's - Een HDPE houer bevat 30 tablette.

IDENTIFIKASIE VAN BONTELVIA 35 mg

Oranjekleurige, sirkelvormige, bikonvekse, filmbedekte tablet met "CL 92" op die een kant gedruk en glad aan die ander kant.

REGISTRASIENOMMER

46/3.2/0694

NAAM EN ADRES VAN DIE HOUER VAN REGISTRASIE

Macleods Pharmaceuticals SA (Edms) Bpk
Grondvloer, Blok 1, Bassonia Estate Kantoorpark (Oos),
Cussonia Weg 1, Bassonia Rock, Uitbr. 12,
Alberton, Gauteng

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420 mm

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Restricted Circulation

PACKAGING RESEARCH & DEVELOPMENT

(Front Page)

ARTWORK / PRINTPROOF APPROVAL FORM

1. Product: BONTELVIA 35 mg (Risedronate sodium Tablets 35 mg)	
2. Country: South Africa	3. Packaging component: Patient Information
4. No. of Colours: 1 Colour	5. Pantone Shade No.: Black
6. Specification: 40 gsm bible paper	
7. Machine Layout No.: NA	8. Dimensions: 420 (L) x 335 (W) mm
9. Design / Style: Booklet	10. Item code No.: PM03841301
11. Artwork has been made: Actual Size	12. Pharma code No.: 31486 mini
13. Barcode/NDC No: NA	14. Supersedes Item code No: NA
15. Revision no: 00	16. A/W File name: E:\ANDA Regulatory\South Africa\BONTELVIA\BONTELVIA 35 PI&PIL - PM03841301.cdr
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PRD	M.A. HOLDER	RAD	QC	PRODN	QA
31/01/23		31/01/23	04/02/23		07/02/23

Note: 1. To follow overleaf checklist for approval of Artwork / Print proof.

Instructions to Vendor :

1. Before processing, please ensure First pull out / Commercial supply should match with approved Artwork with respect to Design, Size, Fonts & Text.
2. Print proof to represent full printing area with Station Numbers.

QA 07/02/23

FRM/CQA/021/04-02

Reason for revision :	Item code	Artwork Release Date	Artwork Implementation Date
1) New Artwork for South Africa	PM03841301		

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