SCHEDULING STATUS:

S4

BONRIX 2 mg/2 ml (concentrate solution for dilution for IV infusion)

BONRIX 6 mg/6 ml (concentrate solution for dilution for IV infusion)

Ibandronic acid

Read all of this leaflet carefully before you are given BONRIX:

- 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.

What is in this leaflet

1. What **BONRIX** is and what it is used for.
2. What you need to know before you are given **BONRIX**.
3. How **BONRIX** is administered.
4. Possible side effects
5. How **BONRIX** should be stored.
6. Contents of the pack and other information.

1. WHAT BONRIX IS AND WHAT IT IS USED FOR

- Ibandronic acid belongs to a group of medicines called bisphosphonates.
- It can be prescribed for you if you have a raised calcium level in your blood due to a tumour.
- **BONRIX** works by reducing the amount of calcium that is lost from your bones, which helps to stop your bones getting weaker.
- **BONRIX** is used in adults and may be prescribed for you if you have breast cancer that has spread to your bones.
- It helps to prevent your bones from breaking and helps prevent other bone problems.

2. WHAT YOU NEED TO KNOW BEFORE YOU ARE GIVEN BONRIX

You should not be given BONRIX:

- If you are hypersensitive (allergic) to ibandronic acid or any of the other ingredients of **BONRIX** (listed in section 6) or any other medicines belonging to the group bisphosphonates
- If you are pregnant or breastfeeding
- If you have too little calcium in your blood.

Warnings and precautions

Special care should be taken with BONRIX

- If you are under the age of 18.
- If you have low levels of calcium or other minerals in the body.
- As it can cause a severe allergic reaction or shock.
- If you have kidney problems.
- If you have heart problems, the doctor may recommend that you limit your daily fluid intake.
- If you have an unhealed open wound in your mouth.
- If you are having dental treatment or surgery, tell your dentist that you are being treated with **BONRIX**.
- If you have cancer, anaemia (shortage of red blood cells), suffer from a bleeding. disorder, have an infection, if you are smoking.
- If you are using corticosteroids for inflammation, on chemotherapy, using angiogenesis inhibitors to stop the growth of new blood vessels for the treatment of cancer, radiotherapy from head to neck.
- If you suffer from ear pain, discharge from the ear or an ear infection.
- If you experience thigh, hip or groin pain.
- If you are allergic to any other bisphosphonates.

While being treated, you should maintain good oral hygiene (including regular teeth brushing) and receive routine dental check-ups. If you wear dentures you should make sure these fit properly. If you are under dental treatment or will undergo dental surgery (e.g. tooth extractions), inform your doctor about your dental treatment.

Children and adolescents

BONRIX should not be used in children as safety has not been established.

Other medicines and BONRIX

- Always tell your healthcare professional if you are taking any other medicine (This includes complementary or traditional medicines).
- Tell your doctor if you are being given a type of antibiotic called “aminoglycoside”, as both medicines cause low levels of calcium in the blood.

Pregnancy, breastfeeding and fertility:

- 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 professional, for advice before **BONRIX** is administered to you.
- Do not use **BONRIX** while you are pregnant or breastfeeding.

Driving and using machines:

BONRIX causes headaches and dizziness and can affect your ability to drive and use machines.

It is not always possible to predict to what extent **BONRIX** may interfere with your daily activities. You should ensure that you do not engage in the above activities until you aware of the measure to which **BONRIX** affects you.

Excipients

This medicine contains less than 1 mmol sodium (23 mg) per vial, i.e. ‘essentially sodium free’.

3. HOW BONRIX IS ADMINISTERED

- You will not be expected to give yourself **BONRIX**. It will be given to you by a person qualified to do so.
- It will be given to you as an infusion into your vein.
- Your doctor may do regular blood tests to check your calcium levels.
- Your doctor may prescribe calcium or Vitamin D.
- Your doctor will work out how much **BONRIX** you will be given depending on your illness.
- Your doctor will tell you how long your treatment with **BONRIX** will last.
- If you have the impression that the effect of **BONRIX** is too strong or too weak, tell your doctor or pharmacist.
- Taking enough calcium and vitamin D is important.

If you are given more BONRIX than you should receive:

Since a health care provider will administer **BONRIX,** he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

4. POSSIBLE SIDE EFFECTS:

- **BONRIX** can have side effects
- Not all side effects reported for **BONRIX** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using **BONRIX**, please consult your doctor, pharmacist or other healthcare professional for advice.
- **If any of the following happens, tell your doctor immediately:**
    - Swelling of the face, tongue or throat area, hives, flushed skin, nausea, vomiting, abdominal pain, weak and rapid pulse, difficulty breathing that can be signs of anaphylactic shock.
    - Rash, red or peeling skin.
    - Fever, sore throat, tiredness, burning pain of the skin, sores in the mouth and on the lips, including the genital and anal regions, that can be signs of Stevens-Johnson syndrome.
- These are all very serious side effects. If you have them, you may have had a serious allergic reaction to **BONRIX**. You may need urgent medical attention.
- Other side effects that frequently occur are:
    - Flu-like symptoms – fever, chills, muscle pain
    - Low calcium levels – you may notice muscle aches or stiffness. A blood test will be required to confirm this.
    - Pain in bone
    - Infections
    - Problems with your parathyroid gland – you may notice a lump in your neck, difficulty swallowing or speaking
    - Headache, dizziness, changes in taste
    - Problems with your eyes like cataracts
    - Heart rhythm problems
    - Sore throat
    - Diarrhoea, vomiting, stomach pain, indigestion, teeth problems

    - Skin rashes
    - Muscle and joint pain
    - Feeling thirsty
- The following side effects occur less frequently:
    - Difficulty breathing
    - Bladder or vaginal infection
    - Skin growths
    - Changes to blood cells, called anaemia – you may feel weakness and tired
    - Difficulty sleeping, feeling anxious, emotional instability
    - Headache, nerve pain, forgetfulness
    - Deafness
    - Heart problems
    - Increase in blood pressure
    - Fluid in lungs
    - Mouth ulcers, itching or tingling around the lips
    - Hair loss
    - Weight loss
    - Pain at injection site
    - Swelling beneath the skin due to an allergic reaction
    - Decrease in sense of smell
    - Inflammation of the eye
    - Fluid-filled blisters that are often located along creases in the skin
    - Thigh, hip or groin pain that can be signs of a bone fracture
    - Pain, swelling, redness or other signs of infection in the gums, mouth sores not healing, loose teeth, numbness or heavy feeling in the jaw that can be signs of a bone disease in the jaw
    - Ear pain, discharge from the ear or an ear infection
- Tell your doctor if any of the above side effects gets serious or lasts longer than a few days.
- 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, pharmacist or nurse. 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 Reaction 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 **BONRIX.**

5. HOW BONRIX SHOULD BE STORED

- Store in the original packaging at or below 25 °C.
- STORE ALL MEDICINES OUT OF REACH OF CHILDREN.
- Intravenous infusion solution should be used immediately.
- Only clear solution without particles should be used.
- Discard any unused solution.
- Do not freeze.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What BONRIX contains:

- The active substance is ibandronic acid.
- The other ingredients are glacial acetic acid, sodium acetate, sodium chloride and water for injection.

What BONRIX looks like and contents of the pack

BONRIX 2 mg/2 ml injection: clear, colourless, sterile solution, free from visible particles.

BONRIX 6 mg/6 ml injection: clear, colourless, sterile solution, free from visible particles.

BONRIX 2 mg/ 2ml is packaged in a 6 ml, clear, colourless glass vial (type I) with 20 mm grey rubber stopper and 20 mm aluminium sea with a lavender flip-off cap, which is further packed in an outer carton containing 1 vial.

BONRIX 6 mg/ 6ml is packaged in a 6 ml, clear, colourless glass vial (type I) with 20 mm grey rubber stopper and 20 mm aluminium seal with a pink flip-off cap, which is further packed in an outer carton containing 1 vial.

HOLDER OF CERTIFICATE OF REGISTRATION

Accord Healthcare (Pty) Ltd

Tuscany Office Park

6 Coombe Place

Rivonia

Gauteng

South Africa

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BONRIX 2 mg/ 2 ml: 49/3.2/0583

BONRIX 6 mg/ 6 ml: 49/3.2/0584