SCHEDULING STATUS
S4

BONIVA® 3 mg/3 mL, Injection
Ibandronic acid
Sugar free

Read all of the leaflet carefully before you are given BONIVA 3 mg/3 mL
- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- BONIVA 3 mg/3 mL 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 BONIVA 3 mg/3 mL is and what it is used for
2. What you need to know before you receive BONIVA 3 mg/3 mL
3. How to receive BONIVA 3 mg/3 mL
4. Possible side effects
5. How to store BONIVA 3 mg/3 mL
6. Contents of the pack and other information

1. What BONIVA 3 mg/3 mL is and what it is used for
BONIVA 3 mg/3 mL belongs to a group of medicines called bisphosphonates. It does not contain hormones.

BONIVA 3 mg/3 mL is for intravenous injection by a healthcare provider. Do not inject BONIVA 3 mg/3 mL yourself.

BONIVA 3 mg/3 mL is prescribed for you to treat osteoporosis. Osteoporosis is a thinning and weakening of the bones, which is common in women after menopause. At menopause, a woman's ovaries stop producing the female hormone, estrogen, which helps to keep her skeleton healthy.

Other things that can increase the risk of osteoporosis include:
- not enough calcium and vitamin D in the diet
- smoking, or drinking too much alcohol
- not enough walking or other weight-bearing exercise
- a family history of osteoporosis.

Many people with osteoporosis have no symptoms. If you have no symptoms, you may not know if you have the condition. However, osteoporosis makes you more likely to break bones if you fall or hurt yourself. A broken bone after the age of 50 may be a sign of osteoporosis. Osteoporosis can also cause back pain, height loss and a curved back.

BONIVA 3 mg/3 mL prevents loss of bone from osteoporosis and helps to rebuild bone. Therefore, BONIVA 3 mg/3 mL makes bone less likely to break.

A healthy lifestyle will also help you to get the most benefit from your treatment. This includes eating a balanced diet rich in calcium and vitamin D; walking or any other weight-bearing exercise; not smoking and not drinking too much alcohol.

2. What you need to know before you receive BONIVA 3 mg/3 mL
BONIVA 3 mg/3 mL should not be administered to you:
- If you are hypersensitive (allergic) to ibandronic acid, or any of the other ingredients of BONIVA 3 mg/3 mL listed in section 6).
- If you have, or believe that you may have, low blood calcium, please consult your doctor.
- If your kidneys are not functioning normally.

Warnings and precautions
Take special care with BONIVA 3 mg/3 mL
Some patients need to be especially careful when taking BONIVA 3 mg/3 mL.
Tell your doctor:
- If you have or if you previously had any kidney problems, kidney failure or needed dialysis, or if you have any other disease that may affect your kidneys.
- If you have any disturbances of mineral metabolism (such as vitamin D deficiency).
- If you should take calcium and vitamin D supplements while receiving BONIVA 3 mg/3 mL. If you are unable to do so, you should inform your doctor.
- If you have any problems with your mouth or teeth such as poor dental health, gum disease, or a planned tooth extraction or you don't receive routine dental care.
- If you have previously been treated with a bisphosphonate (used to treat or prevent bone disorders).
- If you are taking medicines called corticosteroids (such as prednisolone or dexamethasone).
- If you have cancer.
- If you have ear problems or ear infections.
- If you have pain in the thigh, hip, groin arms or legs.
- If you have heart problems and the doctor recommended to limit your daily fluid intake.

Your doctor may ask you to undergo a dental examination before starting treatment with BONIVA 3 mg/3 mL.

You should maintain good oral hygiene and receive routine dental check-ups while being treated with BONIVA 3 mg/3 mL.

Contact your doctor and dentist immediately if you experience any problems with your mouth or teeth such as loose teeth, pain or swelling, or non-healing of sores or discharge.

If you experience one of the following symptoms, such as shortness of breath/difficulty breathing, tight feeling in throat, swelling of tongue, dizziness, feeling of loss of consciousness, redness or swelling of face, body rash, nausea and vomiting, you should immediately alert your doctor or nurse as these are signs of an allergic reaction (see section 4).

Children and adolescents
BONIVA 3 mg/3 mL must not be used in children or adolescents below 18 years.

Other medicines and BONIVA 3 mg/3 mL
Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

Pregnancy and breastfeeding
Do not take BONIVA 3 mg/3 mL if you're pregnant or breastfeeding. If you are breastfeeding, you may need to stop in order to take BONIVA 3 mg/3 mL.

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 health care provider for advice before receiving BONIVA 3 mg/3 mL.

Driving and using machines
You can drive and use machines as it's expected that BONIVA 3 mg/3 mL has no or negligible effect on your ability to drive and use machines.

It is not always possible to predict to what extent BONIVA 3 mg/3 mL may interfere with your daily activities. You should ensure that you do not engage in the above activities until you are aware of the measure to which BONIVA 3 mg/3 mL affects you.

BONIVA 3 mg/3 mL contains sodium
BONIVA 3 mg/3 mL contains less than 1 mmol sodium (23 mg) per dose (3 ml), that is to say essentially "sodium-free".

3. How to receive BONIVA 3 mg/3 mL
Dosage and frequency of administration
The recommended dose of BONIVA 3 mg/3 mL for the intravenous injection is 3 mg (1 pre-filled syringe) once every 3 months.

Method and route of administration
The injection should be given into the vein by a physician or qualified/trained healthcare worker. Do not administer the injection to yourself.

The solution for injection must be administered into a vein only, and not anywhere else in the body.

Continuing to use BONIVA 3 mg/3 mL
To get the most benefit from the treatment it is important to continue receiving the injections every 3 months for as long as your doctor prescribes it for you. BONIVA 3 mg/3 mL can treat osteoporosis only for as long as you keep receiving the treatment, even though you won't be able to see or feel a difference.

You should also take calcium and vitamin D supplements, as recommended by your doctor.

If too much BONIVA 3 mg/3 mL is given
You may develop low levels of calcium, phosphorus or magnesium in the blood. Your doctor may take steps to correct such changes and may give you an injection containing these minerals.

If a dose of BONIVA 3 mg/3 mL is missed
You should arrange an appointment to get the next injection as soon as possible. After that, go back to getting the injections every 3 months from the date of the most recent injection.

4. POSSIBLE SIDE EFFECTS
BONIVA 3 mg/3 mL can cause side effects.

Not all side effects reported for BONIVA 3 mg/3 mL are included in this leaflet. Should your general health worsen or if you experience any untoward effects while receiving BONIVA 3 mg/3 mL, please consult your health care provider for advice.

If any of the following happens, tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching,
- fainting,
- sores, blistering and peeling of the skin.

These are all very serious side effects. If you have them, you may have had a serious reaction to BONIVA 3 mg/3 mL. 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:
- low blood calcium levels (hypocalcaemia), symptoms include muscle cramps and/or tingling sensation in the fingers or lips,
- pain and inflammation of the eye(s),
- a crack or break (fracture) of the thigh bone or other bones in your arms or legs, symptoms include pain, weakness or discomfort in your thigh, hip, groin, arms or legs,
- pain, swelling and sores in the mouth,
- ear pain, a feeling of fullness in the ear, loss of hearing or a ringing sensation in the ears.

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

Tell your doctor if you notice any of the following:
Common side effects:
- headache,
- stomach pain or burning, indigestion, diarrhoea, nausea, constipation,
- pain in your joints, muscle or back,
- flu-like symptoms (fever, chills or feverishness and aches or pains in the muscles, bones and joints),
- tiredness.

Uncommon side effects:
- coughing, breathlessness, wheezing or tight chest,
- inflammation of a vein, symptoms include redness, warmth and pain in the affected area,
- bone pain,
- redness, pain, and swelling around the site of injection,
- feeling weak.

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

Reporting of side effects
If you get side effects, talk to your doctor, 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 SAHPRA website. By reporting side effects, you can help provide more information on the safety of BONIVA 3 mg/3 mL.

5. How to store BONIVA 3 mg/3 mL
- Store all medicines out of reach of children.
- Store at or below 30 °C.
- Store in the original package.
- Don’t use after the expiry date stated on the syringe and carton.
- Do not store in a bathroom.
- 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 BONIVA 3 mg/3 mL contains
The active ingredient is ibandronic acid.
Each pre-filled syringe contains 3 mg ibandronic acid per 3 mL of solution.

The other ingredients are glacial acetic acid, sodium acetate, sodium chloride, water for injection.

What BONIVA 3 mg/3 mL looks like and contents of the pack
Clear, colourless solution in a pre-filled syringe.

1 or 4 pre-filled syringe(s) made of colourless glass and has a grey rubber plunger stopper and grey tip cap packed together with an injection stainless-steel needle(s), in an outer carton.

Not all pack sizes may be marketed.

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SKEDULERINGSTATUS
S4

BONIVA® 3 mg/3 mL, Inspuiting
Ibandronaatsuur
Suikervry

Lees die hele biljet noukeurig deur voordat BONIVA 3 mg/3 mL aan u gegee word
- Hou hierdie biljet. U sal dit dalk weer moet lees.
- Indien u verdere vrae het, raadpleeg asseblief u dokter of u apteker.
- BONIVA 3 mg/3 mL is aan u persoonlik voorgeskryf en u moet nie u medisyne met ander mense deel nie. Dit kan hulle benadeel, selfs al ervaar hul dieselfde simptome as u.

Wat is in hierdie biljet
1. Wat BONIVA 3 mg/3 mL is en waarvoor dit gebruik word
2. Wat u moet weet voordat u BONIVA 3 mg/3 mL ontvang
3. Hoe om BONIVA 3 mg/3 mL te ontvang
4. Moontlike newe-effekte
5. Hoe om BONIVA 3 mg/3 mL te bêre
6. Inhoud van die verpakking en ander inligting

1. Wat BONIVA 3 mg/3 mL is en waarvoor dit gebruik word
BONIVA 3 mg/3 mL behoort aan 'n groep medisyne wat bisfosfonate genoem word. Dit bevat nie hormone nie.

BONIVA 3 mg/3 mL is vir intraveneuse inspuiting deur 'n gesondheidsorgverskaffer. Moenie BONIVA 3 mg/3 mL self inspuit nie.

BONIVA 3 mg/3 mL word aan u voorgeskryf om osteoporose te behandel. Osteoporose is 'n verdunning en verswakking van die bene, wat algemeen by vroue na menopouse voorkom. By menopouse hou 'n vrou se eierstokke op om die vroulike hormoon, estrogeen, te produseer, wat help om haar skelet gesond te hou.

Ander dinge wat die risiko van osteoporose kan verhoog, sluit in:
- nie genoeg kalsium en vitamien D in die dieet nie
- rook of te veel alkohol drink
- nie genoeg stap of ander gewigdraende oefening nie
- 'n familiegeskiedenis van osteoporose.

Baie mense met osteoporose het geen simptome nie. Indien u geen simptome het nie, weet u dalk nie of u die toestand het nie. Osteoporose maak u egter meer geneig om bene te breek indien u val of uself seermaak. 'n Gebreekte been na die ouderdom van 50 kan 'n teken van osteoporose wees. Osteoporose kan ook rugpyn, lengteverlies en 'n geboë rug veroorsaak.

BONIVA 3 mg/3 mL voorkom verlies van been as gevolg van osteoporose en help om been te herbou. Daarom maak BONIVA 3 mg/3 mL been minder geneig om te breek.

'n Gesonde leefstyl sal u ook help om die meeste voordeel uit u behandeling te kry. Dit sluit in die eet van 'n gebalanseerde dieet ryk aan kalsium en vitamien D; stap of enige ander gewigdraende oefening; nie rook nie en nie te veel alkohol drink nie.

2. Wat u moet weet voordat u BONIVA 3 mg/3 mL ontvang

BONIVA 3 mg/3 mL moet nie aan u toegedien word nie:

- Indien u hipersensitief (allergies) is vir ibandronaatsuur, of enige van die ander bestanddele van BONIVA 3 mg/3 mL (gelys in afdeling 6).
- Indien u lae bloedkalsium het, of glo dat u dalk het, raadpleeg asseblief u dokter.
- Indien u niere nie normaal funksioneer nie.

Waarskuwings en voorsorgmaatreëls

Wees veral versigtig met BONIVA 3 mg/3 mL

Sommige pasiënte moet veral versigtig wees wanneer hulle BONIVA 3 mg/3 mL neem.
Lig u dokter in:

- Indien u nierprobleme het, nierversaking het of dialise benodig, of indien u voorheen dit gehad het, of indien u enige ander siekte het wat u niere kan beïnvloed.
- Indien u enige versteurings van minerale metabolisme het (soos vitamien D-tekort).
- Indien u kalsium- en vitamien D-aanvullings moet neem terwyl u BONIVA 3 mg/3 mL ontvang. Indien u dit nie kan doen nie, moet u u dokter in kennis stel.
- Indien u enige probleme met u mond of tande het, soos swak tandheelkundige gesondheid, tandvleissiekte of 'n beplande tandekstraksie of u nie roetine tandheelkundige sorg ontvang nie.
- Indien u voorheen met 'n bisfosfonaat behandel is (wat gebruik word om beenafwykings te behandel of te voorkom).
- Indien u medisyne neem wat kortikosteroïede genoem word (soos prednisoloon of deksametasoon).
- Indien u kanker het.
- Indien u oorprobleme of oorinfeksies het.
- Indien u pyn in die dy, heup, lies, arms of bene het.
- Indien u hartprobleme het en die dokter aanbeveel het om u daaglikse vloeistofinname te beperk.

U dokter kan u vra om 'n tandheelkundige ondersoek te ondergaan voordat u met behandeling met BONIVA 3 mg/3 mL begin.

U moet goeie mondhigiëne handhaaf en roetine-tandheelkundige ondersoeke ontvang terwyl u met BONIVA 3 mg/3 mL behandel word.

Kontak u dokter en tandarts onmiddellik indien u enige probleme met u mond of tande ervaar soos los tande, pyn of swelling, of nie-genesende sere of afskeiding.

Indien u een van die volgende simptome ervaar, soos kortasem/moeilike asemhaling, benoude gevoel in keel, swelling van tong, duiseligheid, gevoel van bewussynsverlies, rooiheid of swelling van gesig, liggaamsuitslag, naarheid en braking, moet u u dokter of verpleegkundige onmiddellik waarsku aangesien dit tekens van 'n allergiese reaksie is (sien afdeling 4).

Kinders en adolessente

BONIVA 3 mg/3 mL moet nie by kinders of adolessente jonger as 18 jaar gebruik word nie.

Ander medisyne en BONIVA 3 mg/3 mL

Lig altyd u gesondheidsorgverskaffer in indien u enige ander medisyne neem. (Dit sluit alle komplementêre of tradisionele medisyne in.)

Swangerskap en borsvoeding

Moenie BONIVA 3 mg/3 mL neem indien u swanger is of borsvoed nie. Indien u borsvoed, moet u dalk stop om BONIVA 3 mg/3 mL te neem.

Indien u swanger is of borsvoed, dink u is dalk swanger of van plan is om 'n baba te hê, raadpleeg asseblief u dokter, apteker of ander gesondheidsorgverskaffer vir advies voordat u BONIVA 3 mg/3 mL ontvang.

Bestuur en gebruik van masjinerie
U kan bestuur en masjinerie gebruik aangesien daar verwag word dat BONIVA 3 mg/3 mL geen of ‘n weglaatbare effek op u vermoë om te bestuur en masjiene te gebruik sal hê.

Dit is nie altyd moontlik om te voorspel tot watter mate BONIVA 3 mg/3 mL met u daaglikse aktiwiteite kan inmeng nie. U moet seker maak dat u nie aan bogenoemde aktiwiteite deelneem totdat u bewus is van die mate waartoe BONIVA 3 mg/3 mL u beïnvloed nie.

BONIVA 3 mg/3 mL bevat natrium
BONIVA 3 mg/3 mL bevat minder as 1 mmol natrium (23 mg) per dosis (3 mL), dit wil sê in wese "natriumvry".

3. Hoe om BONIVA 3 mg/3 mL te ontvang

Dosis en frekwensie van toediening
Die aanbevole dosis BONIVA 3 mg/3 mL vir die intraveneuse inspuiting is 3 mg (1 voorafgevulde spuit) een keer elke 3 maande.

Metode en roete van toediening
Die inspuiting moet deur 'n dokter of gekwalifiseerde/opgeleide gesondheidsorgwerker in die aar gegee word. Moenie die inspuiting aan uself toedien nie.

Die oplossing vir inspuiting moet slegs in 'n aar toegedien word, en nêrens anders in die liggaam nie.

Gaan voort om BONIVA 3 mg/3 mL te gebruik
Om die meeste voordeel uit die behandeling te kry, is dit belangrik om voort te gaan om die inspuitings elke 3 maande te ontvang solank as wat u dokter dit vir u voorskryf. BONIVA 3 mg/3 mL kan osteoporose slegs behandel solank u aanhou om die behandeling te ontvang, al sal u nie 'n verskil kan sien of voel nie.

U moet ook kalsium- en vitamien D-aanvullings neem, soos aanbeveel deur u dokter.

Indien te veel BONIVA 3 mg/3 mL gegee word
U kan lae vlakke van kalsium, fosfor of magnesium in die bloed ontwikkel. U dokter kan stappe neem om sulke veranderinge reg te stel en kan u 'n inspuiting gee wat hierdie minerale bevat.

Indien 'n dosis BONIVA 3 mg/3 mL gemis word
U moet 'n afspraak reël om die volgende inspuiting so gou moontlik te ontvang. Gaan daarna voort om die inspuitings elke 3 maande vanaf die datum van die mees onlangse inspuiting, te ontvang.

4. MOONTLIKE NEWE-EFFEKTE

BONIVA 3 mg/3 mL kan newe-effekte veroorsaak.

Nie alle newe-effekte wat vir BONIVA 3 mg/3 mL aangemeld is, word in hierdie biljet ingesluit nie. Indien u algemene gesondheid verswak of indien u enige ongewenste gevolge ervaar terwyl u BONIVA 3 mg/3 mL ontvang, raadpleeg asseblief u gesondheidsorgverskaffer vir advies.

Indien enige van die volgende gebeur, lig u dokter dadelik in of gaan na die ongevalle-afdeling by u naaste hospitaal:
- swelling van die hande, voete, enkels, gesig, lippe en mond of keel, wat probleme kan veroorsaak om te sluk of asem te haal,
- veluitslag of jeukerigheid,
- floute
- sere, blaasvorming en afskilfering van die vel.

Hierdie is alles baie ernstige newe-effekte. Indien u dit ervaar, het u dalk 'n ernstige reaksie op BONIVA 3 mg/3 mL gehad. U sal dalk dringende mediese hulp of hospitalisasie benodig.

Lig u dokter dadelik in, of gaan na die ongevalle-afdeling by u naaste hospitaal indien u enige van die volgende opmerk:
- lae kalsiumvlakke in die bloed (hipokalsemie); simptome sluit in spierkrampe en/of tintelende sensasie in die vingers of lippe,
- pyn en inflammasie van die oog (s),
- 'n kraak of breuk (fraktuur) van die dybeen of ander bene in u arms of bene; simptome sluit in pyn, swakheid of ongemak in u dy, heup, lies, arms of bene,
- pyn, swelling en sere in die mond,
- oorpyn, 'n gevoel van volheid in die oor, gehoorverlies of 'n gevoel van gelui in die ore.

Hierdie is alles ernstige newe-effekte. U sal dalk dringend mediese hulp benodig.

Lig u dokter in indien u enige van die volgende opmerk:
Algemene newe-effekte:
- hoofpyn
- maagpyn of brand, slegte spysvertering, diarree, naarheid, hardlywigheid,
- pyn in u gewrigte, spiere of rug,
- griepagtige simptome (koors, kouekoors of koorsagtigheid en pyn in die spiere, bene en gewrigte),
- moegheid.

Minder algemene newe-effekte:
- hoes, asemloosheid, hygende asemhaling of benoude bors,
- inflammasie van 'n aar; simptome sluit in rooiheid, warmte en pyn in die aangetaste area,
- beenpyn,
- rooiheid, pyn en swelling rondom die plek van inspuiting,
- voel swak.

Indien u enige newe-effekte opmerk wat nie in hierdie biljet genoem word nie, raadpleeg asseblief u dokter of apteker.

Aanmelding van newe-effekte
Indien u newe-effekte ervaar, raadpleeg u dokter, apteker of verpleegkundige. U kan ook newe-effekte by SAHPRA aanmeld via die Med Safety Toep (Medsafety X SAHPRA) en eAanmeldingsplatform (who-umc.org) wat op SAHPRA se webwerf gevind kan word. Deur newe-effekte aan te meld, kan u help om meer inligting oor die veiligheid van BONIVA 3 mg/3 mL te verskaf.

5. Hoe om BONIVA 3 mg/3 mL te bêre
- Bêre alle medisyne buite bereik van kinders.
- Bêre teen of benede 30 °C.
- Bêre in die oorspronklike verpakking.

- Moenie gebruik ná die vervaldatum wat op die inspuiting en kartonboksie aangedui word nie.
- Moenie in 'n badkamer bêre nie.
- Neem alle ongebruikte medisyne terug na u apteker.
- Moenie ongebruikte medisyne in afvoerpype of rioolstelsels (bv. toilette) weggooi nie.

6. Inhoud van die verpakking en ander inligting
Wat BONIVA 3 mg/3 mL bevat
Die aktiewe bestanddeel is ibandronaatsuur.
Elke voorafgevulde inspuiting bevat 3 mg ibandronaatsuur per 3 mL oplossing.

Die ander bestanddele is geltserasynsuur, natriumasetaat, natriumchloried, water vir inspuiting.

Hoe BONIVA 3 mg/3 mL lyk en die inhoud van die verpakking
Helder, kleurlose oplossing in 'n voorafgevulde inspuiting.

1 of 4 voorafgevulde inspuiting(s) gemaak van kleurlose glas en het 'n grys rubber suierprop en grys puntdoppie verpak saam met 'n vlekvrye staal inspuitingsnaald(e), in 'n buitenste kartonboksie.

Nie alle verpakkingsgroottes word dalk bemark nie.

Houer van Sertifikaat van Registrasie
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