SCHEDULING STATUS
S4

BONIVA® 150 mg, film coated tablets
Ibandronic acid
Contains sugar: Lactose monohydrate 162,75 mg per tablet

Read all of the leaflet carefully before you start taking BONIVA 150 mg
- 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.
- BONIVA 150 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 BONIVA 150 mg is and what it is used for
2. What you need to know before you take BONIVA 150 mg
3. How to take BONIVA 150 mg
4. Possible side effects
5. How to store BONIVA 150 mg
6. Contents of the pack and other information

1. What BONIVA 150 mg is and what it is used for
BONIVA 150 mg belongs to a group of medicines called bisphosphonates. It does not contain hormones.

BONIVA 150 mg 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 150 mg prevents loss of bone from osteoporosis and helps to rebuild bone. Therefore, BONIVA 150 mg 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 take or use BONIVA 150 mg

Do not take BONIVA 150 mg

- If you are hypersensitive (allergic) to ibandronic acid, or any of the other ingredients of BONIVA 150 mg (listed in section 6.1).
- If you have, or believe that you may have, low blood calcium, please consult your doctor.
- If your kidneys are not functioning normally.
- If you have certain problems with your gullet/food pipe (oesophagus) such as narrowing or difficulty swallowing.
- If you can't stand or sit upright for up to an hour at a time.

Do not give BONIVA 150 mg to children or adolescents.

Warnings and precautions

Some people need to be especially careful while they're taking BONIVA 150 mg.
Tell your doctor:

- If you have any disturbances of mineral metabolism (such as vitamin D deficiency).
- 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.

Your doctor may ask you to undergo a dental examination before starting treatment with BONIVA 150 mg.

You should maintain good oral hygiene and receive routine dental check-ups while being treated with BONIVA 150 mg.

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.

You should take calcium and vitamin D supplements while receiving BONIVA 150 mg.

If you have ever had problems with your oesophagus (the tube connecting your mouth to your stomach). Problems in your oesophagus might give you symptoms including severe pain in the chest, severe pain after swallowing food and/or drink, severe nausea, or vomiting. If you develop these symptoms, speak to your doctor straight away.

Children and adolescents

BONIVA 150 mg must not be used in children or adolescents below 18 years.

Other medicines and BONIVA 150 mg

Always tell your health care provider if you are taking any other medicines. (This includes all complementary or traditional medicines.)

Mention anything you're taking which you bought over the counter, without a prescription; or any supplements containing calcium, magnesium, iron or aluminium.

Aspirin and other non-steroidal anti-inflammatory medicines (NSAIDs) may irritate the stomach and intestine. Bisphosphonates (like BONIVA 150 mg) may also do so. So be especially careful

if you take painkillers or anti-inflammatories while you're taking BONIVA 150 mg. (NSAIDs include ibuprofen, diclofenac sodium and naproxen.)

After swallowing your monthly BONIVA 150 mg tablet, wait for 1 hour before taking any other medication, including indigestion tablets or medicine, calcium supplements, or vitamins.

BONIVA 150 mg with food and drink
Do not take BONIVA 150 mg with food and drink (except plain water). BONIVA 150 mg is less effective if it is taken with food.

Pregnancy, breastfeeding and fertility
Do not take BONIVA 150 mg if you're pregnant or breastfeeding. If you're breastfeeding, you may need to stop in order to take BONIVA 150 mg.

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 taking BONIVA 150 mg.

Driving and using machines
You can drive and use machines. It's very unlikely that BONIVA 150 mg will affect your ability to drive and use machines.

BONIVA 150 mg contains lactose monohydrate and macrogol
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking BONIVA 150 mg.

Macrogol may cause stomach upset and diarrhoea.

3. How to take BONIVA 150 mg
Do not share medicines prescribed for you with any other person.

Always take BONIVA 150 mg exactly as your doctor or pharmacist has told you. If you are not sure about anything, ask your doctor or pharmacist.

The usual dose of BONIVA 150 mg is one tablet once a month.

Taking your monthly tablet
It's important to follow these instructions carefully. They are designed to help your BONIVA 150 mg tablet reach your stomach quickly, so it's less likely to cause irritation.

- Take one BONIVA 150 mg tablet once a month.
- Choose one day of the month that will be easy to remember. You can choose either the same date (such as the 1st of each month) or the same day (such as the first Sunday of each month) to take your BONIVA 150 mg tablet. Choose the date that best fits your routine.
- Take your BONIVA 150 mg tablet at least 6 hours after you last had anything to eat or drink except plain water.
- Take your BONIVA 150 mg tablet
  - after you first get up for the day, and
  - before you have anything else to eat or drink (on an empty stomach).
- Swallow your tablet with a full glass of plain water (at least 180 mL).
- Do not take your tablet with mineral water, fruit juice or any other drinks.
- Swallow your tablet whole – do not chew it, crush it or let it dissolve in your mouth.
- For the next hour (60 minutes) after you've taken your tablet

- **do not lie down**; if you do not stay upright (standing or sitting), some of the medicine could leak back into your oesophagus



- **do not eat anything**



- **do not drink anything** (except plain water if you need it)
- **do not take any other medicines**

- After you've waited for an hour, you can have your first food and drink of the day. Once you've eaten, it's okay to lie down if you wish, and to take any other medication you need.

Do not take your tablet at bedtime or before you get up for the day.

Continuing to take BONIVA 150 mg
It's important to keep taking BONIVA 150 mg every month, as long as your doctor prescribes it for you. BONIVA 150 mg can treat osteoporosis only as long as you keep taking it.

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

If you take more BONIVA 150 mg than you should
In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you've taken more than one tablet by mistake, drink a full glass of milk and talk to your doctor straight away.

Do not make yourself vomit, and do not lie down — this could cause BONIVA 150 mg to irritate your oesophagus.

If you forget to take BONIVA 150 mg
If you forget to take your tablet in the morning of your chosen day, do not take a tablet later in the day. Instead, follow these instructions:
When is your next scheduled dose due?
If your next scheduled dose is more than 7 days away (or if your missed dose is less than 3 weeks late)

- take one tablet the next morning after the day you remember.
- then, go back to taking your tablets on the scheduled days you've marked on your calendar.

If your next scheduled dose is only 1 to 7 days away (or if your missed dose is more than 3 weeks late)

- wait until your next scheduled dose is due and take it as normal.
- then, go back to taking your tablets on the scheduled days you've marked on your calendar.

Never take two BONIVA 150 mg tablets within the same week.

4. Possible side effects

BONIVA 150 mg can have side effects.

Not all side effects reported for BONIVA 150 mg are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking BONIVA 150 mg, 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 150 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:
- 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),
- irritation of the oesophagus, symptoms include severe pain in the chest, severe pain after swallowing food or drink, severe nausea, or vomiting,
- 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,
- heartburn, indigestion, diarrhoea, stomach ache, nausea,
- pain in the muscles or joints, muscle cramps, stiffness of the muscles
- flu-like symptoms (aches, pain, feeling of discomfort).

Uncommon side effects:
- coughing, breathlessness, wheezing or tight chest,
- dizziness,
- vomiting, passing of wind or having gas,
- back pain,
- tiredness.

Rare side effects:
- inflammation of the duodenum (first section of the bowel), symptoms include burning or cramping of the stomach, feeling bloated, lack of appetite or tar-coloured or dark stools.

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 150 mg.

5. How to store BONIVA 150 mg

- Store all medicines out of reach of children.
- Store at or below 30 °C.
- Keep in the original package until required for use.
- Don't use after the expiry date stated on the 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 150 mg contains
The active ingredient is ibandronic acid.
Each film-coated tablet contains 150 mg ibandronic acid.

The other ingredients are:
Tablet core: colloidal anhydrous silica, crospovidone, lactose monohydrate, microcrystalline cellulose, povidone and stearic acid. Film-coating: hypromellose, macrogol 6 000, talc and titanium dioxide.

What BONIVA 150 mg looks like and contents of the pack
White to off-white film-coated tablets, of oblong shape, marked "BNVA" on one side and "150" on the other side.

BONIVA 150 mg is available in pack sizes of 1 or 3 tablets in aluminium-aluminium or PVC/PVDC (duplex)-aluminium blisters.

Not all pack sizes and/or pack types may be marketed.

Holder of Certificate of Registration
Adcock Ingram Limited
1 New Road,
Erand Gardens,
Midrand, 1685
Customer Care: 0860 ADCOCK / 232625

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SKEDULERINGSTATUS
S4

BONIVA® 150 mg, filmbedekte tablette
Ibandronaatsuur
Bevat suiker: Laktosemonohidraat 162,75 mg per tablet

Lees hierdie hele biljet noukeurig deur voordat u BONIVA 150 mg begin neem
- Hou hierdie biljet. U sal dit dalk weer moet lees.
- Indien u verdere vrae het, raadpleeg asseblief u dokter, apteker, verpleegkundige of ander gesondheidsorgverskaffer.
- BONIVA 150 mg 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 150 mg is en waarvoor dit gebruik word
2. Wat u moet weet voordat u BONIVA 150 mg neem
3. Hoe om BONIVA 150 mg te neem
4. Moontlike newe-effekte
5. Hoe om BONIVA 150 mg te bêre
6. Inhoud van die verpakking en ander inligting

1. Wat BONIVA 150 mg is en waarvoor dit gebruik word
BONIVA 150 mg behoort tot 'n groep medisyne wat bisfosfonate genoem word. Dit bevat nie hormone nie.

BONIVA 150 mg word aan u voorgeskryf om osteoporose te behandel. Osteoporose is 'n verdunning en verswakking van die bene, wat algemeen by vroue ná menopouse voorkom. Tydens 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, mag u dalk nie weet dat 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 150 mg voorkom verlies van been as gevolg van osteoporose en help om been te herbou. BONIVA 150 mg maak dus been minder geneig om te breek.

'n Gesonde leefstyl sal u ook help om die meeste voordeel uit u behandeling te verkry. 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 drink nie te veel alkohol nie.

2. Wat u moet weet voordat u BONIVA 150 mg neem of gebruik
Moenie BONIVA 150 mg neem nie
- Indien u hipersensitief (allergies) is vir ibandronaatsuur, of enige van die ander bestanddele van BONIVA 150 mg (gelys in afdeling 6.1).

- Indien u tans lae bloedkalsium het, of glo dat u dit dalk gehad het, raadpleeg asseblief u dokter.
- Indien u niere nie normaal funksioneer nie.
- Indien u sekere probleme met u slukderm/kospyp (esofagus) het, soos vernouing of probleme om te sluk.
- Indien u nie vir 'n uur op 'n slag regop kan staan of sit nie.

Moenie BONIVA 150 mg aan kinders of adolessente gee nie.

Waarskuwings en voorsorgmaatreëls
Sommige mense moet veral versigtig wees terwyl hulle BONIVA 150 mg neem.
Lig u dokter in:
- Indien u enige versteurings van minerale metabolisme het (soos vitamien D-tekort).
- 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 bobeen, heup, lies, arms of bene het.

U dokter kan u vra om 'n tandheelkundige ondersoek te ondergaan voordat u met behandeling met BONIVA 150 mg begin.

U moet goeie mondhigiëne handhaaf en roetine tandheelkundige ondersoeke ontvang terwyl u met BONIVA 150 mg 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 sere wat nie genees nie of afskeiding.

U moet kalsium- en vitamien D-aanvullings neem terwyl u BONIVA 150 mg ontvang.

Indien u al ooit probleme met u slukderm gehad het (die buis wat u mond met u maag verbind). Probleme met u slukderm kan u simptome gee wat insluit, erge pyn in die bors, erge pyn nadat u kos en/of vloeistof gesluk het, erge naarheid of braking. Indien u hierdie simptome ontwikkel, raadpleeg dadelik u dokter.

Kinders en adolessente
BONIVA 150 mg moet nie by kinders of adolessente jonger as 18 jaar gebruik word nie.

Ander medisyne en BONIVA 150 mg
Lig altyd u gesondheidsorgverskaffer on indien u enige ander medisyne neem. (Dit sluit alle komplementêre of tradisionele medisyne in.)

Noem enigiets wat u neem wat u oor die toonbank gekoop het, sonder 'n voorskrif; of enige aanvullings wat kalsium, magnesium, yster of aluminium bevat.

Aspirien en ander nie-steroïed anti-inflammatoriese medisyne (NSAIM's) kan die maag en ingewande irriteer. Bisfosfonate (soos BONIVA 150 mg) kan dit ook doen. Wees dus veral versigtig indien u pynstillers of anti-inflammatoriese middels neem terwyl u BONIVA 150 mg neem. (NSAIMs sluit ibuprofeen, natriumdiklofenak en naprokseen in).

Nadat u die maandelikse BONIVA 150 mg tablet gesluk het, wag vir 1 uur voordat u enige ander medikasie neem, insluitend tablette vir slegte spysvertering of medisyne, kalsiumaanvullings of vitamiene.

BONIVA 150 mg saam met kos en drank
Moenie BONIVA 150 mg saam met kos en drank neem nie (behalwe gewone water). BONIVA 150 mg is minder effektief indien dit saam met kos geneem word.

Swangerskap, borsvoeding en vrugbaarheid
Moenie BONIVA 150 mg neem indien u swanger is of borsvoed nie. Indien u borsvoed, moet u dalk stop om BONIVA 150 mg 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 150 mg neem.

Bestuur en gebruik van masjinerie
U kan bestuur en masjinerie gebruik. Dit is baie onwaarskynlik dat BONIVA 150 mg u vermoë om te bestuur en masjinerie te gebruik sal beïnvloed.

BONIVA 150 mg bevat laktosemonohidraat en makrogol
Indien u deur u dokter meegedeel is dat u 'n onverdraagsaamheid teenoor sommige suikers het, kontak u dokter voordat u BONIVA 150 mg neem.

Makrogol kan die maag omkrap en diarree veroorsaak.

3. Hoe om BONIVA 150 mg te neem
Moenie medisyne wat aan u voorgeskryf is, met enige ander persoon deel nie.

Neem altyd BONIVA 150 mg presies soos u dokter of apteker u ingelig het. Indien u nie seker is oor iets nie, raadpleeg u dokter of apteker.

Die gewone dosis BONIVA 150 mg is een tablet een keer per maand.

Neem u maandelikse tablet
Dit is belangrik om hierdie instruksies noukeurig te volg. Hulle is ontwerp om te help dat u BONIVA 150 mg tablet vinnig u maag bereik, sodat dit minder geneig is om irritasie te veroorsaak.

- Neem een BONIVA 150 mg tablet een keer per maand.
- Kies een dag van die maand wat maklik sal wees om te onthou. U kan óf dieselfde datum (soos die 1ste van elke maand) óf dieselfde dag (soos die eerste Sondag van elke maand) kies om u BONIVA 150 mg tablet te neem. Kies die datum wat die beste by u roetine pas.
- Neem u BONIVA 150 mg tablet ten minste 6 ure nadat u laas iets gehad het om te eet of te drink, behalwe gewone water.
- Neem u BONIVA 150 mg tablet
  - nadat u vir die eerste keer die dag opgestaan het, en
  - voordat u iets anders eet of te drink (op 'n leë maag).
- Sluk u tablet met 'n vol glas gewone water (ten minste 180 mL).
- Moenie u tablet met mineraalwater, vrugtesap of enige ander drankies neem nie.
- Sluk u tablet heel – moenie dit kou, fyndruk of dit in u mond laat oplos nie.
- Vir die volgende uur (60 minute) nadat u die tablet geneem het

- **moenie gaan lê nie**; indien u nie regop bly nie (staan of sit), kan van die medisyne in u slukderm teruglek



- **moenie iets eet nie**



- **moenie iets drink** nie (behalwe gewone water indien u dit nodig het)
- **moenie enige ander medisyne neem nie**

- Nadat u 'n uur gewag het, kan u die eerste kos en drank van die dag neem. Sodra u geëet het, is dit goed om te gaan lê indien u wil, en om enige ander medikasie te neem wat u nodig het.

Moenie u tablet neem teen slaaptyd, of voordat u opstaan vir die dag nie.

Gaan voort om BONIVA 150 mg te neem
Dit is belangrik om aan te hou om BONIVA 150 mg elke maand te neem, vir so lank as wat u dokter dit vir u voorskryf. BONIVA 150 mg kan osteoporose slegs behandel solank u aanhou om dit te neem.

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

Indien u meer BONIVA 150 mg neem as wat u moes
In die geval van oordosering, raadpleeg u dokter of apteker. Indien nie een beskikbaar is nie, kontak die naaste hospitaal of gifhulpsentrum.

Indien u per ongeluk meer as een tablet geneem het, drink 'n vol glas melk en raadpleeg dadelik u dokter.

Moenie uself laat opgooi nie, en moenie gaan lê nie - dit kan veroorsaak dat BONIVA 150 mg u slukderm irriteer.

Indien u vergeet om BONIVA 150 mg te neem
Indien u vergeet om u tablet in die oggend van u gekose dag te neem, moenie later in die dag 'n tablet neem nie. Volg eerder hierdie instruksies:
Wanneer is dit tyd vir u volgende geskeduleerde dosis?
Indien u volgende geskeduleerde dosis meer as 7 dae weg is (of indien u vergete dosis minder as 3 weke laat is)

- neem een tablet die volgende oggend na die dag wat u onthou.
- neem dan weer u tablette op die geskeduleerde dae wat u op u kalender gemerk het.

Indien u volgende geskeduleerde dosis net 1 tot 7 dae weg is (of indien u vergete dosis meer as 3 weke laat is)

- wag totdat dit tyd is vir die volgende geskeduleerde dosis en neem dit soos normaal.

- neem dan weer u tablette op die geskeduleerde dae wat u op u kalender gemerk het.

Moet nooit twee BONIVA 150 mg tablette binne dieselfde week neem nie.

4. Moontlike newe-effekte
BONIVA 150 mg kan newe-effekte hê.

Nie alle newe-effekte wat vir BONIVA 150 mg aangemeld is, word by hierdie biljet ingesluit nie. Indien u algemene gesondheid verswak of indien u enige ongewenste gevolge ervaar terwyl u BONIVA 150 mg neem, 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 150 mg gehad. U sal dalk dringende mediese hulp of hospitalisasie nodig hê.

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/oë,
- irritasie van die slukderm, simptome sluit in erge pyn in die bors, erge pyn na die sluk van kos of drank, erge naarheid of braking,
- '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 bobeen, heup, lies, arms of bene,
- pyn, swelling en sere in die mond,
- oorpyn, 'n gevoel van volheid in die oor, gehoorverlies of 'n luiende sensasie in die ore.

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

Lig u dokter in indien u enige van die volgende opmerk:
Algemene newe-effekte:
- hoofpyn
- sooibrand, slegte spysvertering, diarree, maagpyn, naarheid,
- pyn in die spiere of gewrigte, spierkrampe, styfheid van die spiere
- griepagtige simptome (pyn, gevoel van ongemak).

Ongewone newe-effekte:
- hoes, kortasem, hygende asemhaling of benoude bors,
- duiseligheid
- braking, laat van winde of gas hê,
- rugpyn,
- moegheid.

Newe-effekte wat skaars is:
- inflammasie van die duodenum (eerste gedeelte van die derm), simptome sluit in branderigheid of krampe van die maag, opgeblase gevoel, gebrek aan eetlus of teerkleurige of donker stoelgang.

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

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 die SAHPRA se webwerf gevind kan word. Deur newe-effekte aan te meld, kan u help om meer inligting oor die veiligheid van BONIVA 150 mg te verskaf.

5. Hoe om BONIVA 150 mg te bêre
- Bêre alle medisyne buite bereik van kinders.
- Bêre teen of benede 30 °C.
- Hou in die oorspronklike verpakking totdat dit benodig word vir gebruik.
- Moenie gebruik ná die vervaldatum wat op die kartonboksie vermeld 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 150 mg bevat
Die aktiewe bestanddeel is ibandronaatsuur.
Elke filmbedekte tablet bevat 150 mg ibandronaatsuur.

Die ander bestanddele is:
Tabletkern: kolloïdale watervrye silika, kruispovidoon, laktosemonohidraat, mikrokristallyne sellulose, povidoon en stearіensuur. Filmbedekking: hipromellose, makrogol 6 000, talk en titaandioksied.

Hoe BONIVA 150 mg lyk en die inhoud van die verpakking
Wit tot naaswit filmbedekte tablette, van langwerpige vorm, gemerk "BNVA" aan die een kant en "150" aan die ander kant.

BONIVA 150 mg is beskikbaar in verpakkingsgroottes van 1 of 3 tablette in aluminium-aluminium of PVC/PVDC (dupleks)-aluminium stulpstroke.

Nie alle verpakkingsgroottes en/of verpakkingstipes word dalk bemark nie.

Houer van Sertifikaat van Registrasie
Adcock Ingram Limited
New Road 1
Erand Gardens,
Midrand, 1685
Kliëntediens: 0860 ADCOCK / 232625

Hierdie biljet is mees onlangs hersien op
17 Januarie 2025

Registrasie nommer
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adcock ingram

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