SCHEDULING STATUS
S4

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM
BIO-AMIODARONE 200 mg (tablets).

Read all of this leaflet carefully before you start taking BIO-AMIODARONE.
- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- BIO-AMIODARONE 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.

1. WHAT BIO-AMIODARONE CONTAINS
Active ingredient: Amiodarone hydrochloride.
Other ingredients: colloidal anhydrous silica, lactose monohydrate, magnesium stearate, maize starch, povidone and pregelatinised starch.
Contains sugar (lactose monohydrate).

2. WHAT BIO-AMIODARONE IS USED FOR
BIO-AMIODARONE belongs to a group of medicines called anti-dysrhythmics.
It works by controlling the uneven beating of your heart (called 'dysrhythmias').
BIO-AMIODARONE is used to:
- treat uneven heartbeats where other medicines either have not worked or cannot be used
- treat an illness called Wolff-Parkinson-White Syndrome. This is where your heart beats unusually fast
- treat other types of fast or uneven heartbeats known as 'atrial flutter' or 'atrial fibrillation'
- treat fast heartbeats which may happen suddenly and may be uneven. BIO-AMIODARONE is used only when other medicines cannot be used.

3. BEFORE YOU TAKE BIO-AMIODARONE
Do not take BIO-AMIODARONE:
- if you are hypersensitive (allergic) to amiodarone, iodine or any of the other ingredients of BIO-AMIODARONE
- you have a slower than usual heartbeat (called 'sinus bradycardia') or an illness called 'sino-atrial' heart block
- you have any other problems with your heartbeat and do not have a pacemaker fitted
- you have ever had thyroid problems. Your doctor should test your thyroid before giving you this medicine
- you are taking certain other medicines which could affect your heartbeat (see 'How to use BIO-AMIODARONE' below)
- you are pregnant or breastfeeding (see 'PREGNANCY AND BREASTFEEDING' below)
- you suffer from porphyria
- you suffer from high blood pressure
- you are taking any other anti-dysrhythmic medicines, e.g. sotalol, stimulant laxatives and injectable diltiazem, to regulate your heartbeat
- you are taking medicines such as astemizole, bepridil, IV erythromycin, halofantrin, pentamidin, sparfloxacin, sultopride, terfenadine, and vincamin.

Take special care with BIO-AMIODARONE:
- you have heart failure
- you have liver problems
- you have any problems with your lungs or have asthma
- you have any problems with your eyesight. This includes an illness called 'optic neuritis'
- you are about to have an operation
- you are elderly (over 65 years of age). The doctor will need to monitor you more carefully
- you have a pacemaker or implantable cardioverter defibrillator (ICD). Your doctor will check that your device is working properly shortly after you start taking the tablets or if your dose is changed.

Due to substantial toxicity, BIO-AMIODARONE is intended for use only in patients with indicated life-threatening dysrhythmias. BIO-AMIODARONE has several potentially fatal toxicities of which the most important are lung toxicity, followed by liver damage.
Keep out of direct sunlight while taking this medicine and for a few months after you have finished taking it.
This is because your skin will become much more sensitive to the sun and may burn, tingle or severely blister if you do not take the following precautions:
- make sure you use high factor sun cream
- always wear a hat and clothes which cover your arms and legs.

Taking BIO-AMIODARONE with food and drink:
Do not drink grapefruit juice while taking BIO-AMIODARONE. This is because drinking grapefruit juice while taking BIO-AMIODARONE can increase your chance of getting side effects.

Pregnancy and Breastfeeding:
If you are pregnant or breastfeeding your baby while taking BIO-AMIODARONE, please consult your doctor, pharmacist or other healthcare professional for advice.
You should not be given BIO-AMIODARONE if you are pregnant or breastfeeding.

Driving and using machinery:
You may have blurred eyesight after taking BIO-AMIODARONE. If this happens, do not drive or use any tools or machinery.

Important information about some of the ingredients of BIO-AMIODARONE:
BIO-AMIODARONE contains lactose and should not be administered to patients with rare hereditary problems, or a history of lactose intolerance, Lapp lactose deficiency or glucose-galactose malabsorption.

Using other medicines with BIO-AMIODARONE:
Always tell your healthcare professional if you are using any other medicines (this includes complementary or traditional medicines).
- other medicines for an uneven heartbeat (such as sotalol, quinidine-like medicines, procainamide, disopyramide)
- medicines for infections (such as intravenous erythromycin)
- medicines for malaria (such as halofantrine)
- medicines used for hay fever, rashes or other allergies called antihistamines (such as terfenadine, astemizole)
- stimulant laxatives (such as bisacodyl)
- verapamil and diltiazem
- steroids (systemically used gluco- and mineralocorticosteroids), tetracosactide and IV administered amphotericin B
- oral anticoagulant medication (such as warfarin)
- phenytoin.

If you are to be operated, the anaesthetist should be informed that you are taking BIO-AMIODARONE as potentially serious complications can occur.

4. HOW TO TAKE BIO-AMIODARONE
Take BIO-AMIODARONE by mouth. Swallow the tablets whole; do not crush or chew your tablets.
Do not share medicines prescribed for you with any other person.
Always take BIO-AMIODARONE exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.
In some cases, your doctor may then decide to either increase or lower the amount you take each day. This will depend on how you react to BIO-AMIODARONE.
Your doctor will tell you how long your treatment with BIO-AMIODARONE will last.
If you have the impression that the effect of BIO-AMIODARONE is too strong or too weak, tell your doctor or pharmacist.

Elderly:
The doctor may give you a lower dose of BIO-AMIODARONE. Also, the doctor should check your blood pressure and thyroid function regularly.

If you take more BIO-AMIODARONE than you should:
In the event of overdosage, consult your doctor or pharmacist. If neither is available, seek help at the nearest hospital or poison control centre.
Take the medicine pack with you. This is so the doctor knows what you have taken.
The following effects may happen: feeling dizzy, faint or tired, confusion, slow heartbeat, damage to the liver or vomitting.

If you forget to take / missed a dose of BIO-AMIODARONE:
If you forget a dose, take it as soon as you remember it. However, if it is nearly time for the next dose, skip the missed dose.
Do not take a double dose to make up for a forgotten tablet.

Effects when treatment with BIO-AMIODARONE is stopped:
Keep taking BIO-AMIODARONE until your doctor tells you to stop. Do not stop taking BIO-AMIODARONE just because you feel better. If you stop taking this medicine the uneven heartbeats may come back. This could be dangerous.

5. POSSIBLE SIDE EFFECTS
BIO-AMIODARONE can have side effects. Not all side effects reported for BIO-AMIODARONE are included in this leaflet. Should your general health worsen while taking BIO-AMIODARONE, please consult your doctor, pharmacist or other healthcare professional for advice.

The following side effects were reported frequently:
- micro-deposits develop in the eye in majority of patients. These are reversible on stopping therapy
- high blood pressure
- toxicity of the nervous system
- sensitivity of the skin to light
- lung disease.

Less frequent reported side effects are:
- lack of coordination of muscle movements and dizziness
- blue-grey colouring of skin on face, neck and arms
- uneven or fast heartbeat (new or exacerbated)
- over or under active thyroid gland
- inflammation of the epididymis (a curved structure at the back of the testicle in which sperm matures and is stored).

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

6. STORING AND DISPOSING OF BIO-AMIODARONE
- Store at or below 25 °C in a dry place. Protect from light.
- Do not remove the blisters from the cartons until required for use.
- KEEP ALL MEDICINES OUT OF REACH OF CHILDREN.
- Do not use after the expiry date printed on the blister.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

7. PRESENTATION OF BIO-AMIODARONE
Boxes containing 30 tablets in PVC/ALU blister.

8. IDENTIFICATION OF BIO-AMIODARONE
Round, scored flat white tablets, diameter 9.5 mm.

9. REGISTRATION NUMBER
34/6.2/0119

10. NAME AND ADDRESS OF THE REGISTRATION HOLDER
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11. DATE OF PUBLICATION
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Date of latest revision of the text as approved by Council: 30 September 2011
Date of notification with regard to amended Reg. 9 and 10: February 2015.

SKEDULERING STATUS
S4

HANDELSNAAM, STERKTE EN FARMASEUTIESE VORM
BIO-AMIODARONE 200 mg (tablette)

Lees hierdie inligtingsblad noukeurig voordat u begin om BIO-AMIODARONE te neem.
- Bewaar hierdie inligtingsblad. Dit mag nodig wees om dit weer te lees,
- Indien u enige verdere vrae het, raadpleeg asseblief u dokter of apteker.
- BIO-AMIODARONE is vir u persoonlik voorgeskryf en u moet nie u medisyne met ander persone deel nie. Dit mag skadelik vir hul wees, selfs al is hul simptome dieselfde as die wat u ervaar.

1. WAT BIO-AMIODARONE BEVAT
Aktiewe bestanddeel: Amiodaroon hidroklodied
Ander bestanddele: kolloïdale watervrye silika, laktose monohidraat, magnesium stereaat, mieliestysel, povidoon en vooraf-gelatineerde stysel
Bevat suiker (laktose monohidraat)

2. WAARVOOR WORD BIO-AMIODARONE GEBRUIK
BIO-AMIODARONE behoort aan 'n groep medisyne genaamd antidisritmiese middels.
Dit werk deur onreëlmatige hartklop te beheer (genaamd 'disritmieë').
BIO-AMIODARONE word gebruik om:
- behandeling van onreëlmatige hartklop waar ander medisyne nie gewerk het nie, of nie gebruik kon word nie
- behandeling van 'n toestand genaamd Wolff-Parkinson-White Sindroom. Dit is wanneer die hart ongewoon vinnig klop.
- behandel ander tipes van vinnige of onreëlmatige hartklop bekend as 'atriale fladder' of 'atriale fibrillasie'
- behandel skielike, vinnige hartklop wat ook onreëlmatig kan wees. BIO-AMIODARONE word slegs gebruik indien ander medisyne nie gebruik kan word nie.

3. VOORDAT U BIO-AMIODARONE NEEM
Moet nie BIO-AMIODARONE neem, indien:
- u hipersensitief (allergies) is vir amiodaroon, jodium of enige ander bestanddeel van BIO-AMIODARONE nie
- indien u 'n stadiger as gewone hartklop het (genaamd 'sinus bradikardie') of 'n toestand genaamd 'sino-atriale' hartblok.
- indien u enige ander probleme met u hartklop het en u nie 'n pasaangeër het nie
- indien u al voorheen skildklier probleme ondervind het. U doktor moet u skildklier toets voordat hierdie medisyne gegee word
- indien u ander medikasie neem wat u hartklop kan beïnvloed (sien 'Hoe om BIO-AMIODARONE te gebruik' hieronder)
- as u swanger is of borsvoed (sien 'SWANGERSKAP EN LAKTASIE' hieronder)
- u aan porfirie ly
- u aan hoë bloeddruk ly
- u enige ander antidisritmiese medisyne neem, bv. Sotalol, stimulerende-lakseermiddels en inspuitbare diltiasem, om u hartklop te reguleer
- indien u medisyne neem soos astemisool, bepridiel, IV eritromisien, halofantrien, pentamidien, sparfloksasien, sultopried, terfenadien of vinkamisien

Neem spesiale sorg met BIO-AMIODARONE:
- as u hartversaking het
- u lewerprobleme het
- u enige probleme met u longe of asma ondervind
- u enige probleme met u sig het. Dit sluit in 'n toestand genaamd 'optiese neuritis'
- u op die punt is om 'n operasie te ondergaan
- u bejaard is (oor 65 jaar in ouderdom). Die doktor sal u meer versigtig wil monitor
- u 'n pasaangeër of inplantbare kardioverter defibrillator (IKD) het. U doktor sal wil seker maak dat u toestel behoorlik werk kort nadat u die tablette begin neem of as u dosering verander.

As gevolg van wesenlike toksisiteit, word BIO-AMIODARONE slegs aanbeveel vir gebruik in pasiënte met lewensgevaarlike disritmieë. BIO-AMIODARONE het baie potensiële fatale toksisiteite waarvan die mees belangrike longtoksisiteit is, gevolg deur lewerskade.
Vermy direkte sonlig tydens gebruik van die medikasie en vir 'n paar maande nadat u gebruik daarvan gestaak het. *Dit is omdat u vel meer sensitief vir die son sal word, en u makliker sal brand, tinteling of ernstige blase kan voorkom, indien u nie die volgende voorsorgmaatreëls neem nie:*
- maak seker om 'n hoë faktor sonskerm te gebruik
- dra altyd 'n hoed en klere wat u arms en bene bedek

Neem van BIO-AMIODARONE met voedsel en drank:
Moet nie pomelosap drink terwyl u BIO-AMIODARONE neem nie. Dit is omdat pomelosap die voorkoms van newe-effekte sal verhoog terwyl u BIO-AMIODARONE neem.

Swangerskap en Borsvoeding:
Indien u swanger is of u baba borsvoed terwyl u BIO-AMIODARONE neem, moet u asseblief met u dokter, apteker of enige ander gesondheidsorgwerker konsulteer vir advies.
U moet nie BIO-AMIODARONE toegedien word indien u swanger is of borsvoed nie.

Bestuur en gebruik van masjinerie:
U mag versteurde sig ervaar nadat u BIO-AMIODARONE geneem het. Indien dit gebeur, moet u nie bestuur of enige ander masjinerie gebruik nie.

Belangrike inligting oor sommige van die bestanddele van BIO-AMIODARONE:
BIO-AMIODARONE bevat laktose en moet dus nie toegedien word aan pasiënte met seldsame oorerflike probleme, of 'n geskiedenis van laktose onverdraagsaamheid nie, Lapp-laktose ontoereikendheid of glukose-galaktose wanabsorpsie.

Gebruik van ander medisyne saam met BIO-AMIODARONE:
Lig altyd u gesondheidsorgwerker in, indien u enige ander medikasie neem (dit sluit komplimentêre of tradisionele medisyne in)

- Ander medisyne vir onreëlmatige hartklop (soos sotalol, kinidien-agtige medisyne, prokaïenamied, disopiramied):
- Medisyne vir infeksies (soos binneaarse eritromisien)
- Medisyne vir malaria (soos halofantrien)
- Medisyne vir hooikoors, uistlag of ander allergieë genaamd antihistamiene (soos terfenadien, astemisool)
- Stimulant lakseermiddels (soos bisakodiel)
- Verapamiel and diltiasem
- Steroïede (sistemies gebruik as gluko-en mineraalkortikosteroïede,) tetrakosaktiede en IV toegediende amfoterasien B
- Orale bloedverdunnings-medikasie (soos warfarien)
- Fenitoïen

Indien u op 'n operasie moet ondergaan, moet die narkotiseur ingelig word dat u BIO-AMIODARONE gebruik, omdat dit die moontlikheid van ernstige komplikasies kan verhoog.

4. HOE OM BIO-AMIODARONE TE NEEM
Neem BIO-AMIODARONE per mond. Sluk die tablette heel, moet nie fyndruk of kou nie. Moet nie medisyne wat vir u voorgeskryf is met ander persone deel nie.
Neem altyd BIO-AMIODARONE presies soos deur u dokter aanbeveel. U moet seker maak by u dokter of apteker as u onseker is.
In sommige gevalle, sal u dokter besluit om die hoeveelheid wat u per dag neem te verhoog of te verlaag. Dit sal afhang van hoe u op BIO-AMIODARONE reageer.
U dokter sal u inlig hoe lank die behandeling met BIO-AMIODARONE sal duur.
Indien u die indruk kry dat die effek van BIO-AMIODARONE op u te sterk of te swak is, moet u die dokter of apteker inlig.

Bejaardes:
Die dokter kan u moontlik 'n laer dosering van Bio-AMIODARONE gee. Die dokter moet ook u bloeddruk en skildklierfunksie gereeld nagaan.

Indien u meer BIO-AMIODARONE neem as wat u moet:
In die geval van oordosering, raadpleeg u dokter of apteker. As hul nie beskikbaar is nie, gaan na die naaste hospitaal of gifbeheersentrum.
Neem die medisyne verpakking saam. Dit is sodat die dokter weet wat u geneem het.
Die volgende effekte kan gebeur: duiseligheid, swakheid of moegheid, verwarring, stadige hartklop, skade aan die lewer of braking.

Indien u vergeet om BIO-AMIODARONE te neem, of 'n dosis oorslaan:
Indien u vergeet om 'n dosis te neem, neem so gou as u onthou. Indien dit egter naby aan die tyd vir die volgende dosering is, slaan dan die oorgeslaande dosis oor.
Moet nie dubbele dosisse neem om op te maak vir 'n oorgeslaande tablet nie.

Effek wanneer behandeling met BIO-AMIODARONE gestaak word:
Hou aan om BIO-AMIODARONE te neem totdat u dokter u aanraai om te staak. Moet nie behandeling met BIO-AMIODARONE staak , net omdat u beter voel nie. As u ophou om die medisyne te neem, kan die onreëlmatige hartkloppings terugkom. Dit kan gevaarlik wees.

5. MOONTLIKE NEWE-EFFEKTE
BIO-AMIODARONE kan newe-effekte hê. Nie alle newe-effekte wat al aangemeld is vir BIO-AMIODARONE is ingesluit in hierdie inligtingsblad nie. Indien u gesondheid verswak terwyl u BIO-AMIODARONE neem, raadpleeg u dokter, apteker of ander gesondheidsorgwerker vir raad.

Die volgende newe-effekte is algemeen aangemeld:
- mikro-neerslae wat in the oë van 'n groot hoeveelheid pasiënte ontwikkel. Hierdie is omkeerbaar wanneer behandeling gestaak word
- hoë bloeddruk
- toksisiteit van die senuweesisteem
- sensitiwiteit van die vel teenoor lig
- longsiekte

Minder algemene newe-effekte aangemeld is:
- verlies aan spierbeweging ko-ordinasie en duiseligheid
- blou-grys verkleuring van die vel of die gesig, nek en arms
- onreëlmatige of vinnige hartklop (nuut of vererger)
- oor-en onder aktiwiteit van die skildklier
- inflammasie van die epididimus ('n geboë struktuur aan die agterkant van die testikel waarin die sperm volwasse word en gestoor word)

Indien u enige ander newe-effekte wat nie in hierdie inligtingsblad genoem word nie, waarneem, lig asseblief u dokter of apteker in.

6. BEWARING EN VERNIETIGING VAN BIO-AMIODARONE
- Bewaar teen of benede 25 °C in 'n droë plek. Beskerm teen lig.
- Moet nie die stulpstoke uit die karton haal, tot dit benodig word vir gebruik nie.
- HOU ALLE MEDISYNE BUITE DIE BEREIK VAN KINDERS.
- Moet nie gebruik na die vervaldatum soos gedruk op die verpakking nie.
- Handig alle ongebruikte medisyne terug aan u apteker.
- Moet nie ongebruikte medisyne in dreineringsisteme of rioolsisteme wegspoel nie. (bv. toilette)

7. AANBIEDING VAN BIO-AMIODARONE
Karton wat 30 tablette in PVC/ALU stulpstroke bevat.

8. IDENTIFIKASIE VAN BIO-AMIODARONE
Ronde plat wit tablette met deursnee, 9,5 mm.

9. REGISTRASIE NOMMER
34/6.2/0119

10. NAAM EN ADRES VAN DIE REGISTRASIE HOUER

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