PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S3

1. NAME OF THE MEDICINE

IVABRADINE 5 UNICORN 5 mg film coated tablet

IVABRADINE 7,5 UNICORN 7,5 mg film coated tablet

Ivabradine

Contains sugar:

IVABRADINE 5 UNICORN contains 50 mg lactose monohydrate per film-coated tablet.

IVABRADINE 7,5 UNICORN contains 75 mg lactose monohydrate per film-coated tablet.

Read all of this leaflet carefully before you start taking IVABRADINE UNICORN

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist
- IVABRADINE UNICORN 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 IVABRADINE UNICORN is and what it is used for
2. What you need to know before you take IVABRADINE UNICORN
3. How to take IVABRADINE UNICORN

4. Possible side effects

5. How to store IVABRADINE UNICORN

6. Contents of the pack and other information

1. What IVABRADINE UNICORN is and what it is used for

IVABRADINE UNICORN contains ivabradine - a heart lowering medicine that regulates the heart rate. This lowers the heart's need for oxygen.

IVABRADINE UNICORN is used

- for the treatment of a condition called angina pectoris (which causes chest pain) in adult patients whose heart rate is over or equal to 70 beats per minute.. It is also used in combination with beta-blockers in adult patients whose condition is not fully controlled with a beta-blocker.
- to treat heart failure to reduce cardiovascular events, in combination with beta-blockers, or when you cannot either use or tolerate beta-blockers.

2. What you need to know before you take IVABRADINE UNICORN

Do not take IVABRADINE UNICORN:

- if you are hypersensitive (allergic) to ivabradine, or to any of the ingredients of IVABRADINE UNICORN
- If you have 3rd degree AV block (an abnormal heart rhythm).
- if you have a pacemaker
- if you have very low blood pressure or a slow heart rate (below 70 beats per minute)
- if you are suffering from cardiogenic shock (a heart condition treated in hospital)
- if you have heart failure which has recently become worse, or heart failure with

abnormality of ECG called bundle branch block

- if you are having a heart attack
- if you suffer from unstable angina (a severe form in which chest pain occurs very frequently and with or without exertion)
- if you congenital (inborn) long QT syndrome (heart rhythm disorder) seen on your ECG, or are taking medicines to control this disorder
- if you are taking medicines for the treatment of fungal infections (such as ketoconazole, itraconazole), macrolide antibiotics (such as azithromycin, clarithromycin, telithromycin or erythromycin given orally), medicines to treat HIV infections (such as nelfinavir, ritonavir)
- if you are taking a medicinal plant called St John's Wort
- if you have moderate or severe liver disease
- if you are taking medicines called verapamil or diltiazem for high blood pressure, chest pain and certain heart rhythm conditions
- if you are a woman able to have children and not using appropriate contraception with proven efficacy
- if you are taking any of the following heart medicine (quinidine, disopramide, bepridil, sotolol, ibutilide, amiodarone)
- if you use antidepressants, medicines for mental disorders
- if you have had a recent stroke
- if you suffer from a heart rhythm disorder

Warnings and precautions

Take special care with IVABRADINE UNICORN:

If you are taking IVABRADINE UNICORN and chest pain (angina) and your symptoms do not improve within 3 months, your doctor may discontinue this treatment.

- if you suffer from heart rhythm disorders (such as irregular heartbeat, palpitation, increase in chest pain) or sustained atrial fibrillation (a type of irregular heartbeat), or an abnormality of electrocardiogram (ECG) called 'long QT syndrome'
- your doctor will regularly check your heart rate in case it slows down (with symptoms such as tiredness, dizziness or shortness of breath) during treatment and adjust your dose if necessary
- if you have an unstable heart condition, as this needs to be stabilised before taking IVABRADINE UNICORN
- If you have symptoms such as tiredness or shortness of breath (this could mean your heart is slowing down too much)
- if you use other heart medicines that may slow down your heart rate, such as verapamil or diltiazem (see Do not take IVABRADINE UNICORN)
- if you suffer from a condition called congenital QT syndrome, where your heart-beat is fast and erratic
- if you suffer from any irregular heart beat conditions or an irregular pulse rate, your doctor will monitor your heart regularly
- if you suffer from symptoms of atrial fibrillation (pulse rate at rest unusually high (over 110 beats per minute) or irregular, without any apparent reason, making it difficult to measure)
- if you suffer from severe heart failure or heart failure with abnormality of ECG called 'bundle branch block'
- if you notice any deterioration in vision whilst taking IVABRADINE UNICORN or

have an eye condition called retinitis pigmentosa

- if you have a heart condition called Wolf-Parkinson-White syndrome (causing rapid heartbeat)
- if you have moderate to severe liver disease (see Do not take IVABRADINE UNICORN)
- if you have abnormal heart valves
- if you suffer from uncontrolled blood pressure, especially after a change in your antihypertensive treatment
- if you suffer from mild to moderate low blood pressure
- if you have recently suffered a stroke
- if you have severe kidney disease

Other medicines and IVABRADINE UNICORN

Always tell your healthcare provider if you are taking any other medicine. (This includes complementary or traditional medicines.)

Do not take IVABRADINE UNICORN with the following medicines (see Do not take IVABRADINE UNICORN):

- Antifungals (ketoconazole, itraconazole), antibiotics (ciclosporin, gestodene, clarithromycin, erythromycin, josamycin, telithromycin), HIV medicine (nelfinavir, ritonavir) and nefazodone
- Diltiazem and verapamil – to treat chest pain (angina) and prevent strokes, heart attacks and kidney problems as the effect of IVABRADINE UNICORN may be increased

Taking the following with IVABRADINE UNICORN is not recommended:

- Grapefruit juice, as this may enhance the effect of IVABRADINE UNICORN
- Heart medicines such as quinidine, disopramide, bepridil, sotolol, ibutilide may affect the way IVABRADINE UNICORN works (see Do not take IVABRADINE UNICORN)
- Antidepressants, medicines for mental disorders such as pimozide, ziprasidone, sertindole, mefloquine and halofantrine (used to treat malaria), pentamidine (to treat fungal infections), cisapride (to treat acid reflux) and erythromycin IV (antibiotic)

Taking the following medicines with IVABRADINE UNICORN must be done with caution:

- fluconazole (used in the treatment of yeast infections)
- Rifampicin (antibiotic), sedatives called barbiturates, phenytoin (to treat epilepsy) and St John's Wort (a medicinal plant), as this may affect the dose of IVABRADINE UNICORN
- Water tablets (called thiazide diuretics and loop diuretics) may increase the risk of reduced potassium levels in your blood and abnormal heartbeat

IVABRADINE UNICORN with food and drink

IVABRADINE UNICORN should be taken with food.

Avoid grapefruit juice during treatment with IVABRADINE UNICORN.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking IVABRADINE UNICORN.

Do not take IVABRADINE UNICORN if you are pregnant or are planning to have a baby (see Do not take IVABRADINE UNICORN).

Do not take IVABRADINE UNICORN if you are breastfeeding your baby.

Do not take IVABRADINE UNICORN if you are able to become pregnant unless you use reliable contraceptive measures (see Do not take IVABRADINE UNICORN).

Driving and using machines:

IVABRADINE UNICORN may cause temporary luminous visual phenomena (a temporary brightness in the field of vision). If this happens to you, be careful when driving or using machines at times when there could be sudden changes in light intensity, especially when driving at night.

It is not always possible to predict to what extent IVABRADINE UNICORN may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which IVABRADINE UNICORN affects them.

IVABRADINE UNICORN contains lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking IVABRADINE UNICORN.

3. How to take IVABRADINE UNICORN

Do not share medicines prescribed for you with any other person. Always use IVABRADINE UNICORN exactly as your doctor has instructed. You should check with your doctor or pharmacist if you are unsure.

Your doctor will decide on your dose of IVABRADINE UNICORN after assessing your heart condition.

IVABRADINE UNICORN tablets must be taken orally twice daily, i.e. once in the morning and once in the evening. IVABRADINE UNICORN tablets should be taken with food.

Adults:

The usual recommended starting dose of IVABRADINE UNICORN is 5 mg twice daily.
After two to four weeks of treatment, your doctor may increase the dose to 7,5 mg twice daily. dose to 2,5 mg (half a tablet|) twice a day.

Elderly:

In patients aged 75 years or more, your doctor will advise the starting dose of IVABRADINE UNICORN. In some cases, your doctor may prescribe half the dose i.e., one half 5 mg tablet (corresponding to 2,5 mg ivabradine) in the morning and one half 5 mg tablet in the evening.

Children:

The safety and efficacy of IVABRADINE UNICORN in children aged below 18 years have not yet been established. No data are available (see Do not take IVABRADINE UNICORN).

Your doctor will tell you how long your treatment with IVABRADINE UNICORN will last. Do not stop treatment early because treatment for angina or chronic heart failure is normally life- long.

If you have the impression that the effect of IVABRADINE UNICORN is too strong or too weak, tell your doctor or pharmacist.

If you take more IVABRADINE UNICORN than you should:

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

Symptoms of overdose may include:

- your heart rate will slow down and you may feel lightheaded, tired and dizzy

If you forget to take IVABRADINE UNICORN:

If you forget to take IVABRADINE UNICORN, take it as soon as you remember. If it is almost time for you next dose, skip the missed dose and continue to take the tablet or tablets at the usual time. Do not take a double dose to make up for forgotten individual doses.

If you stop taking IVABRADINE UNICORN

As the treatment for angina or chronic heart failure is usually life-long, you should discuss with your doctor before stopping IVABRADINE UNICORN.

4. Possible side effects

IVABRADINE UNICORN can have side effects.

Not all side effects reported for IVABRADINE UNICORN are included in this leaflet. Should your general health worsen, or if you experience any untoward effects while using IVABRADINE UNICORN, please consult your healthcare provider for advice.

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

- swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing
- rash or itching
- fainting

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to IVABRADINE UNICORN. 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 heart rate making you feel dizzy, tired or lightheaded
- irregular rapid contraction of the heart, abnormal perception of heartbeat, palpitations
- increased (high) or decreased (low) blood pressure

- blurred vision, distortion of light (brief moments of increased brightness, most often caused by sudden changes in light intensity)
- breathing problems (dyspnoea)

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

Tell your doctor if you notice any of the following:

Frequent side effects:

- headache, dizziness
- blurred vision

Less frequent side effects:

- abnormal blood test results (excess of eosinophils a type of white blood cell)
- gout (high blood levels of uric acid in the blood)
- sensation of spinning (vertigo)
- nausea, constipation, diarrhoea
- muscle cramps
- elevated creatinine in blood (a breakdown product of muscle), abnormal ECG heart tracing

The following side effects have been reported but the frequency for them to occur is not known:

- double vision, decreased or loss of vision
- abdominal pain
- swelling, rash, hives, skin reddening, itching, or other skin disorders

- feeling tired and weak, extreme exhaustion (fatigue), abnormal physical weakness, loss of strength (asthenia), general feeling of discomfort or illness (malaise)

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 or pharmacist. 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 Reporting Form**", found on SAHPRA's website: www.sahpra.org.za under "online services". By reporting side effects, you can help provide more information on the safety of IVABRADINE UNICORN.

5. How to store IVABRADINE UNICORN

- Store at or below 25 °C.
- Keep the blister strips in the outer carton until required for use.
- Store all medicines out of reach of children.
- Do not use after the expiry date printed on the blister or carton.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What IVABRADINE UNICORN contains

IVABRADINE 5 UNICORN contains 5,39 mg ivabradine hydrochloride corresponding to 5

mg of ivabradine base.

IVABRADINE 7,5 UNICORN contains 8,085 mg ivabradine hydrochloride corresponding to 7,5 mg of ivabradine base.

The other ingredients are colloidal anhydrous silica, croscarmellose sodium, lactose monohydrate, magnesium stearate (E470b), microcrystalline cellulose (E460(i)), Opadry White (consisting of glycerol (E422), hypromellose (E464), magnesium stearate (E470b), macrogol 6000 (E1521), titanium dioxide (E171)).

What IVABRADINE UNICORN looks like and contents of the pack

IVABRADINE 5 UNICORN: White coloured, oval shape, biconvex, film-coated tablet, scored and engraved with ´5´ on one side, plain on the other side.

IVABRADINE 7,5 UNICORN: White coloured, oval shape, biconvex, film coated tablet, scored and engraved with ´7.5´ on one side, plain on the other side.

Aluminium/aluminium blister strips packed in an outer carton containing 14, 28 or 56 tablets.

Holder of certificate of registration

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