

PATIENT INFORMATION LEAFLET

Ivolan 5 mg and Ivolan 7,5 mg

SCHEDULING STATUS

S3

IVOLAN 5 mg film coated tablets

IVOLAN 7,5 mg film coated tablets

Ivabradine

IVOLAN is sugar free

Read all of this leaflet carefully before you start taking IVOLAN

- 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.
- IVOLAN 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 IVOLAN is and what it is used for
2. What you need to know before you take IVOLAN
3. How to take IVOLAN
4. Possible side effects
5. How to store IVOLAN
6. Contents of the pack and other information

1. What IVOLAN is and what it is used for

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

IVOLAN is used:

- for the treatment of a condition called angina pectoris (which causes chest pain) in adult

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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 IVOLAN

Do not take IVOLAN:

- if you are hypersensitive (allergic) to ivabradine, or to any of the ingredients of IVOLAN (see section 6)
- 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 ECG abnormalities, 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 have 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

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- 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, sotalol, 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 IVOLAN:

- if you are taking IVOLAN, 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 electrocardiogram (ECG) abnormality 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 IVOLAN
- 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 **IVOLAN**)
- if you suffer from a condition called congenital QT syndrome, where your heartbeat is fast and erratic
- if you suffer from any irregular heartbeat 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)

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- if you suffer from severe heart failure or heart failure with an ECG abnormality called 'bundle branch block'
- if you notice any deterioration in vision whilst taking IVOLAN or have an eye condition called retinitis pigmentosa
- if you have a heart condition called Wolff-Parkinson-White syndrome (causing rapid heartbeat)
- if you have moderate to severe liver disease (see Do not take IVOLAN)
- 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 IVOLAN

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

Do not take IVOLAN with the following medicines (see Do not take IVOLAN):

- 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 IVOLAN may be increased

Taking the following with IVOLAN is not recommended:

- Grapefruit juice, as this may enhance the effect of IVOLAN
- Heart medicines, such as quinidine, disopramide, bepridil, sotalol and ibutilide, may affect the way IVOLAN works (see Do not take IVOLAN)

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- 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 IVOLAN 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 IVOLAN
- Water tablets (called thiazide diuretics and loop diuretics) may increase the risk of reduced potassium levels in your blood and abnormal heartbeat.

IVOLAN with food and drink

IVOLAN should be taken with food.

Avoid grapefruit juice during treatment with IVOLAN.

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 provider for advice before taking IVOLAN.

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

Do not take IVOLAN if you are breastfeeding your baby.

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

Driving and using machines

IVOLAN 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.

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It is not always possible to predict to what extent IVOLAN 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 IVOLAN affects them.

3. How to take IVOLAN

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

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

IVOLAN tablets must be taken orally twice daily, i.e. once in the morning and once in the evening.

IVOLAN tablets should be taken with food.

Adults:

The usual recommended starting dose of IVOLAN is 5 mg twice daily.

After two to four weeks of treatment, your doctor may increase the dose to 7,5 mg twice daily.

However, should your resting heartbeat reduce to less than 50 beats per minute, your doctor will reduce the dose to 2,5 mg (half a tablet) twice a day.

Elderly:

In patients aged 75 years or older, your doctor will advise the starting dose of IVOLAN. 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 IVOLAN in children aged below 18 years have not yet been established. No data are available.

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

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

If you take more IVOLAN than you should

In the event of overdose, 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 IVOLAN:

If you forget to take IVOLAN, take it as soon as you remember. If it is almost time for your 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 IVOLAN

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

4. Possible side effects

IVOLAN can have side effects.

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

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

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- 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 IVOLAN. 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)

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- 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, pharmacist or nurse. You can also report side effects to SAHPRA via the online service for adverse drug reaction reporting by following the link:

<https://www.sahpra.org.za/Publications/Index/8> ". By reporting side effects, you can help provide more information on the safety of IVOLAN. You can also send an email directly to the company, pharmacovigilance@pharmadynamics.co.za to ensure safety of the product.

5. How to store IVOLAN

Store all medicines out of reach of children.

Store at or below 30 °C

Do not remove tablet from blister until required for use.

Do not use after the expiry date stated on the carton.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

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6. Contents of the pack and other information

What IVOLAN contains:

The active substance is ivabradine.

IVOLAN 5 mg contains 5,96 mg ivabradine oxalate corresponding to 5 mg of ivabradine base.

IVOLAN 7,5 mg contains 8,94 mg ivabradine oxalate corresponding to 7,5 mg of ivabradine base.

The other ingredients are:

Colloidal anhydrous silica, crospovidone Type A, hydrogenated castor oil, microcrystalline cellulose.

Coating:

Carnuba wax

Opadry Orange

Opadry Orange:

HPMC 2910/Hypromellose, iron oxide yellow (E172), iron oxide red (E172), microcrystalline cellulose, stearic acid, titanium dioxide.

What IVOLAN looks like and contents of the pack

IVOLAN 5 mg: Salmon coloured, oblong shaped, biconvex, film coated tablet with a break-line on one side and plain on the other side.

The tablet can be divided into equal doses.

IVOLAN 7,5 mg: Salmon coloured, arc triangular shaped, biconvex, film coated tablet, plain on both sides.

IVOLAN tablets are packed into PVC film coated with PCTFE clear 250/76 and aluminium foil blister packs.

Blister strips are packed into a printed outer carton.

Each carton contains 56 tablets.

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Holder of Certificate of Registration

Pharma Dynamics (Pty) Ltd

1st Floor, Grapevine House, Steenberg Office Park

Silverwood Close

Westlake, Cape Town

7945, South Africa

Tel: +2721 707 7000

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IVOLAN 5 mg: A51/7.1.4/0921

IVOLAN 7,5 mg: A51/7.1.4/0922*

*This strength is currently not marketed