

PEXSIG

Perhexiline maleate

Consumer Medicine Information

Consumer Medicine Information

What is in this leaflet?

This leaflet answers some common questions about PEXSIG (perhexiline maleate) tablets.

It does not contain all of the available information about PEXSIG tablets.

It does not replace talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking PEXSIG tablets against the expected benefits.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What is PEXSIG

The name of your medicine is PEXSIG and is available in a 100 mg strength tablet.

The active ingredient is called perhexiline maleate.

Perhexiline belongs to a group of medicines called anti-anginal agents.

These are used to reduce the frequency of moderate to severe attacks of angina pectoris (severe chest pain caused by heart disease).

PEXSIG acts by increasing the efficiency of the heart.

Only use PEXSIG when your doctor prescribes it for you.

Ask your doctor if you have any questions about why PEXSIG has been prescribed for you.

If you have any concerns you should discuss this with your doctor.

This medicine is available only with a doctor's prescription.

Before you take PEXSIG

When you must not take it.

Do not take PEXSIG if you have:

- **Liver disease**
- **Kidney disease**
- **If you have ever had any unusual or allergic reaction to PEXSIG or any of its ingredients.**

If you are not sure, talk to your doctor about it.

When should I be careful about using PEXSIG?

You should tell your doctor before starting treatment with PEXSIG if you:

- **Have diabetes: if you use insulin or take a certain type of anti-diabetic tablet you may need to adjust your dosage during the first few days after starting on PEXSIG.**
- **Have kidney or liver disease.**
- **Are taking any medicines (whether prescription or non-prescription).**

Your doctor needs to know about other drugs you may be taking, particularly medicines known as beta-blockers and anti-diabetics. If your doctor wants you to stop taking beta-blockers, you must not stop them suddenly; but should withdraw them gradually over several days.

Should I use PEXSIG during pregnancy or breastfeeding?

Tell your doctor if you are pregnant or intend to become pregnant. As there is no experience with the use of PEXSIG in pregnant women, your doctor must weigh the potential benefits against the possible risks.

Do not take PEXSIG if you are breastfeeding.

Do not use PEXSIG after the expiry date (EXP) printed on the pack.

Do not purchase or use PEXSIG if the packing shows signs of tampering.

Do not give PEXSIG to children.

Should I drive or operate machinery while taking PEXSIG?

PEXSIG may cause dizziness or unsteadiness in some patients. If affected, do not drive a vehicle, operate machinery or do anything else that could be dangerous if you are dizzy or faint.

Should I take PEXSIG with other medicines?

Tell your doctor about any other medicines that you take, including medicines bought without a doctor's prescription.

There are several medicines, particularly medicines known as beta-blockers (used for heart conditions and high blood pressure) and anti-diabetics (used to treat diabetes), which may affect the way PEXSIG works.

Your doctor may still want you to take these other medicines but may need to adjust the dose of them or take other precautions.

You can still check with your doctor or pharmacist to see if you are taking any of these types of medicines.

How to take PEXSIG properly.

How much PEXSIG should I take?

The dose will be decided by your doctor and will depend on your condition and how you respond to PEXSIG.

A common starting dose is one PEXSIG tablet taken once or twice a day; your doctor may increase or decrease this dose at intervals, usually 2 to 4 weeks, based on the results obtained.

Generally, the dose should not exceed three PEXSIG tablets a day in divided doses. In some cases, a dose of 4 PEXSIG tablets per day may be necessary.

Do NOT take more tablets than your doctor has prescribed.

Some patients may require a lower dose than the 100 mg contained in PEXSIG tablets; in this case, PEXSIG tablets can be broken in half, giving 50 mg in each half tablet.

When should I take PEXSIG?

If your doctor has prescribed you more than one PEXSIG tablet per day, you will take them in divided doses as directed by your doctor. For example, if you have been prescribed two tablets per day, your doctor would probably direct you to take one tablet in the morning and one in the evening.

Follow the directions on the pharmacist's label on the pack. PEXSIG tablets should be swallowed whole with a glass of water.

How long do I need to take PEXSIG?

PEXSIG controls your condition but does not cure it. Therefore PEXSIG should be taken every day for as long as your doctor has prescribed it.

What if I miss a dose?

If you miss taking your PEXSIG dose, take the tablet(s) as soon as you remember and then go back to taking it as you would normally.

However, if it is almost time for your next dose, skip the missed dose and take your next dose. If you are unsure about this, ask your pharmacist or doctor.

Do not take a double dose to make up for the missed one.

Further information

Is a doctor's prescription required to obtain PEXSIG tablets? Yes.

Before you start taking PEXSIG, your doctor will examine you and have some blood tests carried out.

While you are taking PEXSIG, the doctor will repeat the examinations and tests at regular intervals (at least once a month) in order to see how you are responding and whether your body is tolerating the treatment.

One of these tests is to measure the amount of PEXSIG in your blood, so that your doctor may adjust the dose, if necessary.

If the blood tests or the examinations reveal certain results, your doctor may decide that you stop taking PEXSIG or change the dose.

If your doctor orders any blood tests, the fact that you are taking PEXSIG may cause some changes in the results which your doctor may discuss with you.

Remember that this medicine is for you. Only a doctor can prescribe it for you. Never give it to someone else. It may harm them even if they have the same condition as you.

What unwanted effects may PEXSIG cause?

Although most people benefit from taking PEXSIG, it may have unwanted effects.

The following unwanted effects have been reported in patients taking PEXSIG (most unwanted effects usually occur in the first few weeks of treatment and some may disappear in 2 to 4 weeks). More often they go away if the dose is reduced. In some cases, they only go away if the treatment is stopped.

Serious unwanted effects

Immediately contact your doctor, or, if your doctor is not available, go to the nearest casualty department at your nearest hospital, if you develop any of the following symptoms:

- **Muscle weakness**
- **Numbness or tingling**
- **Weakness**
- **Loss of appetite**
- **Weight loss**

More common unwanted effects

(reported in 65% of patients)

- **Dizziness or drunken sensation**
- **Difficulty in/or changed walking**
- **Unsteadiness**
- **Nausea**
- **Vomiting**
- **Headache**
- **Lack of appetite and moderate weight loss (2 to 4 Kg)**
- **Temporary increases in blood substances from the liver**
- **Increases in blood fats**
- **Moderate decreases in blood sugar**
- **Alterations to the ECG (the electrical record of heart activity)**

Less common unwanted effects:

- **Profound weakness**
- **Nervousness**
- **Weariness and lack of interest**
- **Inability to sleep**
- **Tremors**
- **Numbness**
- **Tingling**
- **Fainting**
- **Disorders of the urinary and sexual organs**
- **Changes in sexual drive**
- **Flushing or sweating**
- **Rash or itchy rash.**

Rare, more severe, unwanted effects

- **Inflammation of the nerve roots of the skin and spine, and accompanied by fever (the first signs may be numbness, tingling and/or weakness in the legs with difficulty in walking)**
- **Severe lack of sugar in the blood**
- **Significant weight loss (more than 10%) and liver disease.**

Other unwanted effects not listed above may also occur in some patients. Tell your doctor if you notice any other unwanted effects or are concerned, or troubled in any way, by unwanted effects.

In case of overdose

If you accidentally take too many tablets, you will likely have the following symptoms:

- **Nausea**
- **Vomiting**
- **Unsteady walking**
- **Headache**

More severe symptoms, for example, liver damage or irregular or rapid heartbeat, may develop. Damage to the liver could occur.

You should immediately contact your doctor or go to the casualty department of your nearest hospital if you have taken too many PEXSIG tablets.

How should I store PEXSIG tablets?

Keep PEXSIG tablets out of reach of children.

Keep PEXSIG tablets away from direct sunlight and away from the damp and store below 30°Celsius.

Do not store them in the bathroom or near the kitchen sink.

Do not leave it in the car or on windowsills

Keep PEXSIG tablets in the pack given to you by your pharmacist. Only take your tablet(s) out of the bottle when it is time to take them.

Do not use the tablets after the expiry date shown on the pack. Note that the tablets are all right to use until the end of the month of the expiry date.

If your doctor tells you to stop taking PEXSIG tablets, return any left over to your pharmacist for disposal.

Where do I go for further information?

This is not all the information that is available on PEXSIG. If you have any more questions or are not sure about anything, ask your doctor or pharmacist.

Product description

What it looks like

A white to off-white tablet scored on one side. It is supplied in amber glass bottles containing 100 tablets.

Ingredients

Each PEXSIG tablet contains 100 mg of the active ingredient (perhexiline maleate).

Each tablet also contains the following excipients or non-active ingredients:

- **Lactose**
- **Starch-maize**
- **Sucrose**
- **Purified talc**

The tablets do not contain preservatives, gluten or azo dyes.

Sponsor

Sigma Pharmaceuticals (Australia) Pty Ltd (ACN 004 118 594)
96 Merrindale Drive
Croydon Victoria 3136
AUSTRALIA
Phone: (03) 9839 2800

The Australian Registration Number for PEXSIG 100 mg tablets is AUST R 52182

Date of initial preparation: March 1995.

Modified in August 1997 April 2000, March 2009.

File: J:\Croydon\Regulatory and Medical affairs\Medical Affairs\CMI's Approved\SPL and F&M CMI's\M - R Productss:PexsigCMI -New tablet Appearance (remove embossing).doc
March 2009.