

SIGMAXIN Tablets

Contains the active ingredient digoxin

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about SIGMAXIN.

It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits.

Your doctor has weighed the risks of you taking SIGMAXIN against the benefits they expect it will have for you.

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 SIGMAXIN

SIGMAXIN belongs to a group of medicines known as cardiac glycosides. They work by slowing down the rate while increasing the force of your heart when it beats.

It is used to treat certain heart problems, such as:

Chronic Heart failure

Heart failure is when your heart can't pump strongly enough to supply blood needed through out the whole body. It is not the same as a heart attack and does not mean that your heart stops.

Certain type of irregular heart beats

Irregular heart rhythms caused by an electrical problem in the upper chamber of your heart. They cause your heart to beat too fast or in an uneven way.

Your doctor may have prescribed SIGMAXIN for another reason.

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

There is no evidence that SIGMAXIN is addictive.

Before you take SIGMAXIN

When you must not take it

Do not take SIGMAXIN if you have an allergy to:

- **digoxin or other cardiac glycosides**
- **any of the ingredients listed at the end of this leaflet.**

Symptoms of an allergic reaction to SIGMAXIN may include:

- **shortness of breath, wheezing or difficulty breathing**
- **swelling of the face, lips, tongue or other parts of the body**
- **skin rash, itching or hives**

Do not take SIGMAXIN if you have or have had any of the following medical conditions:

- **intermittent or complete heart block or second degree atrioventricular block, (conditions where the heart misses beats) especially if there is a history of Stokes-Adams attacks.**
- **ventricular tachycardia and ventricular fibrillation (a type of irregular heart rhythm).**
- **irregular heart rhythm caused by cardiac glycoside overdose.**
- **certain other irregularities of heart rhythm.**

If you are not sure whether you should start taking SIGMAXIN, talk to your doctor or pharmacist.

Do not take SIGMAXIN after the expiry date (EXP) printed on the pack.

Do not take SIGMAXIN if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

Before you start to take it

Tell your doctor if you have allergies to:

- **any other medicines**
- **any other substances, such as foods, preservatives or dyes**

Tell your doctor if you are pregnant or intend to become pregnant.

Pregnant women may require an adjustment of the dose of SIGMAXIN during pregnancy. SIGMAXIN may have harmful effects on the developing baby if the dose is too high.

Tell your doctor if you are breast-feeding or plan to breast-feed.

Tell your doctor if you have or have had any medical conditions, especially the following:

- Heart disease
- Heart disease caused by lack of vitamin B, known as 'Beri-Beri disease'
- Lung problems
- Liver or kidney problems - effect of SIGMAXIN may be increased because of slower removal from the body
- Thyroid disease - patients with low or high thyroid gland activity may be more or less sensitive to the effects of SIGMAXIN
- High or Low levels of calcium, potassium in your blood
- Low level of magnesium in your blood
- Digestion problems

If you have not told your doctor or pharmacist about any of the above, it is important to tell them before you start taking SIGMAXIN.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and SIGMAXIN may interfere with each other.

These include:

- amphetamine, appetite suppressants, medicines for colds, sinus problems, hay fever or other allergies - may increase the risk of heart rhythm problems
- medicines for heart problems, including high blood pressure (hypertension) and irregular heart beat (arrhythmia)
- diuretics (water tablets),
- potassium supplements
- medicines for cancer
- medicines for depression

- medicines for bacterial infection (antibiotics)
- medicines for fungal infections (antifungals)
- medicines for stomach problems, including for nausea, vomiting, diarrhoea or indigestion
- some laxatives
- medicines for relieving asthma attacks or other breathing problems
- corticosteroids (e.g. hydrocortisone, dexamethasone, prednisolone, prednisone)
- medicines for diabetes (e.g. insulin, glucagon)
- cholestyramine, a medicine used for high cholesterol
- phenytoin, a medicine used to control epilepsy
- indomethacin - medication used for inflammation, gout or arthritis
- St John's Wort

St John's Wort may interfere with SIGMAXIN.

These medicines may be affected by SIGMAXIN, or may affect how well it works. You may need different amounts of your medicine, or you may need to take different medicines. Your doctor will advise you.

If you not sure if any of the above apply to you, talk to your doctor or pharmacist before taking SIGMAXIN.

How to take SIGMAXIN

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the pack, ask your doctor or pharmacist for help.

How much to take

Your doctor or pharmacist will tell you how much SIGMAXIN you will need to take each day. This depends on your condition and whether or not you are taking any other medicines.

How to take it

Tablets:

Swallow SIGMAXIN tablets with a glass of water.

After you begin taking SIGMAXIN your doctor may sometimes check its level in your blood. This will help your doctor find out if your dose needs to be changed.

Do not change your dose of SIGMAXIN unless your doctor tells you to do so.

When to take it

Take SIGMAXIN at same time each day.

Taking SIGMAXIN at the same time each day will have the best effect. It will also help you remember when to take it.

It does not matter if you take SIGMAXIN before or after food.

If you forget to take it

Take it as soon as you remember. However, if it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

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

This may increase the chance of you getting an unwanted side effect.

If you are not sure what to do, ask your doctor or pharmacist.

How long to take it

Continue taking SIGMAXIN for as long as your doctor tells you.

SIGMAXIN helps control your condition, but does not cure it. Therefore, you must take SIGMAXIN every day.

*If you take too much
(Overdose)*

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26), or go to Accident and Emergency at your nearest hospital, if you think that you or anyone else may have taken too much SIGMAXIN. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Symptoms of an overdose to SIGMAXIN include some of the side effects listed below.

Some early warning signs of overdose are loss of appetite, nausea, vomiting, diarrhoea, or extremely slow heart beat.

In infants and small children, the earliest signs of overdose are changes in the rate and rhythm of the heart beat.

Children may not show the other symptoms as soon as adults.

*While you are using
SIGMAXIN*

Things you must do

Tell your doctor immediately if you notice any side effects from SIGMAXIN.

Tell any other doctors, dentists, and pharmacists who are treating you that you are taking SIGMAXIN.

You must tell your doctor, dentist, or pharmacist that you are taking SIGMAXIN before you start taking any medicines you buy from a pharmacy, health food shop or supermarket.

If you plan to have surgery that needs a general anaesthetic, tell your doctor or dentist that you are taking SIGMAXIN.

If you become pregnant while taking SIGMAXIN, tell your doctor immediately.

If you need to have any medical tests while you are taking SIGMAXIN, tell your doctor.
SIGMAXIN may affect the results of some tests.

Be sure to keep all of your doctor's appointments so that your progress can be checked.

Your doctor will check your progress and may want to take some blood tests from time to time. This helps to prevent unwanted side effects.

Things you must not do

Do not give SIGMAXIN to anyone else, even if their symptoms seem similar or they have the same condition as you.

Do not take SIGMAXIN to treat any other complaints unless your doctor tells you to.

Do not stop taking SIGMAXIN, or change the dose, even if you are feeling better, without checking with your doctor.

Things to be careful of

Be careful driving or operating machinery until you know how SIGMAXIN affects you.

SIGMAXIN may cause dizziness, blurred vision, and faintness in some patients. Make sure you know how you react to SIGMAXIN, before you drive a car, operate machinery, or do anything else that could be dangerous if this happens.

Side effects

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Ask your doctor or pharmacist to answer any questions you may have.

If any of the following happen, tell your doctor or pharmacist immediately:

- nausea or vomiting, loss of appetite
- diarrhoea
- lower stomach pain
- slow or irregular heart beats (may be fast in children)
- unusual tiredness or extreme weakness
- general feeling of 'unwellness'
- blurred vision or visual disturbances (e.g. coloured halos around objects ie. yellow, green, or white)
- depression
- headache
- mental disturbances, such as confusion or feeling indifferent
- skin rash
- painful, swollen breasts, or breast enlargement in men
- bleeding or bruising more easily than normal

These may be serious side effects. You may need urgent medical attention. Serious side effects are rare or are caused by a dose of SIGMAXIN that is too high for you.

Tell your doctor immediately if you have:

- Palpitations
- Chest pain
- Shortness of breath or sweating

These can be symptoms of a serious heart problem caused by new irregular heart beats of a different type to those caused by atrial fibrillation (which SIGMAXIN is often used to treat). If these happen, tell your doctor immediately.

Your doctor may do regular checks on your blood levels of digoxin and body salts, as well as your kidney function to make sure SIGMAXIN is working safely for you.

This is not a complete list of side effects. Tell your doctor if you notice anything else that is making you feel unwell, even if it is not on this list.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

After taking SIGMAXIN

Storage

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Keep your SIGMAXIN tablets in the pack until it is time to take them.

If you take the tablets out of the pack, they will not keep well.

Store SIGMAXIN Tablets in a cool, dry place away from light and where temperature stays below 25 °C.

Do not store SIGMAXIN or any other medicine in the bathroom or near a sink.

Do not leave it in the car on hot days or on windowsills.

Heat and dampness can destroy some medicines.

Disposal

If your doctor tells you to stop taking SIGMAXIN has passed its expiry date, ask your pharmacist what to do with any that is left over.

Product description

What it looks like

Tablets: (oral)

SIGMAXIN PG Tablets 62.5mcg, blue, biconvex, round tablet coded "U3A" on the upper face, bottom face plain; in bottles of 200.

SIGMAXIN Tablets 250mcg: white, biconvex, round tablet, scored and coded "X3A" on the upper face, bottom face plain; in blister packs of 100.

Ingredients

Active ingredient:

- Digoxin

Other ingredients:

SIGMAXIN Tablets: lactose, maize starch, rice starch, and magnesium stearate.

SIGMAXIN PG Tablets also contain povidone and indigo carmine - CI73015

The Australian Product Registration Numbers for:

SIGMAXIN Tablets: AUST R 90116

SIGMAXIN PG Tablets: AUST R 90114

Supplier

Sigma Pharmaceuticals (Australia) Pty Ltd

96 Merrindale Drive
Croydon Victoria 3136
Australia

Telephone: (03) - 9839 2800

This leaflet was prepared in May 2002 and updated in January 2009.