



Australian
Rheumatology
Association

PATIENT INFORMATION ON

SITAXENTAN

(Brand name: Thelin)

This information sheet has been produced by the Australian Rheumatology Association to help you understand the medicine that has been prescribed for you. It includes important information about:

- **How you should take your medicine;**
- **The possible side effects;**
- **What tests you will have to monitor your condition; and**
- **Other precautions you should take while taking sitaxentan.**

Please read it carefully and discuss with your doctor.

Important things to remember:

- While taking sitaxentan you should see your treating specialist regularly to make sure the treatment is working as it should, and to minimise any possible side effects.
- Sitaxentan should be taken at the same time each day.
- You should not stop your treatment unless your doctor tells you to.
- You should not increase or reduce the dose of sitaxentan unless your doctor tells you to.
- Contact your doctor at once if you experience symptoms such as nausea, stomach pain, low fever, loss of appetite, dark urine, clay-coloured stools, jaundice (yellowing of the skin or eyes).

What is sitaxentan?

Sitaxentan (brand name Thelin) is a medicine used to treat a condition called pulmonary arterial hypertension (PAH), which means increased pressure in the arteries that carry blood from your heart to your lungs. PAH can occur in a number of rheumatological diseases such as scleroderma, which cause thickening of the blood vessel walls. Symptoms include shortness of breath during routine activity, such as climbing stairs, tiredness and chest pain.

For more information about scleroderma see Scleroderma Australia website www.sclerodermaaustralia.com.au/what_is_scleroderma.html.

How does it work?

Sitaxentan helps lower blood pressure by preventing thickening of the blood vessels, especially those in the lungs and heart. This helps your heart pump blood through the blood vessels in the lungs more efficiently.

What benefit can you expect from your treatment and how is it monitored?

Sitaxentan can reduce the symptoms of PAH and in some cases, prolong life expectancy. It may take up to two months or more before your symptoms start to improve.

Before sitaxentan can be prescribed, you should be assessed by a specialist with experience in managing PAH. You will be asked to have the following tests:

- an ultrasound scan of your heart (echocardiogram);
- a right heart catheter (this is a test to measure the blood pressures in your heart and lungs. It involves inserting a tube into your heart from an artery in your neck or groin); and
- a six minute walk test (6MWT) to measure how far you can walk in six minutes.

Every six months, you will be asked to have the echocardiogram and the 6MWT to check that sitaxentan is still helping your condition.

How is sitaxentan taken?

Sitaxentan comes as 100mg tablets.

What is the dosage and when should it be taken?

The dose is one 100 mg tablet a day.

Sitaxentan should be taken at the same time each a day. If you forget to take a tablet you can take it later in the day. If it is the next day, take the normal dose (do not take a double dose).

Are other medicines taken with sitaxentan?

Sitaxentan may be taken in combination with other medicines, including:

- steroid medicines such as prednisolone;
- anti-inflammatory medicines (NSAIDs) such as naproxen (Naprosyn) or ibuprofen (Brufen/Nurofen);
- simple pain medicines such as paracetamol;
- calcium channel blockers (for Raynaud's disease);
- diuretics (fluid tablets);

- warfarin (blood-thinning medicine) see *Precautions*;
- other treatments for PAH.

There are a number of medicines that should **not** be taken when you are taking sitaxentan (see *Precautions*).

How long is the treatment continued?

Sitaxentan may be given on a long term basis provided it does not cause problems and continues to help your condition. It is usually given for as long as the 6-monthly tests (echocardiogram and 6MWT) show that it is of benefit.

Do not stop taking sitaxentan without first talking to your doctor. If your doctor does decide to stop the treatment, you may need to reduce the dose gradually before you stop the medicine completely.

Are there any side effects?

Most people who take sitaxentan do not experience side effects. Below are some side effects that you might experience with your treatment. Tell your doctor if you experience any problems. A reduction in dose may minimise the side effects so that you can continue to have treatment.

Tell your doctor if you experience any side effects.

Most common possible side effect::

- stomach upset including nausea and diarrhea;
- headache;
- inflamed throat and irritated nose passages;
- flushing;
- ankle and leg swelling;
- dizziness due low blood pressure;
- irregular heart beats;
- tiredness;
- skin rash or irritation;
- low red blood cell levels (anemia).

Less common or rare possible side effects:

- Sitaxentan can cause severe liver problems. Symptoms include nausea, stomach pain, low fever, loss of appetite, dark urine, clay-colored stools, jaundice (yellowing of the skin or eyes). **Call your doctor at once if you have any of these symptoms.**
- Low haemoglobin (anaemia) can be detected on blood tests but rarely causes symptoms.
- There are also a number of other uncommon side effects. It is a good idea to read the leaflet that comes with the medicine as it will list all the cautions and possible side effects.

What precautions are necessary?

Blood tests:

- Your liver function and blood counts for haemoglobin will need to be tested before you start taking sitaxentan, and again each month during your treatment.

Other medicines:

- Sitaxentan can interact with other medicines. You should tell your doctor (including your general practitioner, rheumatologist and others) about all medicines you are taking or plan to take. This includes over the counter or herbal/naturopathic medicines. You should also mention your treatment when you see other health professionals.
- The following medicines may interfere with sitaxentan. Some should not be taken with sitaxentan. For others, the dose may need to be adjusted.
 - cyclosporin (Sandimmune, Neoral);
 - cholesterol lowering medicines;
 - warfarin (a blood thinning medicine) – close monitoring is necessary as the warfarin dose will need to be reduced if sitaxentan is

commenced while you are on warfarin. You must speak to the doctor who prescribed the sitaxentan about how to reduce the dose of warfarin;

- HIV/AIDS medicines lopinavir or ritonavir (Kaletra, Norvir);
- tacrolimus (used to prevent rejection of liver or kidney transplants); and
- rifampicin (used for tuberculosis).
- The risk of side effects from the low doses of aspirin used to prevent heart attack and strokes is not increased when taken with sitaxentan.
- Sitaxentan can be taken safely with anti-inflammatory drugs (NSAIDs), as long as your kidney function is normal.
- The simple pain reliever, paracetamol, and combined medicines such as Panadeine and Panadeine Forte, can be used while taking sitaxentan provided you take them as directed.
- Most vaccines can be given safely with sitaxentan. Pneumovax and yearly flu vaccinations are safe and recommended to reduce your risk of those infections. Talk with your rheumatologist before receiving any vaccines.

Pregnancy and breastfeeding:

- Sitaxentan should not be taken during pregnancy or during breastfeeding.
- If you are a woman of child bearing age you should use effective contraception while taking sitaxentan.
- If you are planning a family or you become pregnant during your treatment you should discuss this with your doctor as soon as possible.

How to store sitaxentan

- Store sitaxentan at room temperature, away from heat, moisture and light (e.g. not in the bathroom).
- Keep out of reach of children.

Questions?

If you have any questions or concerns write them down and discuss them with your doctor.

Your doctor's contact details:

If you have been prescribed sitaxentan, you should see your specialist regularly to make sure the treatment is working as it should and to minimise any possible side effects.

The information in this sheet has been obtained from various sources and has been reviewed by the Australian Rheumatology Association. It is intended as an educational aid and does not cover all possible uses, actions, precautions, side effects, or interactions of the medicines mentioned. This information is not intended as medical advice for individual problems nor for making an individual assessment of the risks and benefits of taking a particular medicine. It can be reproduced in its entirety but cannot be altered without permission from the ARA.

The NHMRC publication: *How to present the evidence for consumers: preparation of consumer publications* (2000) was used as a guide in developing this publication.

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