

SCHEDULING STATUS

S4

THROMBOREDUCTIN 0,5 mg (CAPSULES)

Anagrelide, 0,5 mg

Read all of this leaflet carefully before you start taking THROMBOREDUCTIN

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- THROMBOREDUCTIN 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 THROMBOREDUCTIN is and what it is used for.
2. What you need to know before you take THROMBOREDUCTIN.
3. How to take THROMBOREDUCTIN.
4. Possible side effects.
5. How to store THROMBOREDUCTIN.
6. Contents of the pack and other information.

1. What THROMBOREDUCTIN is and what it is used for

THROMBOREDUCTIN contains the active substance anagrelide. THROMBOREDUCTIN is a medicine that inhibits the development of platelets (thrombocytes) in the bone marrow.



THROMBOREDUCTIN is used to reduce the number of platelets in patients with essential thrombocythaemia (which is disease when the bone marrow produces too many platelets). An excessive number of platelets can cause problems with blood circulation and clotting.

2. What you need to know before you take THROMBOREDUCTIN

Do not take THROMBOREDUCTIN if :

- you are hypersensitive (allergic) to anagrelide, or any of the other ingredients (*see ~~above~~ listed in section 6*);
- you suffer from severe cardiovascular disease;
- you are pregnant or breastfeeding;
- you have moderate to severe liver disease;
- you have severe kidney disease.

Warnings and precautions

Take special care with THROMBOREDUCTIN:

- If you suffer from heart diseases.
- If you have kidney or liver impairment.
- If you take aspirin.
- If you were born with or have a family history of a serious heart problem, called prolonged QT interval (seen on ECG, an electrical recording of the heart functions), or you are taking other medicines that result in abnormal ECG changes or if you have low levels of electrolytes, e.g. potassium, magnesium or calcium (*see section Other medicines and THROMBOREDUCTIN*).
- If you have hypertension.
- If you have lung problems.



- It is recommended that your doctor checks blood parameters, renal and liver function in regular weekly intervals during treatment with THROMBOREDUCTIN until you have reached your target dose, afterwards as decided by your doctor.
- After a 6 months period, you doctor will do blood tests to evaluate your health and your response to THROMBOREDUCTIN.

Other medicines and THROMBOREDUCTIN

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

Tell your doctor if you are taking any of the following medicines:

- There is a possible risk if THROMBOREDUCTIN and aspirin are taken together. Please inform your healthcare professional if you are taking aspirin.
- Medicines that can alter your heart rhythm.
- Certain types of antibiotics used to treat infections, such as enoxacin.
- Fluvoxamine, used to treat depression.
- Certain types of medicines to reduce the amount of acid in the stomach, such as omeprazole.
- Theophylline, used to treat lung diseases such as asthma.
- Medicines used to treat heart disorders, such as milrinone, enoximone, amrinone, olprinone and cilostazol.
- In some patients the use of this medicine may cause indigestion (e.g. diarrhoea) and may reduce the effect of oral contraceptives.

THROMBOREDUCTIN with food and drink and alcohol

Food does not influence the effect of THROMBOREDUCTIN.



Grapefruit juice may prolong the time of this medicine to be removed from your body. It is recommended that you do not drink grapefruit juice while you are taking THROMBOREDUCTIN

Pregnancy and breastfeeding and fertility

- THROMBOREDUCTIN must not be used during pregnancy.
- If you are pregnant or breastfeeding your baby while taking THROMBOREDUCTIN, please consult your doctor, pharmacist or other healthcare professional for advice.
- You have to take contraceptive measures during therapy. Please discuss the issue with your doctor.
- If you plan a pregnancy, discuss this with your doctor. Your doctor will find the best treatment option during pregnancy and breastfeeding.
- THROMBOREDUCTIN must not be used during breastfeeding.

Driving and using machinery

Thromboreductin 0,5 mg may cause dizziness and headache.

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

THROMBOREDUCTIN contains lactose

THROMBOREDUCTIN contains lactose which may have an effect on the control of your blood sugar if you have diabetes mellitus.

Patients with the rare hereditary conditions of lactose or galactose intolerance should not take THROMBOREDUCTIN.

3. How to take THROMBOREDUCTIN

- Do not share medicines prescribed for you with any other person.



- Always take THROMBOREDUCTIN exactly as your doctor or pharmacist has instructed you. You should check with your doctor or pharmacist if you are unsure.
- Please follow the dosing schedule your doctor has decided for you and do not change the dose without informing your doctor.
- If you have the impression that the effect of THROMBOREDUCTIN is too strong or too weak, talk to your doctor or pharmacist.
- The dose will be controlled in regular intervals by your doctor and adapted if necessary.

The usual dose of THROMBOREDUCTIN:

- Treatment with THROMBOREDUCTIN should be started with 0,5 mg daily (one capsule).
- Dose should then be increased or adjusted according to the discretion of your doctor.
- Generally the maintenance dose is 1 to 3 mg/day, dose increases should not exceed 1 capsule (0,5 mg) per week.
- The daily dose should be taken in a 2 to 3 times per day schedule.

How and when should THROMBOREDUCTIN be taken?

- Capsules should be swallowed without chewing with liquid e.g. water, in two (evening and morning) or three (every 8 hours) single doses.
- A change from a current medication to THROMBOREDUCTIN or to a combination of THROMBOREDUCTIN with another platelet reducing agent should be performed stepwise according to the discretion of your doctor.

How long should you take THROMBOREDUCTIN capsules?

- THROMBOREDUCTIN is for continuous use.
- Do not stop without informing the doctor as soon as possible.
- Your doctor will tell you how long your treatment with THROMBOREDUCTIN will last.



If you take more THROMBOREDUCTIN 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.

If you forget to take a dose of THROMBOREDUCTIN

- Do not take double the dose if you did not take the recommended number of capsules of THROMBOREDUCTIN or when you forgot to take your dose.
- This could lead to an increase of adverse events especially upon treatment initiation.
- Take the next dose your doctor has recommended at the scheduled dosing time and inform the doctor on the missed one.

If you stop taking THROMBOREDUCTIN

If you interrupt treatment with THROMBOREDUCTIN inform your doctor and do not stop treatment without talking to your doctor. Stopping treatment without informing you doctor can cause complications.

4. Possible side effects

THROMBOREDUCTIN can have side effects.

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

If any of the following happens, stop taking THROMBOREDUCTIN 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 THROMBOREDUCTIN. 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:

- Severe chest pain and shortness of breath (heart failure/heart attack);
- a very rapid heartbeat and severe chest pain associated with shortness of breath (ventricular tachycardia);
- shortness of breath, swelling in legs or ankles, and lips and skin can turn bluish colour (pulmonary hypertension);
- severe chest pain resulting from insufficient blood flow to the heart (angina pectoris);
- reduced sense of touch or sensation (hypoesthesia);
- accumulation of fluid in the chest or on the lung, lung infection, asthma;
- Torsade de Pointes (a potentially life-threatening, irregular heart rhythm);
- pulmonary fibrosis (an inflammation of the lungs which cause scarring of the lungs);
- tubulointerstitial nephritis (an inflammation of the kidneys).

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

Tell your doctor if you notice any of the following:

The following side effects have been reported frequently:

- Headache;
- reduction in red blood cell number (anaemia), localised skin bleeding;
- accumulation of fluid (oedema);
- sensation of spinning (vertigo), sensation of tingling and 'pins and needles', sleeplessness;
- abnormal eye sight;



- irregular heart beat (palpitations), rapid heart beat (tachycardia), high blood pressure;
- flushing;
- nose bleeds;
- feeling sick (nausea), diarrhoea, indigestion;
- skin itching and/or red skin;
- feeling weak or tired.

The following side effects have been reported less frequently:

- Reduction in blood platelets, bleeding, bruising;
- weight gain;
- depression, nervousness, dry mouth, migraine, reduced sense of touch or sensation (hypoesthesia);
- dryness of the mouth with decreased saliva;
- eye infection;
- ringing in the ears (tinnitus);
- heart rhythm disorders and other effects on the heart;
- shortness of breath, respiratory infection;
- vomiting, gas (flatulence), severe constipation, stomach pain;
- hair loss, itching;
- muscle and joint pain;
- kidney insufficiency, infection of the urinary tract
- pain, weakness;
- low blood pressure;
- inflammation of the stomach, loss of appetite;
- rash;
- increased need to pass water at night;



- increase of liver enzymes;
- “flu-like” like symptoms, chills, feeling of general discomfort;
- chest pain at rest (Prinzmetal angina).

The following side effects have been reported but it is not exactly known how often they occur:

- Torsade de Pointes (a potentially life-threatening, irregular heart rhythm);
- pulmonary fibrosis (an inflammation of the lungs which cause scarring of the lungs);
- tubulointerstitial nephritis (an inflammation of the kidneys);
- stroke.

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 or nurse. 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 Reaction Reporting Form”, found online under SAHPRA’s publications: <https://www.sahpra.org.za/>. By reporting side effects, you can help provide more information on the safety of THROMBOREDUCTIN.

How to store THROMBOREDUCTIN

- Store at or below 25 °C, in the original container.
- Do not use THROMBOREDUCTIN even if the shelf life has not expired and when you observe changes to the colour or the capsules are damaged.
- Return the capsules to your pharmacist.
- Store all medicines out of the reach of children.
- Do not store in a bathroom



- Do not use after the expiry date stated on the label / carton / bottle
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

5. Contents of the pack and other information

What THROMBOREDUCTIN contains:

The active substance is anagrelide

The other ingredients are:

- Povidone, crospovidone, microcrystalline cellulose, magnesium stearate, titanium dioxide E171, indigo carmine E 132 and gelatin.

Contains sugar: Lactose monohydrate

What THROMBOREDUCTIN looks like and contents of the pack

What THROMBOREDUCTIN looks like:

Blue/ blue opaque capsule, filled with a white powder.

THROMBOREDUCTIN is supplied as round, white opaque, polyethylene bottles with a white child resistant screw cap containing 100 capsules per bottle

Holder of Certificate of Registration and Manufacturer

Key Oncologics (Pty) Ltd

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Access to the corresponding Professional Information

Can be obtained on the SAHPRA website.

