THROMBOREDUCTIN 0.5MG CAPSULES

Anagrelide hydrochloride (0.5mg)

What is in this leaflet:

- 1. What Thromboreductin is used for
- 2. How Thromboreductin works
- 3. Before you take Thromboreductin
- 4. How to take Thromboreductin
- 5. While you are using Thromboreductin
- 6. Side effects
- 7. Storage and disposal of Thromboreductin
- 8. Product Description
- Manufacturer & Product Registration Holder
- 10. Date of revision

What Thromboreductin is used for

Thromboreductin is used to reduce the number of platelets in patients who have a disorder where the body produces too many blood platelets.

Large numbers of platelets can cause problems with blood circulation and clotting. Lowering the platelet count reduces the risk of serious problems.

How Thromboreductin works

Thromboreductin works in the body to reduce your platelet count.

Thromboreductin contains a medicine called anagrelide hydrochloride which acts on the bone marrow and slows down platelet production. This action lowers the platelet count in the blood to more normal levels and helps to prevent blood circulation problems.

Before you take Thromboreductin

When you must not use it

- You are allergic to an grelide or any of the other ingredients listed at the end of this leaflet.
- You have moderate or severe liver problems.
- You have moderate or severe kidney problems.

Before you start to take it

Tell your doctor if:

- · You have any problems with your liver or kidneys.
- · You have or think you might have a problem with your heart.
- · You are pregnant or planning a pregnancy.
- · You are breast feeding.

Thromboreductin contains lactose. If you have been told that you have an intolerance to some sugars, contact your doctor before taking the capsules.

Thromboreductin should not be taken during pregnancy. During therapy with Thromboreductin adequate contraceptive measurements have to be applied.

Breastfeeding is not allowed during therapy with Thromboreductin.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without prescription.

How to take Thromboreductin

Always take Thromboreductin capsules as your doctor has told you. The dosage will be set individually for you by your doctor. You should check with your doctor if you are not sure.

How much to take

The usual starting adult dose of Thromboreductin capsules is 1 mg (2 capsules) per day taken as one capsule twice a day, for at least one week.

Since only limited information is available on use in children, the recommended starting dose for children is 0.5 mg (1 capsule) a day.

The dosage for elderly patients will be set individually by the doctor.

When to take it

It is best to take the capsules at the same time every day. They may be taken with food, or after a meal or on an empty stomach.

Your capsules should be swallowed whole with water.

How long to take it

You should not normally stop taking Thromboreductin unless your doctor tells you to. If Thromboreductin has been successfully reducing the extra platelets in your blood, stopping Thromboreductin will cause the number of platelets in your blood to rise again within four days, so that the risk of problems with blood circulation may return.

If you forget to take it

If you forget to take a dose of Thromboreductin, take the missed dose as soon as you remember, unless it is almost time for your next dose. Skip the missed dose if it is almost time for your next regular dose. Do not take two doses at the same time.

If you take too much (overdose)

If you think that you or anyone else may have taken too many Thromboreductin Capsules contact a doctor or pharmacist immediately for advice, or go to a hospital emergency department, even if there are no signs of discomfort or poisoning. Symptoms of an overdose may include fast heartbeat, vomiting, bleeding.

While you are using Thromboreductin

Things you must do

Make sure that all of your doctors and pharmacists know that you are taking Thromboreductin.

Remind them that you are using Thromboreductin if you are about to start any new medicines.

Things you must not do

Do not give your medicine to anyone else, even if they have the same condition as you. It may not be safe for another person to take Thromboreductin.

Do not stop taking your Thromboreductin capsules or change the dosage without checking with your doctor.

Things to be careful of

Thromboreductin may cause dizziness in some patients.

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

Side Effects

Like all medicines, Thromboreductin can cause side effects, although not everybody gets them.

Some serious side effects that may occur include:

 Heart problems, including heart attack or a disturbed heartbeat, enlargement of the heart

THROMBOREDUCTIN 0.5MG CAPSULES

Anagrelide hydrochloride (0.5mg)

- Chest pain with or without overrapid breathing.
- Shortness of breath, wheezing or difficulty breathing.
- Cough.
- Abdominal pain or tenderness, stomach discomfort, vomiting blood or passing black stools.

If you notice any of these effects, please contact your doctor immediately.

The most common side effects with Thromboreductin are:

- Headache
- Aches and pains, including the back and the chest
- Dizziness
- Palpitations, an unusually rapid heartbeat
- Water retention, swelling of the hands or feet
- Abdominal pain
- Difficult or painful breathing
- Tiredness
- Loss of appetite
- Wind, diarrhoea, nausea, vomiting
- Feeling unwell
- Weakness, dizziness
- Fever
- Worsening of a cough
- Tingling sensation like pins and Needles

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel:03-78835550 , or visiting the website portal.bpfk.gov.my (Consumers → Reporting)

Storage and disposal of Thromboreductin

Keep out of the reach and sight of children.

Storage

Store below 25 °C.

Disposal

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

Ask your pharmacist what to do with any unused capsules.

Product Description

What it looks like

Blue hard capsule filled with a white powder.

One package contains 100 blue capsules.

Active ingredient

Each capsule contains 0.5 mg Anagrelide (as anagrelide hydrochloride)

Inactive ingredients

Capsule filling: Lactose Monohydrate, Povidone, Crospovidone, Microcrystalline Cellulose, Magnesium stearate Capsule shell: Titanium dioxide E171, Indigo Carmine E 132, Gelatine

MAL06030794AC

Manufacturer

Haupt Pharma GmBH, Pfaffenrieder Strasse 5, 82515 Wolfatshausen, Germany

Product Registration Holder

Hospira Malaysia Sdn. Bhd. Suite 6, Level 5, Menara LGB Jalan Wan Kadir Taman Tun Dr Ismail 60000 Kuala Lumpur

Date of revision

15 October 2015

Serial Number BPFK(r4/1)151015/00364