

Agrylin Capsules 0.5mg

Anagrelide (as hydrochloride)

Consumer Medication Information Leaflet (RiMUP)

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What Agrylin is used for

Agrylin is used to treat patients with essential thrombocythaemia.

Essential thrombocythaemia is a condition where the bone marrow produces too many blood cells of one type, known as platelets. Platelets help the blood to clot. Large numbers of platelets in the blood can cause serious problems with blood circulation and clotting.

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

How Agrylin works

Agrylin works in the body to reduce your platelet count.

Agrylin 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 Agrylin

When you must not use it

Do not take Agrylin if:

- You are allergic to anagrelide 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 use 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.

Agrylin contains lactose. If you have an intolerance/are sensitive to some sugars you should not take Agrylin.

Agrylin is not recommended in women who are or may become pregnant. If you become pregnant whilst taking Agrylin, you should stop taking the capsules and see your doctor immediately. Women taking Agrylin and who are at risk of becoming pregnant should make sure that they are using adequate contraception.

In combination with acetylsalicylic acid (aspirin), there is an increased risk of major haemorrhages (bleeding) (see Section 'Taking other medicines').

Taking other medicines

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

Some medicines and Agrylin may interfere with each other and may not work properly or cause other effects if taken together. These include:

- Acetylsalicylic acid (aspirin) or a medicine containing acetylsalicylic acid.
- Medicines used to treat depression such as fluvoxamine.
- Medicines used to treat gastrointestinal problems such as omeprazole.
- Medicines used to treat severe asthma and breathing problems such as theophylline.
- Medicines used to treat heart disorders such as milrinone, enoximone, amrinone, olprinone and cilostazol.
- Other medicines used to treat conditions affecting the platelets in your blood.

How to use Agrylin

Follow all instructions given to you by your doctor or pharmacist. They may differ from the information contained in this leaflet.

How much to use

The usual starting adult dose of Agrylin 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.

Then your doctor may either increase or decrease the number of capsules that you take to find the dose best suited to you and which treats your condition most effectively. Any dose increase must be not more than 0.5 mg (1 capsule) in any one week and any single dose taken during the day should be not more than 2.5 mg (5 capsules).

If you are elderly, you should take the normal adult dose.

Your doctor may check for heart disease both before you start and during your treatment.

Blood tests will be done at the beginning of your treatment and then at regular intervals. This will help your doctor to check that Agrylin is working effectively for you.

When to use 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 a glass of water.

How long to use it

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

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If you feel unwell during your course of treatment, tell your doctor.

If you forget to use it

If you forget to take a dose of Agrylin, 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 are not sure what to do, ask your doctor or pharmacist.

If you use too much (overdose)

If you think that you or anyone else may have taken too many Agrylin 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 Agrylin capsules

Things you must do

Make sure that all of your doctors and pharmacists know that you are taking Agrylin. Remind them that you are using Agrylin if you are about to start any new medicines. While on Agrylin, you should take the exact dose prescribed by your doctor.

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 Agrylin. You should not suddenly stop taking this medicine on your own, because you may have increased risk of stroke.

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

Things to be careful of

Agrylin may cause dizziness in some patients. Be careful driving or operating machinery until you know how Agrylin affects you.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Agrylin. Like all medicines, Agrylin can cause side effects, although not everyone

has them. Most side effects are mild and often wear off after a few weeks of treatment.

Some serious side effects that may occur include:

- Heart problems, including heart attack or a disturbed heartbeat, enlargement of the heart
- Stroke
- Chest pain with or without rapid breathing.
- Lung problems, including shortness of breath, wheezing or difficulty breathing.
- Allergic coughing.
- Abdominal pain or tenderness, stomach discomfort, vomiting blood or passing black stools.
- Yellowing of the skin and eyes caused by inflammation of the liver (hepatitis).
- Seizures.

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

The most common side effects with Agrylin 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
- Loss of appetite
- Wind, diarrhoea, nausea, vomiting
- Feeling unwell
- Weakness
- Fever
- Worsening of a cough
- Tingling sensation like pins and needles

Some patients who have been taking Agrylin have experienced: chills, flu symptoms, sensitivity to sunlight, irregular heart beat, bleeding, high blood pressure, angina, low blood pressure that can cause lightheadedness on standing up, blood clots,

widening of the blood vessels, migraine, fainting, mouth ulcers, burping, low levels of red blood cells (anaemia), decreased platelet count, swollen glands in the neck, armpit or groin, infection, an increase in liver enzymes (your doctor may do a blood test which may show an increase in your liver enzymes), flushing, constipation, dry mouth, bruises, muscle aches, painful joints, leg cramps, depression, feeling drowsy, confusion, insomnia (difficulty falling asleep), nervousness, memory loss, dehydration, runny nose, nose bleed, lung infection, infection of the sinuses, hair loss, skin problems, ear problems (ringing in the ear), double-vision, vision problems, pain when passing urine or blood in the urine, inflammation of the kidneys.

If any of these events cause you a problem, you should speak to your doctor.

As a precaution, your doctor may test your blood, liver and kidneys regularly during treatment with Agrylin.

Other side effects not listed above may also occur in some patients. Tell your doctor or pharmacist if you notice any side effects not mentioned in this leaflet.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of Agrylin

Storage

Store Agrylin capsules in their original bottle.

Do not use if the expiry date (EXP) printed on the bottle has passed.

Store Agrylin capsules where the temperature stays below 30°C.

Keep Agrylin capsules out of the reach and sight of children.

Disposal

If your doctor stops your medicine, do not keep any unused capsules unless your doctor tells you to.

Ask your pharmacist what to do with any unused capsules.

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Risalah Maklumat Ubat untuk Pengguna

Product Description

What it looks like

Agrylin Capsules 0.5mg are opaque, white, hard capsules. They are marked with ‘S 063’.

Ingredients:

Each capsule contains 0.5 mg of the active ingredient, anagrelide (as anagrelide hydrochloride).

The other non-medicinal ingredients are:

Capsule contents: povidone, crospovidone, anhydrous lactose, lactose monohydrate, microcrystalline cellulose and magnesium stearate.

Capsule shell: gelatine and titanium dioxide (E171).

Printing ink: shellac, dehydrated alcohol, isopropyl alcohol, butyl alcohol, propylene glycol, strong ammonium solution, potassium hydroxide, black iron oxide (E172), water.

MAL Number:

MAL13055062ACRZ

Manufacturer

Patheon Manufacturing Services LLC
5900 Martin Luther King Jr. Highway
Greenville
North Carolina
27834 United States

Packed by:

Delpharm Evreux
5 Rue Du
Guesclin, Evreux,
27000, France

Product Registration Holder

Takeda Malaysia Sdn. Bhd.
Unit TB-L13-1, Level 13, Tower
B,
Plaza 33, No.1, Jalan Kemajuan,
Seksyen 13, 46200 Petaling Jaya,
Selangor Malaysia

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