

AGRYLIN®

Anagrelide Hydrochloride

Consumer Medicine Information

What is this leaflet?

This leaflet answers some common questions about AGRYLIN capsules. It does not contain all of the available information. Reading this leaflet 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 AGRYLIN capsules against the benefits they expect it will have for you.

If you have any concerns about taking AGRYLIN, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may want to read it again.

Ask your doctor or visit the Health Authority website (in Australia: www.ebs.tga.gov.au and in New Zealand: www.medsafe.govt.nz) for the latest Consumer Medicine Information.

What AGRYLIN are used for

AGRYLIN capsules contain a medicine called anagrelide hydrochloride which acts upon the bone marrow and prevents it from producing too many of the blood cells known as "platelets".

In a disease such as "thrombocythaemia", the bone marrow produces too many of these cells, and the very large numbers of platelets in the blood can cause serious problems with blood circulation. By preventing too many platelets from being made,

AGRYLIN can help prevent these problems.

Your doctor may have prescribed AGRYLIN for another reason. Ask your doctor if you have any questions about why AGRYLIN have been prescribed for you.

AGRYLIN capsules are not addictive.

AGRYLIN is only available on a doctor's prescription.

Before you take AGRYLIN

When you must not take it

Do not take AGRYLIN if:

- You are allergic to anagrelide or any of the other ingredients listed at the end of this leaflet.
- AGRYLIN contains lactose and microcrystalline cellulose. These may cause a problem in a small number of people who are sensitive to them.
- You have severe liver problems.
- You are pregnant or breast feeding.
- The expiry date (EXP) printed on the bottle has passed. If you take AGRYLIN after the expiry date has passed, it may not work as well.
- The packaging is torn or shows signs of tampering.

Before you start to take it

Tell your doctor if:

- You have any allergies.

- You have had or now have any liver or kidney disease.
- You have heart disease, heart failure or are at high risk of vascular events (thrombosis or bleeding).
- You have an intolerance to some sugars, as AGRYLIN contains sugars as lactose.

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.

AGRYLIN should not be taken by anyone under 16 years of age.

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 AGRYLIN may interfere with each other. These include:

- Aspirin or a medicine containing aspirin.
- 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.

- Other medicines used to treat conditions affecting the platelets in your blood.
- Medicines containing sucralfate.

How to take AGRYLIN

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

How much to take

The recommended adult starting dose of anagrelide is 1 mg/day, which can be taken orally in two divided doses. This dosage will then be adjusted until your doctor has decided which dosage is best for you. Any single dose taken during the day should not exceed 2.5 mg. Your total daily dose should not exceed four times this, i.e. 10 mg (20 of the 0.5 mg capsules).

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

When to take it

Take your capsules the same time each day. This will help you remember when to take the capsules.

Food reduces the absorption of AGRYLIN slightly, but this does not have any effect on the ability of AGRYLIN to reduce your platelet count.

How long to take it

You should not normally stop taking AGRYLIN unless your doctor tells you to. If AGRYLIN have been successfully reducing the excess of 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.

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

If you forget to take AGRYLIN

If you forget to take a dose of AGRYLIN, leave out that dose completely. Take your next dose at the normal time it is due.

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

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

If you have trouble remembering to take AGRYLIN, ask your pharmacist for some hints.

If you take too much AGRYLIN

Immediately telephone your doctor or the National Poisons Information Centre (In Australia: telephone 13 11 26; in New Zealand: telephone 0800 POISON or 0800 764 766)) for advice or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much AGRYLIN. Do this even if there are no signs of discomfort or poisoning.

Symptoms of an overdose may include fast heartbeat, vomiting and bleeding.

While you are taking AGRYLIN

Things you must do

Make sure that all your doctors and pharmacists know about your use of AGRYLIN. Remind them if any new medicines are about to be started.

Tell your doctor immediately if you experience shortness of breath and fatigue while taking AGRYLIN.

Things you must not do

Do not take AGRYLIN to treat any complaint other than that directed by your doctor. It may not be safe to take AGRYLIN for another complaint.

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.

Do not stop taking your AGRYLIN 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 may have some side effects. Most side effects are mild and patients often find that these wear off after a few weeks.

Do not be alarmed by the following list of possible side effects. You may not experience any of them.

Some serious side effects that may occur include:

- Heart problems, including heart attack or a disturbed heartbeat, enlargement of the heart. As a precaution, your doctor may have to order some special straightforward heart function tests, both before and during your treatment.
- Chest pain with or without rapid breathing.
- Lung problems, including shortness of breath, wheezing or difficulty breathing.
- Severe abdominal or back pain (pancreatitis)
- Abdominal pain or tenderness, stomach discomfort, vomiting blood or passing black stools.
- Allergic coughing.

- Yellowing of the skin and eyes caused by inflammation of the liver (hepatitis).
- Unexplained bruising or bleeding, which can sometimes be serious if you are also taking aspirin.

If you suffer from any of these effects, you should contact your doctor immediately.

Less serious side effects that may occur include:

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

If these events persist, you should consult your doctor.

As a precaution, your doctor may have your blood, liver and kidney tested regularly during treatment with AGRYLIN.

Other side effects not listed above may also occur in some patients. Tell your doctor if you notice anything else that is making you feel unwell.

dose. If you take them out of their bottle, they may not keep well.

- Keep AGRYLIN in a cool dry place where the temperature stays below 25°C.
- Do not store it or any other medicine in the bathroom or near a sink.
- Do not leave it on a windowsill or in the car on hot or cold days. Heat, cold and dampness can destroy some medicines.
- Keep AGRYLIN 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.

Disposal

Ask your pharmacist what to do with any unused medicine.

Product description

What AGRYLIN look like

AGRYLIN 0.5 mg are white, opaque capsules, containing white powder. They are marked with Shire logo "S" on the cap and "063" on the body in black ink.

Ingredients

Each AGRYLIN capsules contains 0.5 mg of the active ingredient, anagrelide hydrochloride.

AGRYLIN also contain the following inactive ingredients:

- crospovidone
- lactose
- lactose monohydrate
- magnesium stearate
- microcrystalline cellulose
- povidone.

AGRYLIN are available in plastic bottles containing 100 capsules.

Sponsor

AGRYLIN capsules are supplied in Australia by:

Takeda Pharmaceuticals Australia Pty Ltd

Level 39; 225 George Street

Sydney NSW 2000

Australia

Telephone: 1800 012 612

www.takeda.com/en-au

AGRYLIN capsules are supplied in New Zealand by:

Takeda New Zealand Limited

Level 10, 21 Queen Street

Auckland,

New Zealand.

Telephone: 0508 169 077

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After using AGRYLIN

Storage

- Keep AGRYLIN capsules in their bottle until it is time to take your