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 Capsules, ask your doctor or pharmacist.

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

What AGRYLIN Capsules 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 "thrombocytopenia", 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 Capsules can help prevent these problems.

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

AGRYLIN Capsules are not addictive.

AGRYLIN Capsules are only available on a doctor's prescription.

Before you take AGRYLIN Capsules

When you must not take it

Do not take AGRYLIN Capsules if:
- You are allergic to anagrelide or any of the other ingredients listed at the end of this leaflet.
- AGRYLIN Capsules 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 Capsules 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).

If you become pregnant whilst taking AGRYLIN Capsules, you should stop taking the capsules and see your doctor immediately. Women taking AGRYLIN Capsules and who are at risk of becoming pregnant should make sure that they are using adequate contraception.

There is limited information on the use of AGRYLIN capsules in children less than 16 years of age and therefore this medicine should be used with caution.

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 Capsules 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 Capsules

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 Capsules unless your doctor tells you to. If AGRYLIN Capsules have been successfully reducing the excess of platelets in your blood, stopping AGRYLIN Capsules 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 Capsules**

If you forget to take a dose of AGRYLIN Capsules, 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 Capsules, ask your pharmacist for some hints.

**If you take too much AGRYLIN Capsules**

Immediately telephone your doctor or the Poisons Information Centre (telephone 0800 POISON (0800 764766)) 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 Capsules. Do this even if there are no signs of discomfort or poisoning.

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

**Side effects**

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking AGRYLIN Capsules. Like all medicines, AGRYLIN Capsules 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.
- 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).
- 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 Capsules.

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.

Disposal

Ask your pharmacist what to do with any unused medicine.

Product description

What AGRYLIN Capsules look like

AGRYLIN 0.5 mg Capsules 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 n Capsule contains 0.5 mg of the active ingredient, Anagrelide Hydrochloride.

AGRYLIN Capsules also contain the following inactive ingredients:
- crospovidone
- lactose anhydrous
- lactose monohydrate
- magnesium stearate
- microcrystalline cellulose
- povidone.

AGRYLIN Capsules are available in plastic bottles containing 100 capsules.

Sponsor

AGRYLIN Capsules are supplied in Australia by:
Shire Australia Pty Limited
Level 6
123 Epping Rd
North Ryde NSW 2113
Australia

Australian Registration Number:
AGRYLIN Capsules 0.5 mg
AUST R 71752

AGRYLIN Capsules are supplied in New Zealand by:
Shire New Zealand Limited
C/o Crowe Horwath
Level 29, 188 Quay Street
Auckland Central, Auckland
Telephone: 0508 169 077

This leaflet was prepared in November 2018

Agrylin® is a registered trademark of Shire US, Inc.