

AGRYLIN®

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using AGRYLIN?

AGRYLIN contains the active ingredient anagrelide hydrochloride. AGRYLIN is used to treat essential thrombocythaemia.

For more information, see Section [1. Why am I using AGRYLIN?](#) in the full CMI.

2. What should I know before I use AGRYLIN?

Do not use if you have ever had an allergic reaction to AGRYLIN or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use AGRYLIN?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with AGRYLIN and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use AGRYLIN?

- The recommended adult starting dose is 1 mg/day, which can be taken orally in two divided doses.
- Take the tablet the same time each day.

More instructions can be found in Section [4. How do I use AGRYLIN?](#) in the full CMI.

5. What should I know while using AGRYLIN?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using AGRYLIN. If you become pregnant while using this medicine, tell your doctor immediately.
Things you should not do	<ul style="list-style-type: none">• Do not stop using AGRYLIN or change the dosage without checking with your doctor.

<p>Driving or using machines</p>	<ul style="list-style-type: none"> • AGRYLIN may cause dizziness. Be careful driving or operating machinery until you know how AGRYLIN affects you.
<p>Looking after your medicine</p>	<ul style="list-style-type: none"> • Store AGRYLIN in a cool dry place where the temperature stays below 25°C.

For more information, see Section [5. What should I know while using AGRYLIN?](#) in the full CMI.

6. Are there any side effects?

Serious side effects include heart problems, lung problems, yellowing of the skin and eyes caused by inflammation of the liver (hepatitis), and severe abdominal or back pain (pancreatitis).

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI

AGRYLIN®

Active ingredient(s): anagrelide hydrochloride

Consumer Medicine Information (CMI)

This leaflet provides important information about using AGRYLIN. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using AGRYLIN.**

The information in this leaflet was last updated in September 2022. More recent information on the medicine may be available. You should ensure that you speak to your pharmacist or doctor to obtain the most up to date information on this medicine.

Where to find information in this leaflet:

- [1. Why am I using AGRYLIN?](#)
- [2. What should I know before I use AGRYLIN?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use AGRYLIN?](#)
- [5. What should I know while using AGRYLIN?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)
8. Instructions for preparing and injecting AGRYLIN

1. Why am I taking AGRYLIN?

AGRYLIN contains the active ingredient anagrelide hydrochloride. AGRYLIN 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.

2. What should I know before I take AGRYLIN?

Warnings

Do not take AGRYLIN if:

1. you are allergic to anagrelide, or any of the ingredients listed at the end of this leaflet

2. AGRYLIN contains lactose and microcrystalline cellulose. There may cause a problem in a small number of people who are sensitive to them.
3. you have severe liver problems.
4. you are pregnant or breast feeding.
5. 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.
6. the packaging is torn or shows signs of tampering.

Tell your doctor if you:

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

Pregnancy and breastfeeding

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.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements 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.

Your doctor may have to change your dose of other medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while using this medicine.

4. How do I take AGRYLIN?

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.
- If you are not sure, ask your doctor or pharmacist for advice.
- Follow all the directions given to you by your doctor or pharmacist carefully. They may differ from the information in this leaflet.

When to take AGRYLIN

- Take AGRYLIN at 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 to reduce your platelet count.

How long to take AGRYLIN

- 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.
- Abrupt treatment discontinuation or substantial reduction in AGRYLIN's dosage should be avoided, due to potentially severe clotting complications.
- 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 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

You should immediately:

- phone the National Poisons Information Centre (in Australia: telephone 13 11 26; in New Zealand: telephone 0800 POISON or 0800 764 766), or
- contact your doctor, or
- go to Accident and Emergency at the nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

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

5. What should I know while using 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.

Driving or using machines

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

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

Ask your pharmacist what to do with any unused medicines.

6. Are there any 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 are shown below:

Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none">● 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	<p>If these side effects persist, you should consult your doctor.</p>

Less serious side effects	What to do
<ul style="list-style-type: none"> ● Worsening of a cough ● Tingling sensation like pins and needles ● Alopecia (hair loss) 	

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> ● Heart problems, including heart attack, stroke or a disturbed heart 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) 	<p>Call your doctor immediately.</p>

Serious side effects	What to do
<ul style="list-style-type: none"> ● 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. 	

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

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

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side

effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

What AGRYLIN contains

Active ingredient (main ingredient)	Anagrelide hydrochloride
Other ingredients (inactive ingredients)	Crospovidone, lactose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, povidone.

Do not take this medicine if you are allergic to any of these ingredients.

What AGRYLIN looks like

AGRYLIN 0.5 mg capsule (AUST R 71752): White, opaque capsules, containing white powder. They are marked with logo "S" on the cap and "063" on the body in black ink.

AGRYLIN are available in plastic bottles containing 100 capsules.

Who distributes AGRYLIN

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

This leaflet was prepared in September 2022.

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