

Approved PIL

AGRYLIN® 0,5 mg

SCHEDULING STATUS:

S4

AGRYLIN® 0,5 mg capsules

Anagrelide (as hydrochloride)

Contains sugar : Anhydrous lactose (65,8 mg) and lactose monohydrate (53,7 mg)

Read all of this leaflet carefully before you start taking AGRYLIN

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- AGRYLIN has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What AGRYLIN is and what it is used for
2. What you need to know before you take AGRYLIN

3. How to take AGRYLIN
4. Possible side effects
5. How to store AGRYLIN
6. Contents of the pack and other information

1. What AGRYLIN is and what it is used for

AGRYLIN is a medicine which interferes with the development of platelets. It reduces the number of platelets produced by the bone marrow which results in a decrease in the platelet count in the blood towards a more normal level. For this reason it is used to treat patients with essential thrombocythaemia.

Essential thrombocythaemia is a condition which occurs when the bone marrow produces too many of the blood cells known as platelets. Large numbers of platelets in the blood can cause serious problems with blood circulation and clotting

2. What you need to know before you take AGRYLIN

Do not take AGRYLIN:

- If you are hypersensitive (allergic) to anagrelide or to any of the other ingredients in AGRYLIN (listed in section 6). An allergic reaction may be recognised as a rash, itching, swollen face or lips, or shortness of breath.
- If you have moderate or severe liver problems

Warnings and precautions

Take special care with AGRYLIN:

- If you have or think you might have a problem with your heart
- If you have any problems with your liver or kidneys
- If you are pregnant or breastfeeding

While taking AGRYLIN, you should take the exact dose prescribed by your doctor. Do not stop taking the medicine without first talking to your doctor. Do not abruptly stop taking this medicine without consulting your doctor. Abrupt withdrawal of medicine may lead to increased risk of stroke.

Signs and symptoms of stroke may include sudden numbness or weakness in the face, arm, or leg, especially on one side of the body, sudden confusion, trouble speaking, or difficulty understanding speech, sudden trouble seeing in one or both eyes, sudden trouble walking, dizziness, loss of balance, or lack of coordination and sudden severe headache with no known cause. Please seek immediate medical help.

Children and adolescents:

It is not recommended that AGRYLIN be taken by children

Other medicines and AGRYLIN

Always tell your doctor or pharmacist if you are taking or have recently taken any other

medicines, including those not prescribed. (This includes all complementary or traditional medicines)

Tell your doctor if you are taking any of the following medicines:

- Fluvoxamine used to treat depression
 - Omeprazole used to treat gastro-intestinal problems like reflux oesophagitis and duodenal and gastric ulcers
 - Theophylline used to treat severe asthma and breathing problems
 - Medicines used to treat heart disorders, for example, milrinone, enoximone, amrinone, olprinone and cilostazol
 - Acetylsalicylic acid (aspirin) used to treat mild to moderate pain, for example, headaches
 - Other medicines used to treat conditions affecting the platelets in your blood.
- AGRYLIN or these medicines may not work properly if taken together.
- If you are not sure, speak to your doctor or pharmacist for advice.

Pregnancy, breastfeeding and fertility:

Tell your doctor if you are pregnant or are planning to become pregnant. AGRYLIN should not be taken by pregnant women.

Women who are at risk of becoming pregnant should make sure that they are using effective contraception when taking AGRYLIN.

Speak to your doctor if you need advice with contraception.

Breast-feeding:

Tell your doctor if you are breast-feeding or if you are planning to breast-feed your baby. AGRYLIN should not be taken while breast-feeding. You must stop breast-feeding if you are taking AGRYLIN

Driving and using machines:

Dizziness has been reported by some patients taking AGRYLIN. Do not drive or use machinery if you are affected

AGRYLIN contains sugar (lactose)

If you have been told by your doctor that you have an intolerance to lactose, contact your doctor before using AGRYLIN as the use may result in stomach discomfort

3. How to take AGRYLIN

Do not share medicines prescribed for you with any other person.

Follow your doctor's instructions about how and when to take your capsules otherwise you will not fully benefit from your medicine. The amount of AGRYLIN that people take can be different, and this depends on your condition. Your doctor will prescribe the best dose for you. Check with your doctor if you are not sure.

The usual starting dose of AGRYLIN is 1 mg (2 of these capsules) per day, taken as one capsule twice a day, for at least one week. After this time, 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.

Your capsules should be swallowed whole with a glass of water. They may be taken with food or after a meal or on an empty stomach. It is best to take the capsules at the same time every day.

Do not take AGRYLIN with grapefruit juice or grapefruit pieces as it may affect your medicine.

Do not take more or less capsules than your doctor has recommended. Do not stop taking the medicine without first talking to your doctor. You should not suddenly stop taking this medicine on your own.

Your doctor will ask you to have blood tests at regular intervals to check that your

medicine is working effectively.

If you take more AGRYLIN than you should:

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

Show them the pack of AGRYLIN

If you forget to take AGRYLIN:

Take your capsules as soon as you remember. Take your next dose at the usual time.

Do not take a double dose to make up for forgotten individual doses.

4. Possible side effects

Like all medicines, AGRYLIN can have side effects. If you are worried, speak to your doctor.

Not all side effects reported for AGRYLIN are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking AGRYLIN, please consult your health care provider for advice.

Some patients have experienced serious side effects. These have not occurred commonly but if you notice any of the following, contact your doctor immediately or go to the casualty department at your nearest hospital:

- severe chest pain,
- palpitations associated with dizziness or feeling faint,
- severe abdominal or gastro-intestinal pain,
- vomiting blood or passing bloody or black stools,
- breathing difficulties or shortness of breath,
- particularly if your lips or skin turn a bluish colour

Common/Frequent side effects:

- headache,
- dizziness (rarely when standing up or getting out of bed), tiredness,
- palpitations (awareness of a forceful heartbeat which may be rapid or irregular),
- nausea,
- diarrhoea,
- stomach pain,
- indigestion and wind,
- vomiting,
- anaemia (a small reduction in red blood cell count and iron deficiency),
- fluid retention (including swelling of your ankles) or rash.

Uncommon/Less frequent side effects:

- a feeling of weakness or feeling unwell,
- high blood pressure,
- chills or fever,
- fainting,
- heartburn, anorexia,
- constipation,
- bruising,
- localised swelling with fluid (oedema),
- weight loss,
- muscle aches,
- painful joints,
- back pain,
- reduced feeling or tingling in toes or fingers,
- sleeplessness,
- depression,
- confusion,
- nervousness,
- dry mouth,
- loss of memory,
- breathlessness,
- nosebleed,
- lung infection,

- hair loss,
- skin itching or discolouration,
- impotence.
- Your doctor may do a blood test which may show an increase in your liver enzymes.

If any of these side effects cause you a problem, speak to your doctor

A few patients have experienced the following rare side effects:

- heart attack,
- bleeding gums,
- weight gain,
- heart muscle disease,
- loss of coordination,
- difficulty in speaking,
- dry skin,
- migraine,
- visual disturbances or double vision,
- ringing in the ears,
- increased need to pass water at night, pain,
- flu-like symptoms.

The following side effects have been reported but it is not known exactly how often they occur:

- Potentially life-threatening, irregular heartbeat
- Inflammation of the liver, symptoms include nausea, vomiting, itching, yellowing of the skin and eyes, discoloration of stool and urine
- Lung inflammation (signs include fever, coughing, difficulty breathing, wheezing; which causes scarring of the lungs)
- Inflammation of the kidneys
- Stroke (see section 2).

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.

By reporting side effects you can help provide more information on the safety of AGRYLIN.

5. How to store AGRYLIN

Keep all medicines out of the reach and sight of children.

AGRYLIN does not require any special storage conditions, but keep the container tightly closed and do not store in the bathroom.

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

Return any unused capsules to your pharmacist who will dispose of them safely. Do not dispose any unused medicine in drains or sewerage system (toilets, etc.).

Do not use after the expiry date stated on the pack

6. Contents of the pack and other information.

What AGRYLIN contains

The active substance is anagrelide. Each capsule contains 0,5 mg anagrelide (as hydrochloride).

The other ingredients are:

Povidone (E1201) crospovidone, anhydrous lactose, lactose monohydrate, microcrystalline cellulose (E460), magnesium stearate.

Capsule shell: gelatin and titanium dioxide (E171)

Printing ink: shellac, strong ammonium solution, potassium hydroxide (E525), black iron oxide (E172).

What AGRYLIN looks like and contents of the pack

AGRYLIN: Size #4, white opaque, capsule shell containing white powder, and imprinted with "S 063" in black ink.

100 capsules packed in white HDPE 60 cc round bottle; white child resistant polypropylene closure with pulp board liner, heat sealable foil, with pharmaceutical grade cotton and 0,8 g Sorb-it desiccant.

Holder of the certificate of registration

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