

PART III: CONSUMER INFORMATION



anagrelide hydrochloride capsules

This leaflet is part III of a three-part "Product Monograph" published when AGRYLIN was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about AGRYLIN. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for:

AGRYLIN is prescribed for the treatment of patients with thrombocythemia secondary to myeloproliferative disorders. Thrombocythemia is a condition in which there are too many platelets (the little cells which help the blood to clot) in the blood. Myeloproliferative disorders are diseases in which one or more of the types of cells that make up the blood are being overproduced.

Lowering platelet counts results in improving symptoms, including serious symptoms related to blockages in blood vessels and bleeding.

AGRYLIN is intended for long-term usage and has not been evaluated for treatment of the short-term life threatening complications of having too many platelets in the blood.

What it does:

The way that AGRYLIN works in the body to reduce your platelet count is not fully understood. AGRYLIN is believed to reduce the number of platelets by affecting megakaryocytes (the cells that produce platelets). Its action slows down platelet production.

Although AGRYLIN lowers platelet counts to more normal levels, it does not affect the body's natural process to clot blood when needed.

When it should not be used:

You should not take AGRYLIN if you:

- Have severe liver disease
- Are allergic to anagrelide or any of the other nonmedicinal ingredients (see What the nonmedicinal ingredients are:) in AGRYLIN.

What the medicinal ingredient is:

anagrelide hydrochloride

What the nonmedicinal ingredients are:

Black iron oxide, crospovidone, gelatine, lactose anhydrous, lactose monohydrate, magnesium stearate, microcrystalline cellulose, povidone, silicone dioxide, sodium lauryl sulphate, titanium dioxide

What dosage forms it comes in:

Capsule 0.5mg

WARNINGS AND PRECAUTIONS

BEFORE you use AGRYLIN talk to your doctor or pharmacist if:

- You have heart, lung, liver or kidney disease
- You are pregnant or planning a pregnancy
- You are breast feeding

AGRYLIN is not recommended in women who are or may become pregnant.

Limited data are available in patients under the age of 16 years.

Caution should be used when driving vehicles or machinery.

INTERACTIONS WITH THIS MEDICATION

Tell your doctor or pharmacist about any medication that you are taking, including non-prescription medications and natural health products.

Drugs that may interact with AGRYLIN include:

- acetylsalicylic acid,
- fluvoxamine,
- omeprazole,
- theophylline,
- milrinone,
- sucralfate,
- CYP1A2 substrates/inhibitors.

If AGRYLIN is taken in combination with acetylsalicylic acid (ASA), there is an increased risk of major bleeding. Before starting treatment, your doctor will consider for you the potential risks and benefits of using AGRYLIN with acetylsalicylic acid (ASA). If, for any reason, you already have an increased risk of bleeding, you should talk to your doctor.

Grapefruit juice may also interact with AGRYLIN. Food may slow down the rate at which AGRYLIN is absorbed into your body.

PROPER USE OF THIS MEDICATION

Usual Dose:

Take as directed by your doctor.

Your doctor may check for heart disease before starting you on AGRYLIN.

Regular blood tests will be done at the start of your treatment and then at intervals. This will help your doctor monitor the liver’s response to AGRYLIN and that AGRYLIN is working for you. If you have kidney or liver problems, your doctor will monitor their function while you are taking AGRYLIN.

Overdose:

Possible symptoms of an overdose of anagrelide could include low platelet count, which can potentially cause bleeding.

In case of drug overdose, contact a health care practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Missed Dose:

If you miss a dose at the beginning of your treatment, contact your doctor or pharmacist.

If you miss a dose during your long-term treatment, take the missed dose as soon as possible, 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.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

The most common side effects with AGRYLIN are:

Abdominal pain, back pain, cough, digestive problems, headache, diarrhea, fatigue, fever, gas, loss of appetite, malaise, nausea, pain, redness and itching of skin, sore throat, tingling, vomiting, whirling sensation.

You may also experience: bruises, chills, constipation, dry mouth, ear problems (ringing in the ear), flushing, flu symptoms, hair loss, infection, infection of the sinuses, insomnia (difficulty falling asleep), muscle and bone pain, neck pain, nervousness, respiratory disease, changes in weight, skin problems, sweating.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

| Symptom / effect | | Talk with your doctor or pharmacist | | Stop taking drug and call your doctor or pharmacist |
|---------------------|--|-------------------------------------|--------------|---|
| | | Only if severe | In all cases | |
| Very Common | Chest pain | | √ | |
| | Pounding or irregular heartbeat (palpitations) | | √ | |
| | Swelling in your feet or ankles (edema) | | √ | |
| | Trouble breathing or shortness of breath (dyspnea) | | √ | |
| Common | Bleeding | | √ | |
| | Blood in your stools or urine | | √ | |
| | Clot in a blood vessel (painful swollen leg) | | √ | |
| | Confusion | | √ | |
| | Dehydration | | √ | |
| | Depression (inability to concentrate, low mood) | | √ | |
| | Difficulty breathing (asthma) | | √ | |
| | Difficulty swallowing | | √ | |
| | Fast or irregular heartbeat (tachycardia) | | √ | |
| | Fever, cough, chest pain and shortness of breath (common signs of respiratory infection - pneumonia or bronchitis) | | √ | |
| High blood pressure | | √ | | |

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

| Symptom / effect | | Talk with your doctor or pharmacist | | Stop taking drug and call your doctor or pharmacist |
|----------------------|---|-------------------------------------|--------------|---|
| | | Only if severe | In all cases | |
| Common | Irritation or infection of the eye | | √ | |
| | Loss of consciousness | | √ | |
| | Loss of memory | | √ | |
| | Low blood pressure when standing or not (lightheaded, dizzy, shortness of breath or fainting) | | √ | |
| | Nose bleeding | | √ | |
| | Swollen legs or ankles or difficulty breathing (common signs of heart disease or heart failure) | | √ | |
| | Trouble with vision | | √ | |
| | Urinary problems | | √ | |
| Frequency not known* | Allergic coughing | | √ | |
| | Hepatitis (inflammation of the liver-symptoms include: nausea, vomiting, loss of appetite, yellowing of the skin or eyes, dark urine and unusual tiredness) | | √ | |
| | Inflammation of the kidneys (tubulointerstitial nephritis) | | √ | |

* Frequency of event cannot be determined from available data. This is not a complete list of side effects. For any unexpected effects while taking AGRYLIN, contact your doctor or pharmacist.

HOW TO STORE IT

Store from 15°C to 25°C in a light-resistant container. Keep out of reach of children.

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- Report online at www.healthcanada.gc.ca/medeffect
- Call toll-free at 1-866-234-2345
- Complete a Canada Vigilance Reporting Form and:
 - Fax toll-free to 1-866-678-6789, or
 - Mail to: Canada Vigilance Program
Health Canada
Postal Locator 0701D
Ottawa, Ontario
K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at www.healthcanada.gc.ca/medeffect.

NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

This document plus the full Product Monograph, prepared for health professionals can be obtained by contacting the sponsor, Shire Canada Inc.
2250 Alfred-Nobel Blvd., Suite 500
Saint-Laurent, Québec H4S 2C9
1-800-268-2772

This leaflet was prepared by Shire Canada Inc.

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