

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 MEDICATIONWhat the medication is used for:

AGRYLIN is prescribed for the treatment of patients with thrombocythemia secondary to myeloproliferative neoplasms. Thrombocythemia is a condition in which there are too many platelets (the little cells which help the blood to clot) in the blood. Myeloproliferative neoplasms 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 or its container.

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 were born with or have family history of prolonged QT interval (seen on ECG, electrical recording of the heart), or you are taking other medicines that result in abnormal ECG changes or if you have low levels of electrolytes in your blood e.g., potassium, magnesium or calcium
- 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.

Use of AGRYLIN with acetylsalicylic acid (ASA) has been associated with risk of major bleeding events.

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:

- medicines that can alter your heart rhythm
- acetylsalicylic acid
- fluvoxamine
- ciprofloxacin
- omeprazole
- theophylline
- milrinone
- sucralfate
- CYP1A2 substrates/inhibitors/inducers

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 and reductions in blood pressure.

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 seek immediate medical help
		Only if severe	In all cases	
Very Common	Chest pain		√	
	Palpitations: Pounding or irregular heartbeat		√	
	Edema: swelling in your feet or ankles		√	
	Trouble breathing or shortness of breath			√
Common	Bleeding		√	
	Blood in your stools or urine		√	
	Blood Clots: swelling, pain and redness in an arm or leg that can be warm to touch. You may develop sudden chest pain, difficulty breathing and heart palpitations			√
	Confusion		√	
	Dehydration		√	
	Depression: inability to concentrate, low mood		√	
	Asthma: difficulty breathing		√	
	Difficulty swallowing		√	
Fast or irregular heartbeat		√		
Respiratory Infection (pneumonia or bronchitis): fever, cough, chest pain and shortness of breath		√		

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 seek immediate medical help
		Only if severe	In all cases	
Common	High blood pressure		√	
	Hypoesthesia: decreased or loss of feeling or sensation such as numbness		√	
	Irritation or infection of the eye	√		
	Loss of consciousness			√
	Loss of memory		√	
	Low blood pressure: lightheaded, dizzy, shortness of breath or fainting; may occur when you go from lying or sitting to standing up		√	
	Nose bleeding		√	
	Heart disease or heart failure: swollen legs or ankles or difficulty breathing			√
	Trouble with vision		√	
	Urinary problems		√	
Uncommon	Supraventricular tachycardia, Ventricular tachycardia : irregular and abnormally fast heart beat			√
	Pulmonary hypertension: shortness of breath, swelling in legs or ankles or lips and skin can turn bluish colour			√

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 seek immediate medical help
		Only if severe	In all cases	
Frequency not known*	Allergic lung conditions: coughing, severe trouble breathing, shortness of breath, fever, chills, body aches			√
	Liver disorder: nausea, vomiting, loss of appetite, yellowing of the skin or eyes, dark urine and unusual tiredness		√	
	Kidney disorder: decreased urination, nausea, vomiting, swelling of extremities, fatigue		√	
	Torsades de pointes: life-threatening irregular heart rhythm, dizziness, fainting			√

* 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 and sight 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 1908C
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**If you want more information about AGRYLIN:**

- Talk to your healthcare professional
- Find the full product monograph that is prepared for health care professionals and includes the Consumer Information by visiting the Health Canada website <http://hc-sc.gc.ca>, the manufacturer's website www.shirecanada.com, by calling 1-800-268-2772

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