

Package leaflet: Information for the patient

Xagrid 0.5 mg hard capsules anagrelide

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Xagrid is and what it is used for
2. What you need to know before you take Xagrid
3. How to take Xagrid
4. Possible side effects
5. How to store Xagrid
6. Contents of the pack and other information

1. What Xagrid is and what it is used for

Xagrid contains the active substance, anagrelide. Xagrid 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 Xagrid

Do not take Xagrid

- If you are allergic to anagrelide or any of the other ingredients of this medicine (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;
- If you have moderate or severe kidney problems.

Warnings and precautions

Talk to your doctor before taking Xagrid:

- If you have or think you might have a problem with your heart;
- 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 e.g., potassium, magnesium or calcium (see section "Other medicines and Xagrid");

- If you have any problems with your liver or kidneys.

In combination with acetylsalicylic acid (a substance present in many medicines used to relieve pain and lower fever, as well as to prevent blood clotting, also known as aspirin), there is an increased risk of major haemorrhages (bleeding) (see section “Other medicines and Xagrid”).

Children and adolescents

There is limited information on the use of Xagrid in children and adolescents and therefore this medicine should be used with caution.

Other medicines and Xagrid

Tell your doctor or pharmacist if you are taking or have recently taken or might take any other medicines.

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

- Medicines that can alter your heart rhythm e.g., sotalol, amiodarone;
- Fluvoxamine, used to treat depression;
- Certain types of antibiotic, such as enoxacin, used to treat infections;
- 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 (a substance present in many medicines used to relieve pain and lower fever, as well as to prevent blood clotting, also known as aspirin);
- Other medicines used to treat conditions affecting the platelets in your blood, e.g., clopidogrel;
- Omeprazole, used to reduce the amount of acid produced in the stomach;
- Oral contraceptives: If you experience bad diarrhoea whilst taking this medicine, it may reduce how well the oral contraceptive works and use of an extra method of contraception is recommended (e.g., condom). See the instructions in the patient leaflet of the contraceptive pill you are taking.

Xagrid or these medicines may not work properly if taken together.

If you are not sure, speak to your doctor or pharmacist for advice.

Pregnancy and breast-feeding

Tell your doctor if you are pregnant or are planning to become pregnant. Xagrid 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 Xagrid. Speak to your doctor if you need advice with contraception.

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

Driving and using machines

Dizziness has been reported by some patients taking Xagrid. Do not drive or use machines if you feel dizzy.

Xagrid contains lactose

Lactose is an ingredient in this medicine. If you have been told that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. How to take Xagrid

Always take Xagrid exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

The amount of Xagrid that people take can be different, and this depends on your condition. Your doctor will prescribe the best dose for you.

The usual starting dose of Xagrid is 1 mg. You take this dose as one capsule of 0.5 mg twice a day, for at least a 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. Do not crush the capsules or dilute the contents in a liquid. You can take the capsules with food or after a meal or on an empty stomach. It is best to take the capsule(s) at the same time every day.

Do not take more capsules than your doctor has recommended.

Your doctor will ask you to have blood tests at regular intervals to check that your medicine is working effectively and that your liver and kidneys are working well.

If you take more Xagrid than you should

If you take more Xagrid than you should or if someone else has taken your medicine, tell a doctor or pharmacist immediately. Show them the pack of Xagrid.

If you forget to take Xagrid

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 a forgotten dose.

4. Possible side effects

Like all medicines, Xagrid can cause side effects, although not everybody gets them. If you are worried, speak to your doctor.

Serious side effects:

Uncommon: Heart failure (signs include shortness of breath, chest pain, swelling of the legs due to fluid build-up), severe problem with the rate or rhythm of the heartbeat (ventricular tachycardia, supraventricular tachycardia or atrial fibrillation), inflammation of the pancreas which causes severe abdominal and back pain (pancreatitis), vomiting blood or passing bloody or black stools, severe reduction in blood cells which can cause weakness, bruising, bleeding or infections (pancytopenia), pulmonary hypertension (signs include shortness of breath, swelling in legs or ankles, and lips and skin can turn bluish colour).

Rare: Kidney failure (when you pass little or no urine), heart attack.

If you notice any of these side effects, contact your doctor immediately.

Very common side effects: may affect more than 1 in 10 people

Headache.

Common side effects: may affect up to 1 in 10 people

Dizziness, tiredness, rapid heartbeat, irregular or strong heartbeat (palpitations), feeling sick (nausea), diarrhoea, stomach pain, wind, being sick (vomiting), reduction in red blood cell count (anaemia), fluid retention or rash.

Uncommon side effects: may affect up to 1 in 100 people

A feeling of weakness or feeling unwell, high blood pressure, irregular heartbeat, fainting, chills or fever, indigestion, loss of appetite, constipation, bruising, bleeding, swelling (oedema), weight loss, muscle aches, painful joints, back pain, decreased or loss of feeling or sensation such as numbness, especially in the skin, abnormal feeling or sensation such as tingling and ‘pins and needles’, sleeplessness, depression, confusion, nervousness, dry mouth, loss of memory, breathlessness, nosebleed, serious lung infection with fever, shortness of breath, cough, phlegm; hair loss, skin itching or discolouration, impotence, chest pain, reduction in blood platelets, which increases the risk of bleeding or bruising (thrombocytopenia), accumulation of fluid around the lungs or an increase in liver enzymes. Your doctor may do a blood test which may show an increase in your liver enzymes.

Rare side effects: may affect up to 1 in 1,000 people

Bleeding gums, weight gain, severe chest pain (angina pectoris), heart muscle disease, (signs include fatigue, chest pain and palpitations), enlarged heart, accumulation of fluid around the heart, painful spasm of the blood vessels on the heart (while resting, usually at night or early morning) (Prinzmetal angina), loss of coordination, difficulty in speaking, dry skin, migraine, visual disturbances or double vision, ringing in the ears, dizziness on standing up (especially when getting up from a sitting or lying position), increased need to pass water at night, pain, ‘flu-like’ symptoms, sleepiness, widening of blood vessels, inflammation of the large bowel (signs include: diarrhoea, usually with blood and mucus, stomach pain, fever), inflammation of the stomach (signs include: pain, nausea, vomiting), area of abnormal density in the lung, increased creatinine level in blood tests, which may be a sign of kidney problems.

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

- Potentially life-threatening, irregular heartbeat (Torsade de pointes);
- Inflammation of the liver, symptoms include nausea, vomiting, itching, yellowing of the skin and eyes, discoloration of stool and urine (hepatitis);
- Lung inflammation (signs include fever, coughing, difficulty breathing, wheezing; which causes scarring of the lungs) (allergic alveolitis, including interstitial lung disease, pneumonitis);
- Inflammation of the kidneys (tubulointerstitial nephritis).

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 via **the national reporting system** (see below). By reporting side effects you can help provide more information on the safety of this medicine.

United Kingdom

Yellow Card Scheme

Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store

Ireland

HPRA Pharmacovigilance

Website: www.hpra.ie

Malta

ADR Reporting

Website:

www.medicinesauthority.gov.mt/adrportal

5. How to store Xagrid

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and bottle label after EXP. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

If your doctor stops your medicine, do not keep any leftover capsules unless your doctor tells you to. Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Xagrid contains

The active substance is anagrelide. Each capsule contains 0.5 mg anagrelide (as anagrelide hydrochloride).

The other ingredients are:

Capsule contents: povidone (E1201); crospovidone; lactose, anhydrous; lactose monohydrate; cellulose, microcrystalline (E460) and magnesium stearate.

Capsule shell: gelatin and titanium dioxide (E171).

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

What Xagrid looks like and contents of the pack

Xagrid is supplied as opaque, white, hard capsules. They are marked with 'S 063'.

The capsules are provided in bottles containing 100 hard capsules. The bottle also contains a small sealed container. This contains a drying agent to keep the capsules dry. Keep the sealed container in the bottle. Do not remove or eat the drying agent.

Marketing Authorisation Holder and Manufacturer

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Detailed information on this medicine is available on the European Medicines Agency web site: <http://www.ema.europa.eu>. There are also links to other websites about rare diseases and treatments.