

Patient Leaflet According to the Pharmacists' Regulations (Preparations) - 1986

This medicine can be sold only with a doctor's prescription

ANAGRID 0.5 CAPSULES

Active ingredient:

Each capsule of Anagrid 0.5 contains:
Anagrelide (as HCl) 0.5 mg

For list of excipients, please see section 6.

Read this entire leaflet carefully before using this medicine.

This leaflet contains summary information about the medicine. If you have any further questions, please refer to your doctor or pharmacist. This medicine has been prescribed for your illness. Do not pass it on to others. It may harm them, even if you think that their illness is the same as yours.

1. What is the medicine used for?

The medicine is indicated for treatment of patients with essential thrombocythaemia in order to reduce the high blood platelet count and the risk of thrombosis, and to improve the associated symptoms.

Essential thrombocythaemia is a condition which occurs when the bone marrow produces too many platelets (type of blood cells). Large numbers of platelets in the blood can cause problems with blood clotting.

Therapeutic group:

Thrombolytic drugs

2. Before you take the medicine:

Do not use the medicine if:

- Do not use if you are hypersensitive (allergic) to the active ingredient or to any of the other ingredients of the medicine (for list of excipients, please see section 6).
- Do not use if you are pregnant or breastfeeding.
- Do not use if you suffer from moderate or severe liver problems.
- Do not use if you suffer from moderate or severe kidney problems.

Special warnings regarding the use of this medicine:

Before treatment with Anagrid, tell your doctor if:

- You have or think you might have a problem with your heart.
- You suffer from problems with your liver or kidneys.
- You are pregnant or breastfeeding.
- You are sensitive to lactose.

When Anagrid is taken in combination with aspirin, there is an increased risk of major haemorrhages (bleeding). See next section.

Possible interactions when taking other medicines in combination with Anagrid:

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including non-prescription drugs and nutrition supplements. Especially tell your doctor or pharmacist if you are taking any of the following medicines (please note that the following list indicates the active ingredients of the medicines. If you are not sure whether you are taking any of these medicines, please consult your doctor or pharmacist):

- Fluvoxamine (used to treat depression).
- Omeprazole (used to treat gastro-intestinal problems like reflux oesophagitis and duodenal and gastric ulcers).
- Theophylline (used to treat asthma and breathing problems).
- Medicines used to treat heart disorders (for

example, diltiazem, enoximone, amrinone, olprinone and cilostazol).

- Aspirin (used to relieve pain or as a platelets aggregation inhibitor).
- Other medicines affecting the platelets in your blood.

Taking this medicine with food:

The medicine can be taken regardless of mealtimes.

Pregnancy and breastfeeding:

- This medicine should not be taken by pregnant women. Women who might become pregnant should use a contraceptive when taking Anagrid.
- Tell your doctor if you are breastfeeding or if you are planning to breastfeed. Do not use this medicine if you are breastfeeding. You must stop breastfeeding if you are taking this medicine.

Driving and use of machinery:

Use of this medicine may cause dizziness. Do not drive or operate machines if you feel dizzy.

Use in Children:

There is limited information on the use of Anagrid in children and therefore it should be used with caution.

Important information about some of the medicine ingredients:

The medicine contains lactose. If you are sensitive to lactose, inform your doctor before taking this medicine (see section 6).

3. How to use this medicine?

Always take the medicine as your doctor has told you. If you are not sure, check with your doctor or pharmacist.

The dosage and administration will be determined by the doctor only.

The standard dosage is usually:

Starting dose of 1 mg (2 capsules of Anagrid) 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 per day, according to your condition.

Do not exceed the recommended dose.

The capsules should be swallowed whole with a glass of water, regardless of mealtimes.

It is recommended to take the capsules at the same time every day.

There is no information about opening the capsule and its dispersion.

Tests and follow up:

During the treatment your doctor may ask you to perform blood and urine tests to check the effect of the medicine on the body.

If you have accidentally taken a higher dosage:

If you have taken an overdose, or if a child has accidentally swallowed the medicine, proceed immediately to a doctor or a hospital emergency room and bring the package of the medicine with you.

If you forget to take the medicine

at the proper time, take the missed dose as soon as you remember. Take your next dose at the usual time. Do not take two doses at the same time.

You should follow the treatment course as prescribed by your doctor.

Even if your condition improves do not stop taking this medicine without consulting your doctor or pharmacist.

Do not take medicines in the dark! Check the label and the dose each time you take your medicine. Wear glasses if you need them.

4. Side effect:

Like all medicines, the use of Anagrid can cause side effects, in some patients. If these side effects persist or are bothersome or get worse, please consult your doctor.

Do not be alarmed while reading the list of side effects, you may not suffer from any of them.

Contact your doctor immediately, if you

notice any of the following serious side effects (uncommon):

Severe chest pain, palpitations (forceful heartbeat which may be rapid or irregular) associated with dizziness or feeling faint, fainting, severe abdominal or gastro-intestinal pain, vomiting blood, passing bloody or black stools and breathing difficulties or shortness of breath, particularly if your lips or skin turn a bluish color.

Very common side effects (appearing in more than 1 out of 10 patients):

Headache.

Common side effects (appearing in 1 to 10 out of 100 patients):

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

Uncommon side effects (appearing in 1 to 10 out of 1000 patients):

Weakness, feeling unwell, high blood pressure, chills or fever, heartburn, lack of appetite, constipation, bruising, localized oedema with swelling, 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, allergic coughing, breathlessness, nosebleed, lung infection, hair loss, skin itching or discolouration, impotence, increase in liver enzymes.

Rare side effects (appearing in 1 to 10 out of 10000 patients):

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.

Side effects that their frequency is unknown:

Inflammation of the liver (hepatitis) with an increase in liver enzymes, allergic inflammation of the lungs, inflammation of the kidneys.

If at any time you experience side effects that are not mentioned in this leaflet or if you feel an adverse change in your general health, consult your doctor immediately!

5. How to store the medicine?

- Avoid poisoning! This medicine, and all other medicines, must be stored in a safe place out of the reach of children and/or infants, to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by a doctor.
- Do not use the medicine after the expiry date (exp. date) stated on the package. The expiry date refers to the last day of that month.
- Storage conditions: store below 25°C.

6. Additional information

- In addition to the active ingredient this medicine also contains the following **inactive ingredients:**

Lactose, microcrystalline cellulose, crospovidone, povidone K25, magnesium stearate, titanium dioxide (E171), gelatin. Each capsule contains approximately 123 mg lactose.

What does the medicine look like and what does the package contain?

Off-white capsules, 60 capsules per box.

License holder:

 Rafa Laboratories Ltd.,
P.O.Box 405, Jerusalem

Drug registration number in the National Medicines Registry of the Ministry of Health: 1486433344

This leaflet was checked and approved by the Ministry of Health in September 2012.

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