Package leaflet: Information for the patient

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

1. What Anagrelide AOP is and what it is used for

Anagrelide AOP contains the active substance anagrelide. Anagrelide AOP is a medicine that inhibits the development of platelets (thrombocytes) in the bone marrow.

Anagrelide AOP is used to reduce the number of platelets in patients with essential thrombocythaemia (which is disease when the bone marrow produces too many platelets). An excessive number of platelets can cause problems with blood circulation and clotting. Lowering the platelet count reduces the risk of serious health problems.

2. What you need to know before you take Anagrelide AOP

Do not take Anagrelide AOP
- If you are allergic to anagrelide or any of the other ingredients of this medicine (listed in section 6).
- If you have a severe heart disease.
- If you have severe kidney problems.
- If you have moderate to severe liver problems.

Warnings and precautions
Talk to your doctor before taking Anagrelide AOP:
- If you have or you think you may have a heart disease.
- If you were born with or have a family history of prolonged QT interval (seen on ECG, an electrical recording of the heart functions), 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 Anagrelide AOP”).
- If you have a kidney or liver disease.

Children and adolescents
There is limited experience on the use of anagrelide in children and adolescents. Your doctor will decide about the treatment with Anagrelide AOP.

Other medicines and Anagrelide AOP
Tell your doctor or pharmacist if you are taking, 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;
- Certain types of antibiotics used to treat infections, such as enoxacin;
- Fluvoxamine, used to treat depression;
- Certain types of medicines to reduce the amount of acid in the stomach, such as omeprazole;
- Theophylline, used to treat lung diseases such as asthma;
- Medicines used to treat heart disorders, such as milrinone, enoximone, amrinone, olprinone and cilostazol;
- Medicines that affect the platelets in your blood such as acetylsalicylic acid (the simultaneous use of acetylsalicylic acid, also known as aspirin, and Anagrelide AOP may cause an elevated tendency for bleeding).
- In some patients the use of this medicine may cause indigestion (e.g. diarrhoea) and may reduce the effect of oral contraceptives.

Anagrelide AOP with food and drink
Grapefruit juice may prolong the time of this medicine to be removed from your body. It is recommended that you do not drink grapefruit juice while you are taking Anagrelide AOP.

Pregnancy, breast-feeding and fertility
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

Anagrelide AOP should not be taken during pregnancy.
During treatment with Anagrelide AOP, women of childbearing age should use effective contraception.
Anagrelide AOP should not be taken while breast-feeding. You should stop breast-feeding if you are taking this medicine.

Driving and using machines
Do not drive or use machines if you feel dizzy after taking Anagrelide AOP.

Anagrelide AOP contains lactose
This medicine contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take Anagrelide AOP

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

The dose will be set individually for you by your doctor. The usual starting dose of Anagrelide AOP is 1 capsule to 2 capsules per 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. The maximum dose is 10 capsules per day.

If you have a liver or kidney disease, your doctor will decide if you will be treated with Anagrelide AOP.

Anagrelide AOP capsules should be swallowed whole with some 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.

If you take more Anagrelide AOP than you should
If you take more Anagrelide AOP than you should or if anyone else has taken your medicine, immediately tell your doctor or pharmacist. Higher than prescribed doses may cause a decrease in blood

pressure which is associated with dizziness, vomiting and heart rhythm problems.

If you forgot to take Anagrelide AOP
If you forgot to take your capsule at the prescribed time, take it as soon as possible. Do not take a double dose to make up for the forgotten dose.

If you stop taking Anagrelide AOP
Do not stop taking this medicine without consulting with your doctor first.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Stop taking Anagrelide AOP and contact a doctor or go to your nearest emergency department immediately if you experience any of the following symptoms:

Uncommon (may affect up to 1 in 100 people):
- signs include severe chest pain and shortness of breath (heart failure)
- signs include a very rapid heartbeat and severe chest pain associated with shortness of breath (ventricular tachycardia)
- signs include shortness of breath, swelling in legs or ankles, and lips and skin can turn bluish colour (pulmonary hypertension)

Rare (may affect up to 1 in 1,000 people):
- signs include severe chest pain and shortness of breath (heart attack)
- signs include a very rapid heartbeat and severe chest pain associated with shortness of breath (atrial fibrillation)
- signs include severe chest pain resulting from insufficient blood flow to the heart (angina pectoris)

Other side effects that may occur:

Very common side effects (may affect more than 1 in 10 people):
- headache

Common side effects (may affect up to 1 in 10 people):
- reduction in red blood cell number (anaemia), localized skin bleeding
- accumulation of fluid (oedema)
- sensation of spinning (vertigo), sensation of tingling and 'pins and needles', sleeplessness
- irregular heart beat (palpitations), rapid heart beat (tachycardia), high blood pressure
- nose bleeding
- feeling sick (nausea), diarrhoea, indigestion
- skin itching and/or red skin
- back pain
- feeling weak or tired

Uncommon side effects (may affect up to 1 in 100 people):
- reduction in blood platelets, bleeding, haematoma
- weight gain
- depression, nervousness, dry mouth, migraine, reduced sense of touch or sensation (hypoaesthesia)
- vision anomalies, eye infection
- ringing in the ears (tinnitus)
- heart rhythm disorders, circulatory collapse
- shortness of breath, respiratory infection

- vomiting, gas (flatulence), constipation, abdominal pain
- hair loss, itching
- muscle and joint pain
- renal insufficiency, infection of the urinary tract
- pain, weakness

Rare side effects (may affect up to 1 in 1,000 people):
- low blood pressure
- accumulation of fluid in the chest or on the lung, lung infection, asthma
- inflammation of the stomach, eating disorder
- rash
- increased need to pass water at night
- increase of liver enzymes
- "flu-like" like symptoms, chills, feeling of general discomfort
- chest pain at rest (Prinzmetal angina)

The following side effects have been reported but it is not exactly known how often they occur:
- torsade de pointes (a potentially life-threatening, irregular heart rhythm)
- pulmonary fibrosis (an inflammation of the lungs which cause scarring of the lungs)
- tubulointerstitial nephritis (an inflammation of the kidneys)

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 Yellow Card Scheme
Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.
By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Anagrelide AOP

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

Do not store above 30°C. Store in the original package in order to protect from light.

Discard this medicine 100 days after first opening.

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.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicine you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Anagrelide AOP contains

The active substance is anagrelide.
Each hard capsule contains anagrelide hydrochloride monohydrate equivalent to 0.5 mg anagrelide.

The other ingredients are:
Capsule contents: lactose monohydrate, povidone K 30, crospovidone type A, microcrystalline cellulose (E460), magnesium stearate (E470b)
Capsule shell: titanium dioxide (E171), indigo carmine (E132), gelatine, water

What Anagrelide AOP looks like and contents of the pack

Anagrelide AOP is supplied as blue hard capsules with dimensions approximately 14.3 mm, filled with a white powder.

Anagrelide AOP is provided in polyethylene bottles with child-resistant tamper-evident polypropylene screw cap with a desiccant insert. Bottle contains 100 blue capsules.

Marketing Authorisation Holder and Manufacturer
AOP Orphan Pharmaceuticals AG
Wilhelminenstraße 91/II f
1160 Vienna
Austria

This medicinal product is authorised in the Member States of the EEA under the following names:

Austria:	Anagrelid AOP 0,5 mg Hartkapseln
Bulgaria:	Анагрелид АОР 0,5 mg твърди капсули
Czech Republic:	Anagrelid AOP 0,5 mg tvrdé tobolky
Cyprus	Anagrelide AOP 0,5 mg καψάκια, σκληρά
Denmark:	Anagrelid AOP 0,5 mg hårde kapsler
Estonia:	Anagrelide AOP 0,5 mg kõvakapslid
Finland:	Anagrelide AOP 0,5 mg kovat kapselit
France:	PLETARGA 0,5 mg, gélule
Germany:	Thromboreductin 0,5 mg Hartkapseln
Greece:	Anagrelide/AOP 0,5 mg καψάκια, σκληρά
Iceland	Anagrelide AOP 0,5 mg hörð hylki
Latvia:	Anagrelide AOP 0,5 mg cietās kapsulas
Norway:	Anagrelide AOP 0,5 mg harde kapsler
Poland:	Anagrelidum AOP, 0,5 mg, kapsułki twarde
Romania:	Anagrelidă AOP 0,5 mg capsule
Slovakia:	Anagrelid AOP 0,5 mg tvrdé kapsuly
Slovenia:	Anagrelid AOP Orphan 0,5 mg trde kapsule
Sweden:	Anagrelide AOP 0,5 mg hårda kapslar
United Kingdom:	Anagrelide AOP 0.5 mg hard capsules

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