

ANAGRELIDE APOTEX

Anagrelide Hydrochloride

Consumer Medicine Information

For a copy of a large print leaflet, Ph: 1800 195 055

What is in this leaflet

This leaflet answers some common questions about this medicine. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking this medicine against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

What this medicine is used for

ANAGRELIDE APOTEX Capsules contain the active ingredient anagrelide hydrochloride, which acts upon the bone marrow and prevents it from producing too many of the blood cells known as "platelets".

In a disease such as "thrombocythaemia", the bone marrow produces too many of these cells, and the very large numbers of platelets in the blood can cause serious problems with blood circulation. By preventing too many platelets from being made, ANAGRELIDE APOTEX can help prevent these problems.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

This medicine is not addictive.

This medicine is only available on a doctor's prescription.

Before you take this medicine

When you must not take it

Do not take this medicine if you have an allergy to:

- anagrelide
- any of the other ingredients listed at the end of this leaflet

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin

Do not take this medicine if you have or have had any of the following medical conditions:

- severe liver problems
- sensitivity to lactose or microcrystalline cellulose. These may cause a problem in a small number of people who are sensitive to them.

Do not take this medicine if you are pregnant or breast feeding.

Do not give this medicine to a child under the age of 16 years.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any of the following medical conditions:

- any liver or kidney disease.
- heart disease, heart failure or are at high risk of vascular events (thrombosis or bleeding).
- Any intolerance to some sugars, as ANAGRELIDE APOTEX contains sugars as lactose.

Tell your doctor if you are pregnant or plan to become pregnant or are breastfeeding.

If you become pregnant whilst taking anagrelide, you should stop taking the capsules and see your doctor immediately.

Women taking anagrelide and who are at risk of becoming pregnant should make sure that they are using adequate contraception.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and anagrelide may interfere with each other. These include:

- aspirin or any medicine containing aspirin
- medicines used to treat depression e.g. fluvoxamine
- medicines used to treat gastrointestinal problems e.g. omeprazole
- medicines used to treat severe asthma and breathing problems e.g. theophylline
- medicines used to treat heart disorders e.g. milrinone
- other medicines used to treat conditions affecting the platelets in your blood
- Medicines containing sucralfate

These medicines may be affected by anagrelide or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

How to take this medicine

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

How much to take

The recommended adult starting dose of anagrelide is 1 mg/day, which can be taken orally in two divided doses.

This dosage will then be adjusted until your doctor has decided which dosage is best for you.

Any single dose taken during the day should not exceed 2.5 mg. Your total daily dose should not exceed four times this, i.e. 10 mg (20 of the 0.5 mg capsules).

If you are elderly, you should take the normal adult dose.

When to take it

Take your capsules at the same time each day.

This will help you remember when to take the capsules.

Food reduces the absorption of anagrelide slightly, but this does not have any effect on the ability of anagrelide to reduce your platelet count.

How long to take it

Continue taking your medicine for as long as your doctor tells you.

Anagrelide helps to successfully reduce excess platelets in your blood, but does not cure your condition. Stopping anagrelide will cause the number of platelets in your blood to rise again within three or four days and the risk of problems with blood circulation may return.

Abrupt treatment discontinuation or substantial reduction in the dosage should be avoided, due to potentially severe clotting complications.

It is important to keep taking your medicine even if you feel well. You should not normally stop taking anagrelide unless your doctor tells you to.

If you feel unwell during your course of treatment, tell your doctor.

If you forget to take it

If you forget to take a dose of this medicine, leave out that dose completely. Take your next dose at the normal time it is due.

Do not take a double dose to make up for the dose that you missed.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to take this medicine, ask your pharmacist for some hints.

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at the nearest hospital, if you think

that you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning.

Symptoms of an overdose may include fast heartbeat, low blood pressure, vomiting and bleeding.

While you are using this medicine

Things you must do

Tell your doctor immediately if you experience shortness of breath and fatigue while taking this medicine.

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking this medicine.

Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.

It may affect other medicines used during surgery.

If you become pregnant or start to breastfeed while taking this medicine, tell your doctor immediately.

If you are about to have any blood tests, tell your doctor that you are taking this medicine.

It may interfere with the results of some tests.

Keep all your doctor's appointments so that your progress can be checked.

Your doctor may do some tests from time to time to make sure the medicine is working and to prevent unwanted side effects.

Things you must not do

Do not take this medicine to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

Do not stop taking your medicine or change the dosage without checking with your doctor.

Things to be careful of

Be careful driving or operating machinery until you know how this medicine affects you.

Anagrelide may cause dizziness in some patients. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking this medicine.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- headache
- aches and pains, including the back and the chest
- palpitations, an unusually rapid heartbeat
- water retention, swelling of the hands or feet
- abdominal pain
- difficult or painful breathing
- loss of appetite
- rash
- wind, diarrhoea, nausea, vomiting
- feeling unwell
- weakness, dizziness
- fever
- worsening of a cough
- tingling sensation like pins and needles

- alopecia (hair loss)

If these events persist, you should consult your doctor.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- heart problems, including heart attack or a disturbed heartbeat, enlargement of the heart. As a precaution, your doctor may have to order some special straightforward heart function tests, both before and during your treatment
- chest pain with or without rapid breathing
- lung problems, including shortness of breath, wheezing or difficulty breathing
- allergic coughing
- abdominal pain or tenderness, stomach discomfort, vomiting blood or passing black stools
- severe abdominal or back pain (symptoms of pancreatitis)
- yellowing of the skin and eyes caused by inflammation of the liver (hepatitis)
- unexplained bruising or bleeding, which can sometimes be serious if you are also taking aspirin
- visual impairment issues, including double-vision or abnormalities
- symptoms of an allergic reaction including cough, shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue, throat or other parts of the body; rash, itching or hives on the skin

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are very rare.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people.

As a precaution, your doctor may have your blood, liver and kidney

tested regularly during treatment with anagrelide.

Storage and Disposal

Storage

Keep your capsules in the bottle until it is time to take them.

If you take the capsules out of the bottle they may not keep well.

Keep your medicine in a cool dry place where the temperature stays below 25°C.

Do not store this medicine or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

ANAGRELIDE APOTEX capsules 0.5 mg

White, opaque capsules. AUST R 293282.

Available in HDPE bottles containing 100 capsules.

Ingredients

This medicine contains 0.5 mg of anagrelide hydrochloride as the active ingredient.

This medicine also contains the following:

- crospovidone Type A
- lactose anhydrous

- lactose monohydrate
- magnesium stearate
- microcrystalline cellulose
- povidone

This medicine contains sugars as lactose and contains sulfites.

Distributor

Apotex Pty Ltd
16 Giffnock Avenue
Macquarie Park NSW 2113

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