

ANAGRELIDE APOTEX

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using ANAGRELIDE APOTEX?

ANAGRELIDE APOTEX contains the active ingredient anagrelide hydrochloride. ANAGRELIDE APOTEX is used to treat essential thrombocythaemia.

For more information, see Section [1. Why am I using ANAGRELIDE APOTEX?](#) in the full CMI.

2. What should I know before I use ANAGRELIDE APOTEX?

Do not use if you have ever had an allergic reaction to ANAGRELIDE APOTEX or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use ANAGRELIDE APOTEX?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with ANAGRELIDE APOTEX and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use ANAGRELIDE APOTEX?

- The recommended adult starting dose is 1 mg/day, which can be taken orally in two divided doses.
- Take the tablet the same time each day.

More instructions can be found in Section [4. How do I use ANAGRELIDE APOTEX?](#) in the full CMI.

5. What should I know while using ANAGRELIDE APOTEX?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using ANAGRELIDE APOTEX. If you become pregnant while using this medicine, tell your doctor immediately.
Things you should not do	<ul style="list-style-type: none">• Do not stop using ANAGRELIDE APOTEX or change the dosage without checking with your doctor.
Driving or using machines	<ul style="list-style-type: none">• ANAGRELIDE APOTEX may cause dizziness. Be careful driving or operating machinery until you know how ANAGRELIDE APOTEX affects you.
Looking after your medicine	<ul style="list-style-type: none">• Store ANAGRELIDE APOTEX in a cool dry place where the temperature stays below 25°C.

For more information, see Section [5. What should I know while using \[insert medicine\]?](#) in the full CMI.

6. Are there any side effects?

Serious side effects include heart problems, lung problems, yellowing of the skin and eyes caused by inflammation of the liver (hepatitis), and severe abdominal or back pain (pancreatitis).

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

ANAGRELIDE APOTEX

Active ingredient(s): *anagrelide hydrochloride*

Consumer Medicine Information (CMI)

This leaflet provides important information about using ANAGRELIDE APOTEX. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using ANAGRELIDE APOTEX.**

Where to find information in this leaflet:

- [1. Why am I using ANAGRELIDE APOTEX?](#)
- [2. What should I know before I use ANAGRELIDE APOTEX?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use ANAGRELIDE APOTEX?](#)
- [5. What should I know while using ANAGRELIDE APOTEX?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using ANAGRELIDE APOTEX?

ANAGRELIDE APOTEX contains the active ingredient anagrelide hydrochloride. ANAGRELIDE APOTEX 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.

Your doctor may have prescribed ANAGRELIDE APOTEX for another reason. Ask your doctor if you have any questions about why ANAGRELIDE APOTEX have been prescribed for you.

ANAGRELIDE APOTEX capsules are not addictive. ANAGRELIDE APOTEX is only available on a doctor's prescription.

2. What should I know before I use ANAGRELIDE APOTEX?

Warnings

Do not use ANAGRELIDE APOTEX if:

- you are allergic to anagrelide, or any of the ingredients listed at the end of this leaflet
- ANAGRELIDE APOTEX contains lactose and microcrystalline cellulose. There may cause a problem

in a small number of people who are sensitive to them.

- you have severe liver problems.
- you are pregnant or breast feeding.
- the expiry date (EXP) printed on the bottle has passed. If you take ANAGRELIDE APOTEX after the expiry date has passed, it may not work as well.
- the packaging is torn or shows signs of tampering.

Tell your doctor if you:

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

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

If you become pregnant whilst taking ANAGRELIDE APOTEX, you should stop taking the capsules and see your doctor immediately. Women taking ANAGRELIDE APOTEX and who are at risk of becoming pregnant should make sure that they are using adequate contraception.

ANAGRELIDE APOTEX should not be taken by anyone under 16 years of age.

3. What if I am taking other medicines?

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

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

- aspirin or a medicine containing aspirin
- medicines used to treat depression such as fluvoxamine
- medicines used to treat gastrointestinal problems such as omeprazole
- medicines used to treat severe asthma and breathing problems such as theophylline
- medicines used to treat heart disorders such as milrinone

- other medicines used to treat conditions affecting the platelets in your blood
- medicines containing sucralfate.

Your doctor may have to change your dose of other medicines.

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

4. How do I use ANAGRELIDE APOTEX?

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.
- If you are not sure, ask your doctor or pharmacist for advice.
- Follow all the directions given to you by your doctor or pharmacist carefully. They may differ from the information in this leaflet.

When to take ANAGRELIDE APOTEX

- Take ANAGRELIDE APOTEX at the same time each day. This will help you remember when to take the capsules.
- Food reduces the absorption of ANAGRELIDE APOTEX slightly, but this does not have any effect on the ability to reduce your platelet count.

How long to take ANAGRELIDE APOTEX

- You should not normally stop taking ANAGRELIDE APOTEX unless your doctor tells you to. If ANAGRELIDE APOTEX have been successfully reducing the excess of platelets in your blood, stopping ANAGRELIDE APOTEX will cause the number of platelets in your blood to rise again within three or four days, so that the risk of problems with blood circulation may return.
- Abrupt treatment discontinuation or substantial reduction in ANAGRELIDE APOTEX's dosage should be avoided, due to potentially severe clotting complications.
- If you feel unwell during your course of treatment, tell your doctor.

If you forget to use ANAGRELIDE APOTEX

- If you forget to take a dose of ANAGRELIDE APOTEX, 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 you missed.

- If you are not sure what to do, ask your doctor or pharmacist.
- If you have trouble remembering to take ANAGRELIDE APOTEX, ask your pharmacist for some hints.

If you use too much ANAGRELIDE APOTEX

If you think that you have used too much ANAGRELIDE APOTEX, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

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

5. What should I know while using ANAGRELIDE APOTEX?

Things you should do

Make sure that all your doctors and pharmacists know about your use of ANAGRELIDE APOTEX. Remind them if any new medicines are about to be started.

Tell your doctor immediately if you experience shortness of breath and fatigue while taking ANAGRELIDE APOTEX.

Things you should not do

Do not take ANAGRELIDE APOTEX to treat any complaint other than that directed by your doctor. It may not be safe to take ANAGRELIDE APOTEX for another complaint.

Do not give your medicine to anyone else, even if they have the same condition as you. It may not be safe for another person to take ANAGRELIDE APOTEX.

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

Driving or using machines

ANAGRELIDE APOTEX may cause dizziness in some patients. Be careful driving or operating machinery until you know how ANAGRELIDE APOTEX affects you. Looking after your medicine

- Keep ANAGRELIDE APOTEX capsules in their bottle until it is time to take your dose.
- Keep ANAGRELIDE APOTEX in a cool dry place where the temperature stays below 25°C.
- Do not store it or any other medicine in the bathroom or near a sink.

- Do not leave it on a windowsill or in the car on hot or cold days. Heat, cold and dampness can destroy some medicines.
- Keep ANAGRELIDE APOTEX 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.

Ask your pharmacist what to do with any unused medicines.

6. Are there any side effects?

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking ANAGRELIDE APOTEX. Like all medicines, ANAGRELIDE APOTEX may have some side effects. Most side effects are mild, and patients often find that these wear off after a few weeks.

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

Some serious side effects that may occur are shown below:

Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none"> • 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) 	<p>If these side effects persist, you should consult your doctor.</p>

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> • Heart problems, including heart attack, stroke or a disturbed heart heartbeat, enlargement of the heart. As a precaution, your doctor may have to order some special straightforward heart function tests, both before and 	<p>Call your doctor immediately.</p>

<p>during your treatment.</p> <ul style="list-style-type: none"> • Chest pain with or without rapid breathing. • Lung problems, including shortness of breath, wheezing or difficulty breathing. • Severe abdominal or back pain (pancreatitis) • Abdominal pain or tenderness, stomach discomfort, vomiting blood or passing black stools. • Allergic coughing. • 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. 	
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As a precaution, your doctor may have your blood, liver and kidney tested regularly during treatment with ANAGRELIDE APOTEX.

Other side effects not listed here may also occur in some patients. tell your doctor if you notice anything else that is making you feel unwell.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

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

What ANAGRELIDE APOTEX contains

Active ingredient (main ingredient)	Anagrelide hydrochloride 0.5mg
Other ingredients (inactive ingredients)	crospovidone lactose lactose monohydrate magnesium stearate microcrystalline cellulose povidone titanium dioxide gelatin
Potential allergens	This medicine contains sugars as lactose

Do not take this medicine if you are allergic to any of these ingredients.

What ANAGRELIDE APOTEX looks like

ANAGRELIDE APOTEX is White, opaque capsules. (Aust R 293282).

Who distributes ANAGRELIDE APOTEX

Arrotex Pharmaceuticals Pty Ltd
15 – 17 Chapel Street,
Cremorne 3121 Victoria
www.arrotex.com.au

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