Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about ANAGRELIDE SCP.

It does not contain all of the available information. It does not take the place of talking to your doctor or pharmacist.

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

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

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

What ANAGRELIDE SCP is used for

ANAGRELIDE SCP capsules contain a medicine called anagrelide (as hydrochloride monohydrate) 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. ANAGRELIDE SCP capsules can help prevent these problems.

Before you take ANAGRELIDE SCP

When you must not take it Do not take ANAGRELIDE SCP if you:

- have an allergy to anagrelide or any of the ingredients listed at the end of this leaflet
- · have severe liver problems
- · are pregnant or breast feeding.

Do not take ANAGRELIDE SCP if the expiry date (Exp.) printed on the pack has passed.

Do not take ANAGRELIDE SCP if the packaging is torn or shows signs of tampering.

Do not use ANAGRELIDE SCP to treat any other complaint unless your doctor tells you to.

Before you start to take it

Tell your doctor if you have any of the following:

- · you have any allergies,
- you have had or now have any liver or kidney disease
- you have heart disease, heart failure or are at high risk of vascular events (thrombosis or bleeding).

Tell your doctor if you are allergic to any other medicines, foods, dyes or preservatives.

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

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

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

Taking other medicines

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

Some medicines may be affected by ANAGRELIDE SCP, or may affect how well it works. These include:

- · aspirin or a medicine containing aspirin
- medicined used to treat depression such as fluvoxamine.
- medicine 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 can tell you what to do if you are taking any of these medicines.

If you are not sure whether you are taking any of these medicines, check with your doctor or pharmacist.

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

How to take ANAGRELIDE SCP

How much to take

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 day should not exceed 2.5 mg. Your total daily dose should not exceed four times this, ie 10 mg (20 of the 0.5 mg capsules).

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

If you do not understand the instructions in this leaflet, ask your doctor or pharmacist for help.

When to take it

Take your capsules the same time each day. This will help you remember when to take the capsules.

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

How long to take it

You should not normally stop taking ANAGRELIDE SCP capsules unless your doctor tells you to. If ANAGRELIDE SCP capsules have been successfully reducing the excess of platelets in your blood, stopping ANAGRELIDE SCP capsules 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.

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

If you forget to take ANAGRELIDE SCP

If you forget to take a dose of ANAGRELIDE SCP capsules, 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 have trouble remembering to ANGARELIDE SCP capsules, ask your pharmacist for some hints.

If you have any questions about this, check with your doctor or pharmacist.

If you take too much ANAGRELIDE SCP (overdose)

Immediately telephone your doctor, or the Poisons Information Centre (telephone 13 11 26), or go to Accident and Emergency at the nearest hospital, if you think you or anyone else may have taken too much ANAGRELIDE SCP capsules. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention. Symptoms of an overdose may include fast heartbeat, vomiting and bleeding.

While you are taking ANAGRELIDE

Things you must do

Before starting any new medicine, tell your doctor or pharmacist that you are taking ANAGRELIDE SCP.

Tell all the doctors, dentists and pharmacists who are treating you that you are taking ANAGRELIDE SCP.

Things you must not do

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

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

Things to be careful of

ANAGRELIDE SCP may cause dizziness in some patients. Be careful driving or operating machinery until you know how ANAGRELIDE SCP capsules affects you.

Side effects

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

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

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

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

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

- headache
- aches and pains, including the back and the chest
- · palpitations, an usually 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.

As a precaution, your doctor may have your blood, liver and kidney tested regularly during treatment with ANAGRELIDE SCP capsules.

Tell your doctor immediately or go to Accident and Emergency at the nearest hospital if you notice any of the following:

- 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
- yellowing of the skin and eyes caused by inflammation of the liver (hepatitis)
- bleeding, which can sometimes be serious if you are also taking aspirin.

These may be serious side effects. You may need urgent medical attention.

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

After using ANAGRELIDE SCP

Storage

Keep ANAGRELIDE SCP 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.

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 capsules in a cool dry place where the temperature stays below 25°C.

Do not store ANAGRELIDE SCP or any other medicine in the bathroom or near a sink.

Do not leave ANAGRELIDE SCP in the car or on window sills.

Heat and dampness can destroy some medicines.

Disposal

If your doctor tells you to stop taking ANAGRELIDE SCP, or your capsules have passed their expiry date, ask your pharmacist what to do with any that are left over.

Product description

What it looks like

ANAGRELIDE SCP is a capsule with an opaque white body and cap. The capsule is filled with white to off-white powder.

Each bottle contains 100 capsules.

Ingredients

The active ingredient in ANAGRELIDE SCP is an agrelide (as hydrochloride monohydrate). Each capsule contains 0.5 mg of an agrelide.

The capsule also contains:

- lactose monohydrate
- · cellulose microcrystalline
- · povidone
- · croscarmellose sodium
- · silica colloidal anhydrous
- · purified talc
- · magnesium stearate
- · anhydrous lactose.

The capsule shell contains:

- gelatin
- titanium dioxide.

The capsules do not contain gluten, sucrose, tartrazine or any other azo dyes.

Supplier

Southern Cross Pharma Pty Ltd Suite 5/118 Church Street Hawthorn VIC 3122

Australia

Australian registration numbers:

ANAGRELIDE SCP

AUST R 276297

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