Consumer Medicine Information

What is in this leaflet

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

All medicines have risks and benefits.

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

Keep this leaflet with the medicine.

You may need to read it again.

What Anagraine is used for

Anagraine is used for the relief of headache, nausea and vomiting associated with migraine.

Anagraine contains the active ingredients metoclopramide (as metoclopramide hydrochloride anhydrous) and paracetamol.

Metoclopramide helps control nausea and vomiting caused by migraine and other illnesses. It works by blocking the action of a chemical in the brain which causes nausea and vomiting. It also acts in the stomach and upper intestine to increase muscle contractions.

Paracetamol is an analgesic. It provides effective temporary relief from pain.

There is no evidence that Anagraine is addictive.

Before you take it

When you must not take it

Do not take Anagraine if you have ever had an allergic reaction to:

- · metoclopramide
- paracetamol
- any of the ingredients listed at the end of this leaflet.

Symptoms of an allergic reaction may include asthma, wheezing, shortness of breath, swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing, skin rash, itching or hives.

Do not take it if you have any of the following conditions:

- bleeding from the stomach and/or digestive tract
- intestinal blockage
- recent surgery on the stomach and/or digestive tract
- phaeochromocytoma (a rare tumour of the adrenal gland).

Do not use if you have epilepsy (fits).

Do not take Anagraine if:

- you are pregnant, or intend to become pregnant
 It may affect your developing
 - It may affect your developing baby if you take it during pregnancy.
- you are breast-feeding or intend to breast-feed

Anagraine passes into breast milk and therefore may harm the baby.

Do not take Anagraine after the expiry date (EXP) printed on the pack.

Do not take it if the packaging is torn or shows signs of tampering or if the tablets do not look quite right.

Do not give this medicine to children and adolescents under 18 years of age.

The safety of this medicine in children under 18 years of age has not been established.

Talk to your doctor or pharmacist if you are not sure whether you should start taking Anagraine.

Before you start to take it

Tell your doctor or pharmacist if:

- 1. you have allergies to any other medicines, foods, preservatives or dyes.
- 2. you have or have had any of the following medical conditions:
- epilepsy metoclopramide may increase the risk of you having a fit
- breast cancer
- liver or kidney disease
- Parkinson's disease metoclopramide may make this condition worse
- you have had movements that you cannot control, mainly of the tongue, mouth, jaw, arms and legs after taking metoclopramide or medicines used to calm emotional and mental problems.

Tell your doctor or pharmacist if you plan to have surgery.

Anagraine should not be taken immediately after certain types of operations.

If you have not told your doctor or pharmacist about any of the

above, tell them before you take Anagraine.

Taking other medicines

Tell your doctor or pharmacist 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 and Anagraine may interfere with each other. These include:

- medicines used to prevent blood clots
- · medicines used to treat epilepsy
- pain relievers such as codeine and morphine
- some medicines found in travel sickness, hayfever and allergy, stomach cramps and, cough and cold preparations
- medicines used to treat anxiety or help you to sleep
- medicines used to treat certain mental and emotional conditions, such as schizophrenia
- tetracycline antibiotics
- levodopa, a medicine used in the treatment of Parkinson's disease
- digoxin, a medicine used to treat heart failure
- other paracetamol containing products.

These medicines may be affected by Anagraine 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 or pharmacist has a more complete list of medicines to avoid while taking Anagraine.

How to take it

How much to take

Anagraine should be taken at the first sign of a migraine attack.

Adults:

The initial dosage for adults is 1-2 tablets and then 1-2 tablets every four hours, as needed. **Do not take** more than 6 tablets in 24 hours.

Do not take Anagraine for longer than 48 hours at a time unless advised to by a doctor.

How to take it

Swallow the tablet with a glass of water.

If you forget to take it

If symptoms persist take your next dose when you are meant to.

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

This may increase the chance of you getting an unwanted side effect.

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

If you have trouble remembering when to take your 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 Anagraine. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

If you take too much Anagraine you may experience the following symptoms:

- · vomiting
- · stomach pain
- sweating
- · low blood pressure
- · yellowing of the skin
- · drowsiness
- · confusion or fits
- twitching or uncontrolled spasms.

While you are taking it

Things you must do

Tell your doctor or pharmacist if nausea, vomiting or headache persists.

Tell all doctors, dentists and pharmacists who are treating you that you are taking Anagraine.

If you are about to be started on any new medicine, tell your doctor or pharmacist that you are taking Anagraine.

Tell your doctor or pharmacist immediately if you become pregnant while taking Anagraine.

Things you must not do

Do not take Anagraine for longer than 48 hours at a time unless advised to by a doctor.

Do not give this medicine to anyone else, even if they have similar symptoms.

Do not take Anagraine to treat any other complaints unless your doctor or pharmacist tells you to.

Things to be careful of

Do not take Anagraine with other products containing paracetamol, unless advised to do so by a doctor or pharmacist.

Not more than 4 g of paracetamol should be taken in any 24 hour period.

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

Anagraine may cause drowsiness, tiredness or dizziness in some people. If any of these occur, do not drive, operate machinery or do anything else that could be dangerous.

Avoid drinking alcohol while taking Anagraine.

Combining Anagraine with alcohol can make you more sleepy or drowsy.

Side effects

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

Anagraine helps most people with migraines but it may have some unwanted side effects in some people. 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 the following list 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:

- drowsiness, tiredness, dizziness restlessness, fatigue
- · bowel upsets
- · trouble sleeping
- · upset stomach
- · dizziness, headache.

The above list includes the milder side effects of Anagraine.

Tell your doctor as soon as possible if you notice any of the following:

unusual changes mood, such as

- anxiety, depression or agitation
- uncontrolled and repeated movements of the arms, legs, eyes, mouth, tongue, face and jaw. This may be a sign of tardive dyskinesia, a movement disorder which can be potentially irreversible.

The above list includes serious side effects which may require medical attention or hospitalisation.

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

- symptoms of an allergic reaction such as, skin rash, itching or hives; swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing; wheezing or shortness of breath
- a sudden increase in body temperature, extremely high blood pressure, stiff muscles and severe convulsions. These could be signs of a serious side effect called neuroleptic malignant syndrome
- · severe drowsiness or sleepiness
- bluish colouration to the skin, a symptom of blood condition called methaemoglobinaemia.

The side effects listed above are rare, but serious and require urgent medical attention or hospitalisation.

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.

After taking it

Storage

Keep your tablets in the blister pack until it is time to take them.

If you take the tablets out of the blister they may not keep as well.

Keep your tablets in a cool dry place where the temperature stays below 30°C.

Do not store Anagraine 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 young children cannot reach it.

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

Disposal

Dispose of the tablets where children cannot reach them.

If you 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

Anagraine tablets are round, white and scored on one side. They are available in packs of 8 tablets.

Ingredients

Active ingredients:

Each tablet contains 5 mg of metoclopramide hydrochloride anhydrous and 500 mg of paracetamol.

Inactive ingredients:

- · magnesium stearate
- sodium starch glycollate.

Anagraine tablets do not contain lactose, gluten, tartrazine or any other azo dyes.

Sponsor

Aspen Pharmacare Australia Pty Ltd

34-36 Chandos St St Leonards NSW 2065

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