Package leaflet: Information for the patient

Amarhyton 50 mg, prolonged-release capsule, hard

Flecainide acetate

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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Amarhyton is and what it is used for

Amarhyton prolonged-release capsules belongs to the group of medicines that work against cardiac arrhythmia (known as anti-arrhythmics). It inhibits stimulus conduction in the heart and extends the time during which the heart is at rest, causing the heart to pump normally again.

Amarhyton prolonged-release capsules is used:
- for certain serious cardiac arrhythmias, which are often expressed as serious palpitations of the heart or fast heart beat (tachycardia).
- for serious heart rhythm problems (cardiac arrhythmias) that did not respond well to treatment with other medicines, or when other treatments cannot be tolerated.
- for serious atrial arrhythmias when other treatment has been ineffective.

2. What you need to know before you take Amarhyton

Do not take Amarhyton:
- if you are allergic to flecainide or any of the other ingredients of this medicine (listed in section 6).
- if you suffer from another heart condition, different from the heart condition for which you are taking this medicine. If you are unsure, or if you would like additional information, consult your doctor or pharmacist.
- if you are taking certain other antiarrhythmics (sodium channel blockers)
- if you suffer from Brugada syndrome (a genetic heart disease).

Warnings and precautions
Talk to your doctor before taking Amarhyton
- if you suffer from a reduced liver function and/or reduced kidney function, since the concentration of flecainide in the blood may increase. In that event, your doctor may regularly have the concentration of flecainide in the blood checked,
- if you are elderly, since the concentration of flecainide in the blood may increase,
- if you have a permanent pacemaker or temporary pacing electrodes,

- if you have suffered from heart rhythm problems after heart surgery,
- if you suffer from severe slow heart beat (bradycardia) or pronounced blood pressure (hypotension). These conditions should be corrected before using Amarhyton.
- if you have experienced a heart attack.

A lowered or elevated level of potassium in the blood may influence the effect of Amarhyton prolonged-release capsules. Diuretics, medicines that stimulate bowel movement (laxatives) and adrenal cortex hormones (corticosteroids) may lower the level of potassium in the blood. In that event, your doctor may have the amount of potassium in your blood checked.

Children below 12 years
Amarhyton is not approved for use in children below the age of 12 years, however flecainide toxicity has been reported during treatment with flecainide in children who reduced their intake of milk, and in infants who were switched from milk formula to dextrose feedings.

Other medicines and Amarhyton
If you use certain other medicines along with Amarhyton prolonged-release capsules, the medicines can sometimes affect the way each other work and/or their side effects (i.e. there may be interactions).

Interactions may occur when using this medicine with for example:
- digoxin (a medicine to stimulate the heart); Amarhyton prolonged-release capsules may raise the level of digoxin in your blood,
- medicines that reduce the heart's pumping function, such as those known as beta blockers,
- certain medicines against epilepsy (e.g. phenytoin, phenobarbital and carbamazepine): the breakdown of flecainide may be accelerated by these substances,
- cimetidine (an antacid); this may increase the effect of Amarhyton prolonged-release capsules,
- amiodarone (for heart conditions); the dose of Amarhyton must be reduced for some patients,
- medicines against depression (paroxetine, fluoxetine and some other antidepressants),
- clozapine (medicine used to treat schizophrenia),
- mizolastine, astemizole and terfenadine (medicines against allergies),
- quinine and halofantrine (medicines against malaria),
- verapamil (a medicine which lowers the blood pressure),
- quinidine (an anti-arrhythmic),
- medicines to treat HIV-infections (ritonavir, lopinavar and indinavir),
- water tablets (diuretics) such as thiazides and loop diuretics,
- disopyramide (an anti-arrhythmic); do not use Amarhyton prolonged-release capsules if you are also using disopyramide,
- terbinafine (to treat fungal infections),
- bupropion (anti-smoking drug).

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Amarhyton with food and drink
Amarhyton prolonged-release capsules should be taken on an empty stomach or at least one hour before a meal.

Dairy products (milk, infant formula and possibly yoghurt) may reduce the absorption of flecainide in children and infants. Amarhyton is not approved for use in children below the age of 12 years, however Amarhyton toxicity has been reported during treatment with flecainide in children who reduced their intake of milk, and in infants who were switched from milk formula to dextrose feedings.

Pregnancy and breast-feeding
During pregnancy Amarhyton prolonged-release capsules should only be used if the benefit outweighs the risks since flecainide has been shown to cross the placenta in patients taking flecainide during pregnancy. If Amarhyton prolonged-release capsules is used during pregnancy maternal flecainide

plasma levels should be monitored. You must consult your doctor as soon as you suspect you are pregnant, or if you want to have children.

Flecainide is secreted in the mother's milk. Amarhyton prolonged-release capsules should only be used during breast-feeding if the benefit outweighs the risks.

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

Driving and using machines
If you suffer from side effects such as dizziness, double vision or blurred vision, or if you feel light in the head, then your ability to react may have been reduced. This may be dangerous in situations that demand concentration and attentiveness, such as using the road, handling dangerous machinery or working at heights. If you are unsure whether Amarhyton prolonged-release capsules is having a negative effect on your ability to drive, discuss this with your doctor.

3. How to take Amarhyton

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

Your doctor will prescribe a personalised dose, adjusted to fit your complaints. Treatment with Amarhyton prolonged-release capsules will normally be started under medical supervision (if necessary, in the hospital). Follow your doctor's advice closely when taking Amarhyton prolonged-release capsules. Check with your doctor or pharmacist if you are not sure.

<u>When and how should the capsules be taken</u>
Take the capsules by swallowing them with sufficient fluid (e.g. water). The daily dose is usually taken split up over the day, on an empty stomach, or at least one hour before meals.

The general dose is just a guideline and is as follows: the usual starting dose lies between 100 and 200 mg. The dose may be increased by your doctor to a maximum of 400 mg a day.

More elderly patients
Your doctor may prescribe a lower dose for you. The dose for elderly patients should not exceed 300 mg daily

Patients with a reduced kidney or liver function
Your doctor may prescribe a lower dose for you.

Patients with a permanent pacemaker
The daily dose must not exceed 200 mg daily.

Patients who are simultaneously being treated with cimetidine (medicine against stomach disorders) or amiodarone (medicine against heart rhythm problems)
The doctor will check you regularly, and a lower dose will be prescribed for some patients.

During treatment, your doctor will regularly determine the level of flecainide in the blood and what is known as an electrocardiogram (ECG) of the heart will be taken. A simple ECG must be taken once a month and a more extensive ECG once every three months. An ECG will be taken every 2 to 4 days at the start of the treatment and when the dose is raised.

An ECG must be taken more frequently for patients who are receiving a smaller dose than is usually prescribed. The doctor can adjust the doses at intervals of 6 to 8 days. An ECG will be taken for these patients at weeks 2 and 3 after the start of the treatment.

Use in children
These capsules should not be taken by children under the age of 12 years.

If you take more Amarhyton than you should
If you suspect an overdose, you must alert a doctor immediately.

If you forget to take Amarhyton
Take the dose when you discover that you have forgotten to take it, unless you only discover this when it is almost time to take your next dose. In the latter case, you must not take the dose that you forgot as an addition but should continue to follow your schedule. It is important to take the capsules according to the schedule. Consult your doctor if you have any doubts.

Do not take a double dose to make up for a forgotten capsule.

If you stop takingAmarhyton
If you suddenly stop taking Amarhyton prolonged-release capsules you will not get withdrawal symptoms. However, the cardiac arrhythmia will no longer be being controlled as intended. So never stop using it without your doctor knowing.

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.
Some side effects could be serious. If you have any of the side effects listed below, seek immediate medical help:

Common (affects 1 in 100 people):
- Your heartbeat changes; it starts to pound, or it gets faster or slower,
- You have chest pain,
- You become breathless or have other breathing or lung problems,
- You have a fever, become flushed or sweat,
- You faint or you feel faint.

Rare (affects 1 in 10,000 people):
- You have ringing in your ears,
- Your skin and eyes begin to go yellow (jaundice),
- You have fits (seizures).

Other side effects (how often they happen is unknown):
- heart attack,
- cardiac failure/arrest (loss of breathing, and consciousness and loss of heart function).

Like other anti-arrhythmics flecainide can have the effect of inducing arrhythmia. The existing arrhythmia may worsen or a new arrhythmia may occur. The risk of pro-arrhythmic effects is most likely in patients with a structural heart disease and /or significant impairment of the heart function.

Other side effects that may occur include the following:

Very common (may affect more than 1 in 10 patients):
- dizziness,
- light-headedness,
- problems with vision, such as double vision, blurred vision and difficulties to focus.

Common (may affect more than 1 in 100 patients, but in fewer than 1 in 10):

- shortness of breath,
- weakness,
- tiredness (fatigue),
- fever,
- built up of fluid in the tissue (oedema) and discomfort,
- lowering of blood pressure (hypotension).

Uncommon (may affect more than 1 in 1000 patients, but in fewer than 1 in 100):
- nausea,
- vomiting,
- constipation,
- abdominal pain,
- anorexia,
- diarrhoea,
- dyspepsia (pain in upper abdomen, fullness),
- flatulence,
- decrease in red blood cells (which may make the skin pale and cause weakness or breathlessness),
- decrease in white blood cells (which makes you prone to infections),
- decrease in platelets (which can make you bleed or bruise more easily than normal),
- allergic skin reactions such as rash and hair loss.

Rare (may affect more than 1 in 10,000 patients, but in fewer than 1 in 1000):
- lung inflammation (pneumonia),
- tingling of the skin ("as if ants are walking over it"),
- coordination problems,
- difficulties in movement (tics),
- decrease of sensitivity,
- increased sweating,
- temporary loss of consciousness,
- tremor,
- spinning sensation (vertigo),
- flushing,
- sleepiness,
- severe depression,
- anxiety,
- insomnia (difficulty in going to sleep),
- headache,
- nervous disorders e.g. in the arms and legs,
- convulsions,
- confusion,
- seeing things that are not there (hallucinations),
- loss of memory (amnesia),
- hives,
- elevated liver enzymes with or without jaundice (yellow eyes or skin).

Very rare (may affect fewer than 1 in 10,000 patients):
- elevated levels of certain antibodies (shown in blood tests),
- corneal deposits,
- sensitivity to light.

Not known (cannot be estimated from the available data):
- certain changes in the electrocardiogram (increase in PR and QRS intervals),
- increase in pacing threshold in patients with pacemakers or temporary pacing electrodes,
- impairment of the conduction between the upper (atria) and lower (ventricles) chambers of the heart (second or third degree atrioventricular block),
- stopped heart beat,
- feeling your heart beat (palpitations),

- a pause in the normal cardiac rhythm (sinus arrest),
- life-threatening irregular heartbeat (ventricular fibrillation),
- appearance of a certain pre-existing heart disease (Brugada syndrome) which was not seen before the treatment with these capsules,
- scarring of the lungs or lung diseases (pulmonary fibrosis and interstitial lung disease),
- hepatic dysfunction.

If you get any side effects, talk to your doctor or pharmacist. This includes any side effects not listed in this leaflet.

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system of Bulgarian Drug Agency. By reporting side effects you can help provide more information on the safety of this medicine.

Contacts:
Bulgarian Drug Agency
8 Damyan Gruev Str.,
1303 Sofia.
Tel.: +359 2 890 3417
Website: www.bda.bg

5. How to store Amarhyton

Keep this medicine out of the sight and reach of children. The product does not require special storage conditions.

Do not use this medicine after the expiry date which is stated on the carton/blister 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 medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Amarhyton contains
The active substance is flecainide acetate.
- Amarhyton 50 mg prolonged-release capsules: Each capsule contains 50 mg flecainide acetate.

The other ingredients are:
Povidone (K 25)
Cellulose microcrystalline
Crospovidone (type A)
Silica colloidal anhydrousMagnesium stearate
Methacrylic acid and methyl methacrylate
copolymer (1:2)
Macrogol (400)
Talc.

The capsule shells of the various capsules contain the following ingredients:
50 mg: gelatin, titanium dioxide (E171)

What Amarhyton looks like and contents of the pack
Amarhyton 50 mg prolonged-release capsules are gelatine opaque capsules with white body and white cap containing white or almost white round micro-tablets.

Pack sizes: 28 or 30 capsules.
Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer
Tchaikapharma High Quality Medicines Inc.
1 G. M. Dimitrov Blvd, Sofia 1172, Bulgaria
Tel. : + 359 2 962 54 54
FAX: + 359 2 9603 703
e-mail: info@tchaikapharma.com

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