

Package leaflet: Information for the patient

Akilen 40mg film-coated tablets

Verapamil hydrochloride

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

What is in this leaflet

1. What Akilen is and what it is used for
2. What you need to know before you take Akilen
3. How to take Akilen
4. Possible side effects
5. How to store Akilen
6. Contents of the pack and other information

1. What Akilen is and what it is used for

Akilen contains as active ingredient verapamil hydrochloride, which belongs to a group of medicines called calcium channel blockers. Calcium channel blockers change the amount of calcium getting into the muscle cells in your heart and blood vessels. This can change the strength and speed with which your heart beats. It also opens up the blood vessels so blood can be pumped around the body more easily. This helps more oxygen to get to your heart muscle and can lower your blood pressure.

Akilen tablets are used to treat hypertension (high blood pressure), abnormal heart rhythms and to prevent and treat angina (chest pain) attacks.

2. What you need to know before you take Akilen

Do not use Akilen:

- if you are allergic to verapamil hydrochloride or any other ingredients of this medicine (listed in section 6).
- if you have recently had a heart attack.
- if you have heart failure or second or third degree heart block (impaired nerve signal in the heart - causing a very slow heartbeat) or an electrical abnormality of the heart (atrial fibrillation/flutter) causing periods of very fast heartbeat (Wolff-Parkinson-White syndrome).
- if you have problems with your heart valves or “sick sinus syndrome” (irregular heartbeat).
- if you are being treated with injectable beta-blockers.
- if you are pregnant or planning to become pregnant
- if you are already taking a medicine containing ivabradine for the treatment of certain heart diseases.

Warnings and precautions

Talk to your doctor or pharmacist before taking Akilen

- if you have ever suffered from heart failure, or first degree AV block or an irregular heartbeat.
- if you have very low blood pressure.
- if you have liver or kidney disease.
- if you have any neuromuscular diseases e.g. myasthenia gravis, Lambert-Eaton Syndrome or advanced Duchenne muscular dystrophy.

Other medicines and Akilen

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

- beta-blockers used to treat high blood pressure and heart conditions (these include, propranolol and metoprolol).
- alpha blockers used to treat high blood pressure, heart conditions and prostate disorders (these include prazosin and terazosin).

- medicines known as “statins” such as atorvastatin, lovastatin, simvastatin used to lower cholesterol levels.
- any other medicine for high blood pressure or an abnormal heart beat (arrhythmia) such as flecainide, quinidine, digoxin, digitoxin and disopyramide.
- medicines used to treat depression (including the herbal product St John’s Wort), anxiety or psychosis. These may include imipramine, buspirone and lithium.
- glyburide, used to treat certain types of diabetes.
- aspirin, a non-steroidal anti-inflammatory painkiller (NSAID) used to relieve pain and reduce fever.
- midazolam, used as a sedative or anaesthetic.
- medicines known as immunosuppressants such as ciclosporin, sirolimus, everolimus and tacrolimus. These are used to prevent organ transplant rejection.
- theophylline, used to treat asthma.
- doxorubicin, an anti-cancer medicine.
- cimetidine, used to treat indigestion or stomach ulcers.
- carbamazepine, or phenobarbital (phenobarbitone). These medicines are used as anti-convulsants.
- rifampicin, used to treat tuberculosis and other types of infection.
- ritonavir, used to treat HIV.
- erythromycin, clarithromycin and telithromycin, used to treat certain types of infection.
- colchicine or sulfinpyrazone, used to treat gout.
- almotriptan, used to treat migraine.
- dabigatran (medicine to prevent the formation of blood clots).

Verapamil may decrease the glucose-lowering effect of metformin.

Tell your surgeon or dentist that you are taking Akilen if surgery is planned as it may affect the anaesthetic use.

Akilen with food, drink and alcohol

Do not drink grapefruit juice whilst taking your tablets as it can affect the absorption of this medicine. This does not occur with other fruit juices such as orange, apple or tomato juice.

Verapamil can increase the amount of alcohol in the body and the time it takes for alcohol to leave the body. You should avoid excessive amounts of alcohol whilst you are being treated with verapamil.

Pregnancy, breast-feeding and fertility

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

Driving and using machines

Do not drive, operate machinery or do anything that requires you to be alert, until you know how the tablets affect you. Verapamil can make some people feel dizzy and tired.

Akilen contains lactose.

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take Akilen

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

Take your tablets with a glass of water. The tablets should be taken with or shortly after meals. You should swallow the tablets without chewing or crushing them.

The number of tablets that you will need to take will depend on what you are being treated for:

Adults:

Hypertension (high blood pressure)

The recommended dose for hypertension is 40–120 mg of verapamil taken three to four times a day. The maximum dose is 480 mg each day, to be taken in divided doses, as directed by your doctor.

Angina (chest pain)

The recommended dose for angina is 80–120 mg of verapamil taken three to four times a day.

Abnormal heart rhythms

The recommended dose for abnormal heart rhythms is 40–120 mg taken three to four times a day.

If you take more Akilen than you should

You should contact a doctor or go to the nearest hospital casualty department immediately taking your tablets with you.

If you forget to take Akilen

Take the tablets as soon as you remember, unless it is almost time for your next dose. If it is, do not take the missed dose at all. Do not take a double dose to make up for a forgotten dose.

If you stop taking Akilen

Your condition may get worse. It is important that you keep taking these tablets until your doctor tells you to stop. Do not stop just because you feel better.

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.

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

Tell your doctor immediately if you notice any of the following:

- Yellowing of the skin or eyes, a fever, tenderness around the tummy. These are signs that your liver may not be functioning as well as usual.
- Palpitations, chest pains for the first time or chest pains becoming more frequent, swollen ankles, hot and painful hands or feet.
- Unexpected wheezing, difficulty breathing, swelling of the mouth, lips or tongue or severe skin rash. These may be symptoms of an allergic reaction.

Common (may affect up to 1 in 10 people)

- dizziness,
- headache,
- slow heartbeat,
- flushing,
- low blood pressure,
- constipation,

- nausea (feeling sick),
- swollen feet or ankles.

Uncommon (may affect up to 1 in 100 people)

- irregular or fast heartbeat,
- stomach pain,
- tiredness.

Rare (may affect up to 1 in 1,000 people)

- a tingling or prickling feeling on the skin,
- tremor,
- drowsiness,
- a ringing sound in the ears (tinnitus),
- being sick,
- sweating a lot more than usual.

Not known (frequency cannot be estimated from the available data)

- allergic reactions,
- high potassium levels,
- movement disorders,
- paralysis,
- seizures,
- nervousness,
- vertigo,
- heart attack,
- heart failure,
- unusual heartbeat,
- flushing of the face or neck,
- burning pain, redness and swelling of the hands, feet or other extremities,
- difficulty in breathing,
- stomach discomfort,
- swollen gums which start to spread over the teeth,
- bowel obstruction,

- swelling of the mouth, lips or tongue or severe skin rash,
- rash,
- hair loss (alopecia),
- itching,
- aches and pains in the joints and/or muscles and muscle weakness,
- kidney problems,
- impotence,
- breast that leak milk,
- breast enlargement or swelling,
- greater than normal amounts of prolactin (female hormone) in the blood that causes the breasts to product milk,
- increase in liver enzymes.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system:

Malta ADR Reporting Website: www.medicinesauthority.gov.mt/adrportal

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Akilen

Store below 25°C, in the original packaging in order to protect from light

Keep this medicine out of the sight and reach of children.

Do not use the medicine after the expiry date which is stated on the carton and on each blister of tablets after {EXP}.

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 Akilen contains

- The active substance is verapamil hydrochloride.
Each tablet of Akilen 40 mg contains 40 mg of verapamil hydrochloride.
- The other ingredients are:
Microcrystalline cellulose, Lactose monohydrate, Croscarmellose sodium, Silica Colloidal Anhydrous, Magnesium stearate, Polyethylene glycol 6000 and Opadry green OY-3875H (Hypromellose (E464), titanium dioxide (E171), macrogol/polyethylene glycol 400, indigo carmine aluminium lake (E132), iron oxide yellow (E172), iron oxide black (E172))

What Akilen looks like and contents of the pack

The tablet of Akilen 40 mg is very pale green, round, convex, with diameter of core 7 mm.

Combination polyvinylchloride film and aluminium foil blisters of ten tablets.

Blisters are placed, with a patient information leaflet, in a card carton. Packs of 50, 100, 250, 500 and 1000 tablets are available.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

MEDOCHÉMIE LTD, 1-10 Constantinoupolis street, 3011 Limassol, Cyprus

This leaflet was last revised in January 2021.