

Package leaflet: Information for the patient

Caveril 40 mg 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 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 or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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

1. What Caveril is and what it is used for

Caveril contains the active substance verapamil hydrochloride. It 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.

Caveril is 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 Caveril

Do not take Caveril

- if your blood pressure is extremely low as a result of severe heart problems (such as during shock).
- 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 or Lown-Ganong-Levine syndrome).
- if you have problems with your heart valves or “sick sinus syndrome” (irregular heartbeat) and do not have a pacemaker.
- if you are being treated with injectable beta-blockers.

- if you are sensitive (allergic) to verapamil hydrochloride or any of the other ingredients of this medicine (listed in section 6).
- if you are pregnant or planning to become pregnant.
- if you are being treated with ivabradine (for heart conditions).

Warnings and precautions

Talk to your doctor or pharmacist before taking Caveril

- if you have ever suffered from heart failure, or first degree AV block or an irregular heart beat.
- if you have had a recent heart attack.
- 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 Caveril

Tell your doctor or pharmacist if you are taking, have recently taken or might take any of the following 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, phenytoin 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).
- ivabradine, used to treat heart conditions.

- verapamil may decrease the glucose-lowering effect of metformin.

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

Caveril 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.

Caveril 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 Caveril.

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 or pharmacist 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. Caveril can make some people feel dizzy and tired.

Excipient warnings

This product 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.

This product contains sodium.

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

Caveril contains sucrose.

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 Caveril

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 usual dose for hypertension is 40-120 mg of Caveril 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 dose for angina is 80-120 mg of Caveril taken three to four times a day.

Abnormal heart rhythms

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

If you take more Caveril than you should

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

If you forget to take Caveril

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 Caveril

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 your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

Tell your doctor IMMEDIATELY if you experience any of the following side effects:

- 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 (affects less than 1 in 10 people)

- dizziness
- headache
- slow heartbeat
- flushing
- low blood pressure
- constipation
- nausea (feeling sick)
- swollen feet or ankles

Uncommon (affects less than 1 in 100 people)

- irregular or fast heartbeat
- stomach pain
- tiredness

Rare (affects less than 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

Other side effects (how often they happen is not known)

- 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 enlargement or swelling
- greater than normal amounts of prolactin (female hormone) in the blood that causes the breasts to produce/leak 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 (see details below). By reporting side effects you can help provide more information on the safety

of this medicine.

Malta

ADR Reporting Website:

www.medicinesauthority.gov.mt/adrportal

5. How to store Caveril

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

Do not use this medicine after the expiry date which is stated on the label or carton after 'EXP'. The expiry date refers to the last day of that month.

Store below 25 °C. Protect from light and moisture.

6. Contents of the pack and other information

What Caveril contains

- The active substance is verapamil hydrochloride. Each coated tablet contains 40 mg verapamil hydrochloride.
- The other ingredients are: cellulose microcrystalline, lactose monohydrate, povidone, sodium starch glycolate (Type A), magnesium stearate, talc, hypromellose, macrogol 400, titanium dioxide, gelatin, macrogol 6000, sucrose, calcium carbonate, quinolone yellow E104.
See section 2 'Excipients warnings'.

What Caveril looks like and contents of the pack

Yellow, round, coated tablets.

Pack sizes:

PVC/Aluminium blisters. Pack size of 50 coated tablets.

PP containers with PE closure. Pack sizes of 500 and 1000 coated tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Remedica Ltd

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For internal use: mt-pl-caveril-40mg-sc-tabs-a2