

Verapamil Hydrochloride Injection USP

AMERICAN ARPAMIL Injection

Composition:
Each ml contains:
Verapamil Hydrochloride USP 2.5 mg
Water for Injection USP q.s.

FOR IV USE ONLY

IMPORTANT INFORMATION

Read all of this leaflet carefully before you start using 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 nurse.
- If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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

1. What is Verapamil Injection and what it is used for

Verapamil Injection contains the active substance verapamil hydrochloride. Verapamil Injection belongs to a group of medicines called calcium channel blockers. Verapamil Injection is used to treat abnormal heart rhythms such as an irregular or rapid heart rate in adults, and children aged 0 to 15 years.

2. What you need to know before you use Verapamil Injection

Do not take Verapamil Injection:

- If you are allergic to verapamil hydrochloride or any of the other ingredients of this medicine
- If you have had a heart attack with shock.
- If you have had a heart attack, particularly if a slow heartbeat, low blood pressure or a type of heart failure called 'left ventricular failure'.
- If you have an abnormally slow, fast or irregular heartbeat
- If you have second- or third-degree atrioventricular block or sino-atrial block. This is a disorder where parts of your heart may beat at the wrong time causing it not to pump blood around the body very well (unless a permanent pacemaker is in place).
- If you have a problem where your heart beats very slowly (bradycardia), unless you have been fitted with a pacemaker.
- If you have suffered from heart problems such as heart failure, or the heart condition called Wolff-Parkinson-White syndrome.
- If you are currently being treated with valproic acid (for heart conditions).
- If you have very low blood pressure.
- If you are currently receiving intravenous beta-blockers, e.g. atenolol, propranolol.

Warnings and precautions

Talk to your doctor or nurse before using Verapamil Injection. If you are pregnant, planning to become pregnant or breast-feeding.

- If you have liver or kidney problems.
- If you are currently receiving lipid lowering agents (e.g.: simvastatin, atorvastatin or lovastatin).
- If you have a condition where the nerve to muscle transmission is affected e.g. myasthenia gravis, Lambert-Eaton syndrome, advanced Duchenne muscular dystrophy.

Take special care with Verapamil Injection

Your doctor will monitor you closely if:

- you have any other heart problems in addition to the one you are being treated for
- you need any other medication to treat your abnormal heart rhythm
- you need to be given an anaesthetic

Your doctor may perform ECGs and blood pressure monitoring prior to and during treatment to monitor your individual dose.

Other medicines and Verapamil Injection

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

- Beta-blockers such as atenolol, propranolol and metoprolol (used to treat high blood pressure and heart conditions)
- Alpha blockers such as prazosin and terazosin (used to treat high blood pressure and heart conditions)
- Medicines known as 'statins' such as atorvastatin, lovastatin, simvastatin (used to lower cholesterol levels)
- Quinidine, flecainide, disopyramide, digoxin and digitoxin (used to treat high blood pressure or an abnormal heart beat (arrhythmia))
- Dabigatran (medicine to prevent the formation of blood clots) and direct oral anticoagulants (DOACs)
- Valproic acid (used to treat certain heart diseases)
- Medicines used to treat depression, anxiety or psychosis. These include the herbal product St John's Wort or imipramine, bupropion and lithium
- Medicines known as immunosuppressants such as cyclosporine, sirolimus, everolimus and tacrolimus (used to prevent organ transplant rejection)
- Glyburide (Glibenclamide), medicine used to treat certain types of diabetes
- Aspirin (a non-steroidal anti-inflammatory Drug (NSAID)) used to relieve pain and reduce fever)
- Almotriptan (used to treat migraine)
- Midazolam, (used as a sedative or anaesthetic)
- Theophylline (used to treat asthma)
- Cimetidine (used to treat indigestion or stomach ulcers)
- Rifampicin (used to treat tuberculosis and other types of infection)
- Carbamazepine, phenytoin or phenobarbital (phenobarbitone), medicines used as anti-convulsants
- Ritonavir (used to treat HIV)
- Erythromycin, clarithromycin and telithromycin (used to treat types of infection)
- Colchicine or sulfapyrazone (used to treat gout)
- Metformin. Verapamil may decrease the glucose-lowering effect of metformin.

Verapamil Injection with drink and alcohol

- Do NOT drink grapefruit juice whilst taking Verapamil Injection as it can affect the absorption of this medicine. This does not occur with other fruit juices such as orange, apple or tomato juice.
- Before having Verapamil Injection, inform your doctor or nurse if you have recently had alcohol. This is because alcohol can affect how the medicine works.

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

Verapamil may affect your ability to drive or operate machinery, you **MUST** check with your doctor before you do so. This medicine can affect the way the body gets rid of alcohol. This means that you may not have to drink as much for the blood alcohol levels to be above the legal limit to drive. It will also take you longer to sober up. This is particularly important if you have had prolonged intravenous therapy or if you have switched to oral (tablet) treatment.

3. How to use Verapamil Injection

Verapamil Injection is given to you by injection into a vein (intravenously). This will be carried out by a doctor.

The dose will vary according to your condition this will be decided by the doctor. The medical team in the hospital may monitor your blood pressure and ECG (The electrical activity of the heart) throughout your treatment. The usual doses are as follows.

Adults

5-10 mg by slow intravenous injection over a period of 2 minutes. If necessary, an extra 5 mg may be injected after 5 to 10 minutes.

Elderly

In elderly patients, the injection may be given at a slower rate. If necessary, an extra 5 mg may be injected after 5 to 10 minutes.

Use in children and adolescents

0-1 Year: 0.1 to 0.2 mg per kg bodyweight
1-15 years: 0.1 to 0.3 mg per kg bodyweight
The injection may be repeated after 30 minutes, if necessary.

If you use more Verapamil Injection than you should

If you think you have been given too much of this medicine, talk to your doctor or nurse straight away.

If you stop using Verapamil Injection

Your doctor or nurse will let you know when to stop having this medicine. You may need to stop having it gradually. If you have any further questions on the use of this medicine, ask your doctor or nurse.

4. Possible side effects

Like all medicines, Verapamil Injection can cause side effects. Verapamil Injection affects the rhythm of the heart, but may also slow down the heart rate and cause a drop in blood pressure in some patients.

The medical team will therefore monitor you closely during your treatment.

If you experience any of the following side effects tell your doctor IMMEDIATELY:

- Changes in heart rhythm, chest pains for the first time or chest pains becoming frequent
 - Swollen ankles
 - Unexpected wheezing, difficulty breathing, swelling of the mouth, lips or tongue, itching or a severe skin rash
 - Yellowing of the skin or eyes, a fever or tenderness around the middle. These are signs that your liver may not be functioning as well as usual
- Other side effects with verapamil include flushing of the face or neck, sweating, headaches, tiredness, seizures, dizziness, vertigo, nervousness, movement disorders, abnormal discomfort, nausea, abdominal pain or vomiting.
- Other side effects may sometimes occur with long-term verapamil treatment. Tell your doctor if you develop swollen gums which spread over your teeth, or (in males) if your breasts swell. These effects are very rare and resolve on stopping treatment.
- If you experience any other unusual symptoms after you have received Verapamil Injection, tell your doctor or nurse.

Reporting of side effects

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

5. How to store Verapamil Injection

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

Store between 20°C - 25°C. Protect from Light.

6. Contents of the pack and other information What Verapamil Injection contains:

- The active substance is verapamil hydrochloride. Each ampoule of injection solution contains 2.5 mg per ml verapamil hydrochloride.

What Verapamil Injection looks like and contents of the pack

The product is available in 2 ml ampoules.

Marketed by:



**AMERICAN
REMEDIES**

Care & Cure with Research
American Remedies Healthcare Pvt. Ltd.
(An ISO 9001:2015 Certified Company)

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