

VERAPRESS[®] MR 240 Tablets VERAPAMIL HYDROCHLORIDE

Please read this leaflet carefully before you start taking your tablets.

- 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.

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1. WHAT VERAPRESS MR 240 TABLETS ARE AND WHAT THEY ARE USED FOR

The name of your medicine is: Verapress MR 240 Tablets

Verapress MR 240 Tablets belong 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.

Verapress MR 240 Tablets are indicated for the treatment of mild to moderate hypertension (high blood pressure) and the treatment and prevention of angina pectoris (chest pain).

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE VERAPRESS MR 240 TABLETS

If you are unsure if any of the lists applies to you, ask your doctor before you start to take your tablets.

Do not take Verapress MR 240 Tablets:

- If you are allergic (hypersensitive) to Verapamil Hydrochloride or to any of the other ingredients of Verapress MR 240 Tablets (listed in section 6 - Further information).
- If you are having a cardiogenic shock (a sudden and rapid fall in blood pressure).
- If you are having or have recently had a heart attack particularly if a slow heart beat, low blood pressure or left ventricular failure of the heart are involved.
- If you have second or third degree atrioventricular block or sino-atrial block (a disorder where parts of the heart may beat at the wrong time causing the heart not to pump blood around the body very well).
- If you have sick sinus syndrome (a heart beat disorder).
- If you have heart failure that is not currently being treated.
- If you have severe bradycardia (a condition where the heart beats at less than 50 beats per minute).
- If you have low blood pressure where the higher blood pressure reading is below 90.
- If you have Wolff-Parkinson-White syndrome (a heart problem causing rapid heart rate sometimes associated with symptoms such as dizziness or faintness).
- If you are already taking a medicine containing ivabradine for the treatment of certain heart diseases.

Warnings and Precautions

Consult your doctor or pharmacist before taking Verapress MR 240 Tablets if:

- You are pregnant or planning to become pregnant or are breast feeding.
- You suffer or you have ever suffered in the past from low blood pressure, from a condition known as "heart failure", an abnormally slow or irregular heart beat, or any other cardiac problem.
- You suffer or you have ever suffered in the past from kidney or liver disorders. These above mentioned medical conditions may mean that your doctor will need to monitor you more closely.
- You are planning to have medical or dental surgery. This medicine may affect the anaesthetics or other treatments used.
- You have a condition where the nerve to muscle transmission is affected e.g. myasthenia gravis, Lambert-Eaton syndrome, advanced Duchenne muscular dystrophy.

Children and Adolescents

There are no data on the use of verapamil prolonged release tablets in children and adolescents.

Taking other medicines:

Please inform your doctor or pharmacist if you are taking or have recently taken any of the following medicines, even those not prescribed:

- Digoxin and digitoxin (used to treat certain heart conditions, such as heart failure)
- Beta-blockers (e.g. atenolol, metoprolol and propranolol) or any other treatment for heart diseases and high blood pressure
- Prazosin, terazosin (alpha blockers used to treat high blood pressure and heart conditions)
- Anti-arrhythmic agents used to steady an irregular heart beat (e.g. flecainide, quinidine)
- Carbamazepine, phenytoin, phenobarbital (usually used in epilepsy)
- Ciclosporin, sirolimus, everolimus, tacrolimus (normally used following organ transplants to help prevent rejection)
- Theophylline (used for breathing difficulties e.g. asthma)
- Rifampicin (antibiotic action for treatment of various infections such as tuberculosis (TB))
- Lithium (used for psychiatric conditions)
- Cimetidine (used for stomach disorders e.g. ulcers and indigestion)
- Aspirin, a non-steroidal anti-inflammatory painkiller (NSAID) used to relieve pain and reduce fever
- Glibenclamide (used to treat certain types of diabetes)
- Diuretics (water tablets)
- Erythromycin, clarithromycin and telithromycin (used to treat types of infection)
- Doxorubicin (an anti-cancer medicine)
- Imipramine, St John's Wort (used to treat depression)
- Buspirone (used to treat anxiety)
- Colchicine, sulfapyrazone (used to treat gout)
- Ritonavir (used to treat HIV)
- Medicines known as 'statins' used to lower cholesterol levels (e.g. atorvastatin, lovastatin, simvastatin)
- Medicines used to relax muscles (used for anesthesia during surgical procedures)
- Almotriptan (used to treat migraine)
- Midazolam (used as a sedative or anaesthetic)
- Dabigatran (medicine to prevent the formation of blood clots)
- Medicines containing ivabradine for the treatment of certain heart diseases

Drinking alcohol

Verapress MR 240 Tablets will increase the time your body takes to get rid of alcohol. This means that you may not have to drink as much for your blood alcohol level to be above the legal limit to drive. It will also take you longer to sober up.



Other important information

Do not drink grapefruit juice whilst taking your tablets as it can affect the absorption of this medicine.

Pregnancy and breast-feeding:

Consult your doctor or pharmacist if you are pregnant, trying to become pregnant, or breast-feeding.

Driving and using machines:

Verapress MR 240 Tablets can make some people feel dizzy especially when first starting to take the tablets. Do not drive, operate machinery or do anything that requires you to be alert, until you know how the tablets affect you.

Important information about some of the ingredients of Verapress MR 240 Tablets:

This medicinal product contains 32 mg sodium per dose. To be taken into consideration by patients on a controlled sodium diet.

3. HOW TO TAKE VERAPRESS MR 240 TABLETS

Always take Verapress MR 240 Tablets exactly as your doctor has told you. Check with your doctor if you are not sure.

The tablets should not be chewed or crushed. They should be swallowed whole with a glass of water. It does not matter if you have not eaten.

ADULTS:

• **For treatment of hypertension (high blood pressure):** The recommended dose is one Verapress MR 240 tablet a day. Some patients may need to take two tablets per day (one in the morning and one in the evening with about 12 hours between doses). Do not take more than two tablets per day.

• **For the treatment and prevention of angina pectoris (chest pain):** The usual starting dose for angina is one Verapress MR 240 tablet taken twice a day. You should take one tablet in the morning and one in the evening, with a gap of about 12 hours in between them. Your doctor may prescribe a lower dose according to your symptoms.

CHILDREN

Verapress MR 240 Tablets is NOT recommended for children under 12 years of age.

Elderly

The dose will be the same as that for adults. If you have kidney or liver problem, your doctor may lower your dose.

If you take more Verapress MR 240 Tablets than you should

In case of an overdose, contact your nearest hospital casualty department or tell your doctor **IMMEDIATELY** taking your tablets with you.

If you forget to take Verapress MR 240 Tablets

If you forget to take a dose, take it as soon as you remember, unless it is almost time for your next dose. Do not take a double dose to make up for a forgotten dose.

If you have trouble remembering to take your tablets, tell your doctor or your pharmacist. If you take too many tablets by mistake, any side effects (see below) may be worse than usual; in this case see your doctor.

If you stop taking Verapress MR 240 Tablets

It is important that you continue taking the tablets until your doctor tells you to stop. Do **NOT** stop because you feel better. If you stop taking the tablets too soon your condition may get worse. If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Verapress MR 240 Tablets can cause side effects, although not everybody gets them.

If you experience the following side effects you should tell your doctor immediately:

- If you have any unexpected wheezing or difficulty in breathing, if you have Quincke's oedema (swelling of the face with itching), swelling of the mouth, lips, or tongue, or if you develop a skin rash, pruritus (itching), or severe skin rash with

blistering and peeling of the skin. These are signs you are having an allergic reaction.

- If you develop 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.
- If you have bradycardia (slow heart beats), arrhythmia (irregular heart beat), palpitations (awareness of an irregular or rapid heart beat), heart failure, reversible impairment of liver function, chest pains for the first time or chest pains that become more frequent, dizziness, weakness or confusion, swollen ankles, feeling faint or breathless or a burning sensation in the feet, which may become hot and throbbing.
- Swelling of the limbs.
- Hypotension (abnormally low blood pressure).

Do not stop taking the tablets, but tell your doctor if you get any of the following:

Constipation (the most common side effect), flushing of the face or neck, headaches, feeling or being sick, abdominal pain or discomfort, a feeling of dizziness or spinning, tinnitus (ringing or buzzing in the ears), tiredness, tremor, movement disorders, muscle weakness, aches and pains in the joints and/or muscles, skin rash or itching, a tingling or prickling feeling on the skin, numbness and hair loss. Impotence may occur rarely.

Other side effects might occur if Verapress MR 240 is used for a long time. **Tell your doctor** if you develop swollen gums which start to spread over your teeth, or if your breasts swell (males) or start to produce milk (males and females). These effects are rare and are resolved upon stopping taking the tablets.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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. You can also report side effects directly via the Yellow Card Scheme at www.mhra.gov.uk/yellowcard.

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

5. HOW TO STORE VERAPRESS MR 240 TABLETS

Keep out of the sight and reach of children.

Do not use Verapress MR 240 Tablets after the expiry date on the label and carton.

Do not store above 25°C.

Do not use Verapress MR 240 Tablets if you notice any visible signs of deterioration.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Verapress MR 240 Tablets contain:

The active substance is: Verapamil Hydrochloride 240mg.

The other ingredients are: Core: Sodium alginate, Microcrystalline cellulose, Povidone, Hypromellose, Colloidal anhydrous silica, Magnesium stearate.

Coating: Hypromellose, Titanium dioxide, Macrogol, Yellow Lake E-104, Blue Lake E-132 and Carnauba wax.

What Verapress MR 240 Tablets look like and content of the pack:

This medicine can be identified as modified release, light-green film-coated, capsule-shaped, scored tablets.

Verapress MR 240 Tablets are supplied in packs of 28 tablets.

The Manufacturer/Holder of Marketing

Authorisation is:

Dexcel®- Pharma Ltd, 7 Sopwith Way, Drayton Fields, Daventry, Northamptonshire, NN11 8PB, UK.

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