PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S3

VERAHEXAL® 240 SR (film-coated slow release tablets)

Verapamil hydrochloride

VERAHEXAL 240 SR contains sugar (8,84 mg lactose monohydrate per tablet).

Read all of this leaflet carefully before you start taking VERAHEXAL 240 SR

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- VERAHEXAL 240 SR has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What VERAHEXAL 240 SR is and what it is used for
2. What you need to know before you take VERAHEXAL 240 SR
3. How to take VERAHEXAL 240 SR
4. Possible side effects
5. How to store VERAHEXAL 240 SR
6. Contents of the pack and other information

1. What VERAHEXAL 240 SR is and what it is used for

Verapamil is an antihypertensive agent and belongs to a group called the calcium channel blockers. It is used to treat the following conditions:

- Mild to moderate high blood pressure (hypertension).
- Preventative treatment of chest pains (angina pectoris).
- Supraventricular tachydysrrhythmia (abnormally accelerated and defective rhythm of the heartbeat).
- Preventative treatment of abnormal rhythm of the heart after application of an electric shock to restore normal heartbeat.

2. What you need to know before you take VERAHEXAL 240 SR

Do not take VERAHEXAL 240 SR:

- If you are hypersensitive (allergic) to verapamil or any of the other ingredients of VERAHEXAL 240 SR (listed in section 6).
- If you have lowered blood pressure associated with heart shock.
- If you have heart failure.
- If you have second or third degree AV 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 an acute stage of myocardial infarction (heart attack).
- If you have sick sinus syndrome. This is abnormalities which produce a wide variety of intermittent rapid and slow abnormal heart rate and heart rhythm. Common symptoms include palpitations, faintness and fainting.
- If you have left ventricular heart failure (a condition where the left heart ventricle doesn't pump blood efficiently, which prevents your body from getting enough oxygen-rich blood).
- 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 mm Hg.

- 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.
- If you are pregnant, planning to become pregnant or breastfeeding.

Warnings and precautions

Take special care with VERAHEXAL 240 SR:

- If you have severe left ventricular dysfunction of the heart or if you have any degree of left ventricular dysfunction (where the left heart ventricle doesn't pump blood as well as it should, which prevents your body from getting as much oxygen-rich blood as it should), your doctor will not prescribe VERAHEXAL 240 SR.
- If you suffer from hypotension (low blood pressure).
- If you have atrioventricular block (AV-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), your doctor may decide to reduce the dosage or discontinue therapy with VERAHEXAL 240 SR.
- If you suffer from hypertrophic cardiac myopathies (a disease in which the heart muscle becomes abnormally thick, which makes it harder for the heart to pump blood).
- If you suffer or you have ever suffered from liver and kidney disorders. These above mentioned medical conditions may mean that your doctor will need to monitor you more closely.
- Elevated liver enzymes: tell your doctor that you are taking this medicine when going for blood tests, as increases of liver enzymes have been reported during therapy with VERAHEXAL 240 SR – such elevations are usually transient (they are not permanent).
- If you have a condition where the nerve to muscle transmission is affected e.g. myasthenia gravis, Lambert-Eaton syndrome and advanced Duchenne muscular dystrophy.

Other medicines and VERAHEXAL 240 SR

Always tell your health care provider if you are taking any other medicine. This includes all complementary or traditional medicines.

Tell your doctor if you are taking or have taken the following medicines as VERAHEXAL 240 SR should not be used or should be used with caution in combination with the following medicines:

- Aspirin, a non-steroidal anti-inflammatory painkiller (NSAID) used to relieve pain and reduce fever.
- Prazosin, terazosin (alpha blockers used to treat high blood pressure and heart conditions).
- Beta-blockers i.e. propranolol: this combination will be monitored carefully as it can excessively increase the blood pressure lowering effects of verapamil
- Digitalis (digoxin and digitoxin), verapamil increases serum concentrations of digitalis which can result in digitalis toxicity. Your doctor may have to reduce the dosage or temporarily discontinue digitalis therapy.
- Antihypertensives (medicines used to treat high blood pressure), additive blood pressure lowering effects. The dose of other hypotensives (blood pressure lowering medicine) may have to be lowered.
- Disopyramide (used to treat serious irregular heartbeat) should not be administered 48 hours before or 24 hours after verapamil administration.
- Flecainide and quinidine (used to treat serious irregular heart beat).
- Lithium (used for the treatment of psychiatric conditions).
- Carbamazepine, phenytoin, phenobarbital (used to treat epilepsy).
- Imipramine, St John’s Wort (used to treat depression).
- Glibenclamide (used to treat certain types of diabetes).
- Rifampicin (an anti-infective used for the treatment of various infections such as tuberculosis (TB)).

- Erythromycin, clarithromycin and telithromycin (used to treat types of infection).
- Doxorubicin (an anti-cancer medicine).
- Buspirone (used to treat anxiety).
- Midazolam (used as a sedative or anaesthetic).
- Colchicine, sulfinpyrazone (used to treat gout).
- Cimetidine (used for stomach disorders e.g. ulcers and indigestion).
- HIV antiviral medicines such as ritonavir.
- Everolimus, sirolimus, tacrolimus (normally used following organ transplants to help prevent rejection).
- Inhalation anaesthetics may cause excessive decrease in the functional activity of the heart. It is very important to tell your anaesthetist that you are using this medication.
- Neuromuscular blocking agents i.e. medication administered in association with anaesthetics to increase their effectiveness: verapamil may potentiate the effects of these agents.
- Medicines known as ‘statins’ used to lower cholesterol levels (e.g. atorvastatin, lovastatin, simvastatin).
- Almotriptan (used to treat migraine).
- Theophylline (used for breathing difficulties e.g. asthma).
- Dabigatran (medicine to prevent the formation of blood clots).
- Medicines containing ivabradine for the treatment of certain heart diseases.
- Metformin-medicines used to treat diabetes.

VERAHEXAL 240 SR with food, drink and alcohol

VERAHEXAL 240 SR 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.

Do not drink grapefruit juice whilst taking VERAHEXAL 240 SR as it can affect the absorption of this medicine.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

Verapamil does cross the placenta and should not be administered during pregnancy. Verapamil is also excreted in the breast milk. Discontinue breastfeeding while taking verapamil.

Driving and using machines

VERAHEXAL 240 SR 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 VERAHEXAL 240 SR

VERAHEXAL 240 SR contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking VERAHEXAL 240 SR.

3. How to take VERAHEXAL 240 SR

Do not share medicines prescribed for you with any other person.

Always take VERAHEXAL 240 SR exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Hypertension (high blood pressure):

The usual dose is one tablet daily, preferably in the morning.

Should the desired response not be achieved within 7 days, your doctor may increase the dose to 1 tablet in the morning and half a tablet in the evening.

The maximum dose is 1 tablet every 12 hours.

Angina pectoris (chest pains) and supraventricular dysrrhythmia (abnormal rhythm originating above a ventricle):

The usual dose is half to 1 tablet every 12 hours.

If you have the impression that the effect of VERAHEXAL 240 SR is too strong or too weak, talk to your doctor or pharmacist.

If you take more VERAHEXAL 240 SR than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre. Take any remaining tablets and the container with you and show the pack to the doctor.

If you forget to take VERAHEXAL 240 SR

Do not take a double dose to make up for forgotten individual doses. If you miss a dose, drink it as soon as you remember and go on as before. If you are not sure what to do, ask your doctor or pharmacist.

If you stop taking VERAHEXAL 240 SR

It is important that you continue taking the VERAHEXAL 240 SR 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 VERAHEXAL 240 SR, ask your doctor or pharmacist.

4. Possible side effects

VERAHEXAL 240 SR can have side effects.

Not all side effects reported for VERAHEXAL 240 SR are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking VERAHEXAL 240 SR, please consult your health care provider for advice.

If any of the following happens, stop taking VERAHEXAL 240 SR and tell your doctor immediately or go to the casualty department at your nearest hospital:

- 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.
- If you develop a severe skin rash with blistering and peeling of the skin (Stevens-Johnson syndrome) or red skin lesions, often with a purple centre (erythema multiforme).

These are all very serious side effects. If you have them, you may have had a serious reaction to VERAHEXAL 240 SR. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Less frequent side effects:

- Flushing.
- Tender and swollen gums.
- Abnormal liver function.
- Inability to obtain an erection.
- Swelling of the breasts and discharge of milk.

The frequency of the following side effects are unknown:

- Constipation.
- Nausea.
- Vomiting.
- Abdominal pain or discomfort.
- Painful obstruction of the gut.

- Headache.
- A tingling or prickling feeling on the skin (paraesthesia).
- Tremors (uncontrollable shaking).
- Movement disorders.
- A feeling of dizziness or spinning (vertigo).
- Tinnitus (ringing or buzzing in the ears).
- Fatigue.
- Palpitations (irregular and/or forceful beating of the heart).
- Worsening heart failure.
- Sinus arrest with asystole (when a part of the heart stops generating the electrical impulses, which cause it to beat normally, together with the absence of a heartbeat).
- First and second-degree AV 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). First degree is non-serious, whilst second and third degree are more serious.
- Bradycardia (abnormally slow rate of heart rate contractions).
- SA block (a heart rhythm disorder).
- Swelling of the lower limbs (peripheral oedema).
- Fast heartbeat (tachycardia).
- Dizziness.
- Swollen ankles.
- Feeling faint or breathless or a burning sensation in the feet, which may become hot and throbbing.
- Hair loss (alopecia).
- Small, raised areas of bleeding in the skin (purpura).
- Hypotension (lowered blood pressure).
- Muscle weakness.
- Aches and pains in the joints and/or muscles.
- Hepatoxicity (toxic damage to the liver).

- Raise in blood prolactin levels (detected in a blood test).

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reaction Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of VERAHEXAL 240 SR. Suspected side effects can also be reported directly to the HCR via Patientsafety.sacg@novartis.com.

5. How to store VERAHEXAL 240 SR

STORE MEDICINES OUT OF REACH OF CHILDREN.

Store at or below 25 °C.

Store in the original package or container as dispensed by your pharmacist.

Protect from light.

Do not use after the expiry date stated on the label, carton or securitainer.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems e.g. toilets.

6. Contents of the pack and other information

What VERAHEXAL 240 SR contains

The active substance is verapamil hydrochloride.

Each Verahexal 240 SR film-coated slow release tablet contains 240 mg verapamil hydrochloride.

The other ingredients are:

Core:

Colloidal silica anhydrous

Magnesium stearate

Microcrystalline cellulose

Polyvidone

Sodium alginate.

Film-coating:

Green varnish consists of quinolone yellow (E104) and indogitine (E132)

Hypromellose

Lactose monohydrate

Macrogol 4000

Titanium dioxide (E171).

What VERAHEXAL 240 SR looks like and contents of the pack

VERAHEXAL 240 SR is an oblong, light-green film-coated tablet with scores on both sides and smooth, intact surface.

Length: 19,1 to 19,3 mm

Width: 8,1 to 8,3 mm

Height: 6,2 to 6,5 mm

The tablets are packed into white opaque polypropylene securitainers containing 30 or 100 tablets each.

Not all pack sizes are necessarily marketed.

Holder of Certificate of Registration

Sandoz SA (Pty) Ltd[1]

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Access to the corresponding Professional Information

Not applicable.

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