Patient Information Leaflet

Half Securon® SR 120mg modified release tablets
(verapamil hydrochloride)

IMPORTANT INFORMATION
Read all of this leaflet carefully before you start taking this medicine.
• Keep this leaflet as you may need to read it again.
• This leaflet provides a summary of the information currently available about Securon SR and Half Securon SR.
• For further information or advice ask your doctor or pharmacist.
• This medicine is for you only and should never be given to anyone else, even if they appear to have the same symptoms as you.
• Tell your doctor or pharmacist if you experience any side effects.
• The name of this medicine is Half Securon® SR 120mg modified release tablets but will be referred to as Half Securon SR throughout the remainder of this leaflet.
• The strength Securon SR 240mg is also available.

Leaflet contents:
1) What is Securon SR / Half Securon SR and what is it used for?
2) What should you know before taking your tablets?
3) How should you take your tablets?
4) Possible side effects.
5) How should you store your tablets?
6) Further information.

1) WHAT IS SECURON SR / HALF SECURON SR AND WHAT IS IT USED FOR?

Securon SR and Half Securon SR 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.

Securon SR and Half Securon SR tablets are used to treat hypertension (high blood pressure) and to prevent angina (chest pain) attacks. The tablets may also be prescribed following a heart attack, to prevent another attack occurring.

The active ingredient in Securon SR and Half Securon SR tablets is verapamil hydrochloride.

2) WHAT SHOULD YOU KNOW BEFORE TAKING YOUR TABLETS?

If the answer to any of the following questions is ‘YES’ please tell your doctor or pharmacist BEFORE taking any tablets:
• Are you sensitive (allergic) to verapamil or any of the other ingredients in the tablets? (See section 6)
• Are you pregnant or planning to become pregnant, or are you breast feeding?
• Do you have very low blood pressure?
• Do you have or have you ever suffered from heart problems such as heart failure?
• Do you have an abnormally slow or irregular heart beat?
• Have you recently had a heart attack?
• Do you have liver or kidney problems?
• Do you have or have you ever suffered from heart problems such as heart failure or the heart condition called Wolff-Parkinson-White syndrome?
• Do you have a condition where the nerve to muscle transmission is affected e.g. myasthenia gravis, Lambert-Eaton syndrome, advanced Duchenne muscular dystrophy?
• Are you being treated with ivabradine (for heart conditions)?

Taking other medicines
Please tell your doctor or pharmacist if you are taking any medicines with or without a prescription or have recently taken any of the following medicines:
• beta-blockers used to treat high blood pressure and heart conditions (these include atenolol, propranolol and metoprolol)
• alpha blockers used to treat high blood pressure and heart conditions (these include prazosin and terazosin)
• diuretics (also called “water pills”)
• 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 quinidine, flecanide, disopyramide, digoxin and digitoxin
• dabigatran (medicine to prevent the formation of blood clots)
• medicines containing ivabradine for the treatment of certain heart diseases
• medicines used to treat depression (including the herbal product St John’s Wort), anxiety or psychosis. These may include imipramine, buspirone and lithium
• medicines known as immunosuppressants such as ciclosporin, sirolimus, everolimus and tacrolimus. These are used to prevent organ transplant rejection
• glibenclamide, used to treat certain types of diabetes
• aspirin, a non-steroidal anti-inflammatory painkiller (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
• doxorubicin, an anti-cancer medicine
• cimetidine, used to treat indigestion or stomach ulcers
• rifampicin, used to treat tuberculosis and other types of infection
• carbamazepine, phenytoin or phenobarbital (phenobarbital). These medicines are used as anti-convulsants
• ritonavir, used to treat HIV
• erythromycin, clarithromycin and telithromycin, used to treat types of infection
• colchicine or sulfipyrazone, used to treat gout

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

Driving and operating machines
Do NOT drive, operate machinery or do anything that requires you to be alert, until you know how the tablets affect you.

Securon SR and Half Securon SR can make some people feel dizzy, especially when they first start to take the tablets.

Other important information
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.

Drinking alcohol
Securon SR and Half Securon 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 levels to be above the legal limit to drive. It will also take you longer to sober up.

Pregnancy and breast feeding
Please discuss with your doctor if you are pregnant, planning to become pregnant or are breast feeding.
3) HOW SHOULD YOU TAKE YOUR TABLETS?

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

TAKE YOUR TABLETS with a glass of water. You should swallow the tablets without chewing or crushing them. It does not matter if you have not eaten.

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 is one Securon SR 240mg tablet a day. If you have not taken Securon SR 240mg before, your doctor may prescribe a lower dose such as a Half Securon SR 120mg tablet each day.

The maximum dose to treat high blood pressure is 480mg each day. This is usually taken as one Securon SR 240mg tablet in the morning and one in the evening, leaving a gap of about 12 hours between each dose.

Angina (chest pain)

The usual starting dose for angina is one Securon SR 240mg 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.

Following a heart attack

The usual dose following a heart attack is 360mg each day. This may be taken as one Securon SR 240mg tablet in the morning and a Half Securon SR 120mg tablet in the evening or as one Half Securon SR 120mg tablet taken three times a day. The doctor will usually wait at least a week after your heart attack before prescribing these tablets.

CHILDREN:

Securon SR and Half Securon SR are 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 Securon SR and Half Securon SR than you should

If you take more tablets than prescribed (an overdose) you should contact a doctor or go to the nearest hospital casualty department IMMEDIATELY taking your tablets with you.

If you forget to take Securon SR and Half Securon SR

If you forget to take your tablets take them 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 double dose to make up for a forgotten tablet.

If you stop taking Securon SR and Half Securon SR

If you stop taking your tablets 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.

Other things to remember about Securon SR and Half Securon SR

- Securon SR 240mg tablets may be broken in half if your doctor advises you to do so (e.g. if a lower dose has been prescribed).
- The tablets should NOT be crushed, chewed or sucked, as this will affect the modified-release formulation of the product.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4) POSSIBLE SIDE EFFECTS.

As with all medicines, Securon SR and Half Securon SR can cause side effects, although not everyone will suffer from them. If you experience any other unusual symptoms whilst taking your tablets, tell your doctor or pharmacist.

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

- 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.
- Palpitations, chest pains for the first time or chest pains becoming more frequent, swollen ankles, hot and painful hands or feet.
- Swelling of the limbs.
- Unexpected wheezing, difficulty breathing, swelling of the mouth, lips or tongue or severe skin rash.

The most common side effect is constipation. Other side effects include abnormal heart beat, flushing of the face or neck, headaches, feeling or being sick, abdominal pain or discomfort, dizziness, vertigo, 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 Securon SR or Half Securon SR are 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.

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 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 SHOULD YOU STORE YOUR TABLETS?

- Keep out of the sight and reach of children.
- Do not store above 25°C.
- Store in the original package.
- Do not use after the expiry date which is stated on the carton label and blister foil after EXP. The expiry date refers to the last day of that month.
- If your tablets become discoloured or show any sign of deterioration, return them to your pharmacist.
- 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) FURTHER INFORMATION.

What Half Securon SR tablets contain:

Each tablet contains 120mg verapamil hydrochloride.

The other ingredients are: microcrystalline cellulose, sodium alginate, povidone, magnesium stearate, hypromellose, macrogol 400, macrogol 6000, talc, titanium dioxide (E171) and montan wax.

What Half Securon SR tablets look like and contents of the pack:

Half Securon SR tablets are round, white, biconvex and embossed with the word "Knoll" on one side and "120 SR" on the reverse.

The tablets are available in packs of 30, 40 and 60 tablets.

Manufactured by AbbVie Deutschland GmbH & Co.KG., Knollistrasse 50, D-67061 Ludwigshafen, Germany.

Famar Anthoussa, Greece.

Procured from within the EU by Product Licence Holder: MPT Pharma Ltd, Westgate Business Park, Unit 5-7 Tintagel Way, Aldridge, Walsall, WS9 BER, UK.

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