

Securon® IV 2.5 mg/ml aqueous solution for intravenous injection

Verapamil Hydrochloride



IMPORTANT INFORMATION

Read all of this leaflet carefully before you receive Securon IV

- Keep this leaflet as you may need to read it again
- This leaflet provides a summary of the information currently available on Securon IV
- For further information or advice ask your doctor or pharmacist
- Tell your doctor or pharmacist if you experience any side effects

Leaflet contents:

1. What is Securon IV and what is it used for?
2. What should you know before receiving Securon IV?
3. How will you receive Securon IV?
4. Possible side effects
5. How should Securon IV be stored?
6. Further information about Securon IV

1. What is Securon IV and what is it used for?

Securon IV belongs to a group of medicines called calcium channel blockers; its active ingredient is verapamil hydrochloride. Securon IV is used to treat abnormal heart rhythms such as an irregular or rapid heart rate.

2. What should you know before receiving Securon IV?

If the answer to any of the following questions is **'YES'** please tell your doctor or pharmacist **BEFORE** receiving Securon IV:

- Are you are sensitive (allergic) to the active ingredient verapamil hydrochloride or any of the other ingredients in the medicine? (See section 6)
- Are you pregnant, planning to become pregnant or breast-feeding?
- Do you have kidney problems?
- Do you have very low blood pressure?
- Do you have an abnormally slow, fast or irregular heartbeat?
- Do you have or have you ever suffered from heart problems such as heart failure, or the heart condition called Wolff-Parkinson-White syndrome?
- Are you currently receiving intravenous beta-blockers, e.g. atenolol, propranolol?

- 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 condition)?

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

You MUST tell your doctor 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)
- 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, flecainide, 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
- Cimetidine, used to treat indigestion or stomach ulcers
- Rifampicin, used to treat tuberculosis and other types of infection
- Carbamazepine, phenytoin or phenobarbital (phenobarbitone). These medicines are used as anti-convulsants
- Ritonavir, used to treat HIV
- Erythromycin, clarithromycin and telithromycin, used to treat types of infection
- Colchicines or sulfinpyrazone, used to treat gout

Driving and using machinery



Verapamil may affect your ability to drive or operate machinery, you **MUST** check with your doctor before you do so.



This is particularly important if you have had prolonged intravenous therapy or if you have switched to oral (tablet) treatment.

Pregnancy and breast feeding

Please discuss with your doctor if you are pregnant, planning to become pregnant or are breast feeding.

Other important information

Do **NOT** drink grapefruit juice whilst taking Securon IV as it can effect the absorption of this medicine. This does not occur with other fruit juices such as orange, apple or tomato juice.

3. How will you receive Securon IV?

Securon IV 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.

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.

Children:

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.

4. Possible side effects

As with all medicines, Securon IV can cause side effects. Securon IV 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 rare 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 Securon IV, tell your doctor, nurse 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 should Securon IV be stored?

Do not store above 30°C and protect from light. The doctor or nurse will check that the expiry date on the label has not passed before you are given the injection. It should **NOT** be used after the expiry date printed on the label.

6. Further information about Securon IV

What Securon IV contains:

Each ampoule of injection solution contains 2.5 mg per ml verapamil hydrochloride in water for injections and sodium chloride, with hydrochloric acid as pH adjuster.

What Securon IV looks like:

The product is available in 2 ml ampoules, each containing 5 mg of verapamil hydrochloride.

Marketing Authorisation and Manufacturer's Details

Marketing Authorisation Holder:
Mylan Products Ltd.,
20 Station Close,
Potters Bar,
Herts, EN6 1TL, UK

Manufacturer:
FAMAR HEALTHCARE SERVICES
MADRIDSAU. Avda.de Legan.62
28923 Alcorc6n-Madrid, Spain.

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