2. What should you know before receiving Securon IV?

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

- Are you 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 breastfeeding?
- 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 an accessory cardiac pathway or 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 nerves to muscle transmission is affected e.g. myasthenia gravis, Lambert-Eaton syndrome, advanced Duchenne muscular dystrophy?
- Are you being treated with isradipine (for heart condition)?

Your doctor will monitor you closely.

- You may have any other heart problems in addition to the one you are being treated for.
- You may need any other medication to treat your abnormal heart rhythm.
- You need to be given an electrocardiogram (ECG).

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 medicines that are high blood pressure or an abnormal heart beat (arrhythmia) such as quinidine, flecainide, disopyramide, digoxin and digitoxin.

Patients with atrial flutter/fibrillation in the presence of an accessory pathway (e.g. WPW syndrome) may develop increased conduction across the atrioventricular pathway and ventricular tachycardia maybe precipitated.

Combination with labradine (see section Interactions with other medicinal products and other forms of interaction).

4.4. Special Warnings and Precautions for Use

Verapamil may affect multiple functions. For this reason, Securon IV should be used with caution in patients with bradycardia or first degree AV block. Vertebral may affect left ventricular contractility; this effect is small and normally not important but cardiac failure may be precipitated or aggravated. In patients with poor venous function, therefore, Securon IV should only be given after cardiac failure has been controlled with appropriate therapy, e.g. digoxin.

Although the pharmacokinetics of verapamil in patients with renal impairment are not affected, caution should be exercised and careful patient monitoring is recommended. Verapamil is not removed during dialysis.

Caution should be exercised in treatment with HMG CoA reductase inhibitors (e.g., simvastatin, atorvastatin or lovastatin) for patients taking verapamil. These patients should be started at the lowest possible dose of verapamil and titrated upwards. If verapamil treatment is to be added to patients already on HMG CoA reductase inhibitor (e.g., simvastatin, atorvastatin or lovastatin), refer to the advice in the respective statin product information.

Use with caution in the presence of diseases in which neuro muscular transmission is affected such as myasthenia gravis, Lambert-Eaton syndrome, advanced Duchenne muscular dystrophy.

4.6. Pregnancy and Lactation

Although animal studies have not shown any teratogenic effects, verapamil should be avoided during the first trimester of pregnancy unless, in the clinician’s judgement, it is essential for the welfare of the patient. Verapamil crosses the placental barrier and can be detected in umbilical vein blood at delivery.

Human breast milk. Limited human data from oral administration has shown that the infant relative dose of verapamil is 0.1-1.5% of the mother’s oral dose) and that verapamil does not cross the placenta. If compatible with breastfeeding. However, there are currently no reports of verapamil injection or infusion use during breastfeeding. When used in pregnancy, in the first trimester and in labour, the use of verapamil should only be used during lactation if it is essential for the welfare of the mother.

4.8. Undesirable Effects

Adverse events observed in clinical trials are depicted in the following table. Within each system organ class, the adverse drug reactions are ranked under the following headings: common (≥1/10), uncommon (≥1/100, <1/10), rare (≥1/1000, <1/100), very rare (≤1/10 000), including isolated reports.

<table>
<thead>
<tr>
<th>System Organ Class</th>
<th>Frequency</th>
<th>Undesirable Effects</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cardiac disorders/vascular disorders</td>
<td>common</td>
<td>- bradycardia</td>
</tr>
<tr>
<td></td>
<td>uncommon</td>
<td>- hypotension</td>
</tr>
<tr>
<td>Gastrointestinal disorders</td>
<td>uncommon</td>
<td>- nausea</td>
</tr>
</tbody>
</table>

4.9. Overdose

The therapy of verapamil overdosage includes hydration, shock, loss of consciousness, first and second degree AV block [frequently as hemodynamic collapse]. When in the presence of hypotension, plasma concentrations of verapamil may be maintained for up to 24 hours, after which plasma levels of verapamil will decrease in an exponential manner. The half-life of verapamil in plasma is approximately 2.5 hours. In severe cases of verapamil intoxication, hemodialysis may be a useful therapeutic measure. In the absence of specific antidotes, general supportive measures should be applied. In case of moderate or severe intoxication, verapamil should be discontinued.

Cases of seizures during verapamil hydrochloride injection have been reported.

In rare cases of hypersensitivity, bronchospasm accompanied by pruritis and urticaria has been reported.

Other rare reactions from Postmarketing Surveillance or Phase IV Clinical Trials

Other adverse events reported with verapamil are listed below by system organ class.

- Cardiovascular disorders: On rare occasions, cardiovascular events have been reported.
- Reproductive system and breast disorders: On rare occasions, gynaecomastia has been observed in elderly male patients under long-term verapamil therapy. It has been reported that this is a reversible side effect.
- Skin and subcutaneous tissue disorders: Stevens-Johnson syndrome, erythema and hypertrophic.
- Reproductive system and breast disorders: On very rare occasions, gynaecomastia has been observed in elderly male patients under long-term verapamil therapy. It has been reported that this is a reversible side effect.
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Side effects of verapamil therapy that may occur in very rare cases during verapamil treatment and is most probably a hypersensitivity reaction.

4.9. Overdose

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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. 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.

If your doctor decides to stop your treatment, return any leftover medicine to your pharmacist. Do not dispose of leftover medicine carelessly (e.g. down the toilet or in with your general rubbish).

If your medicine becomes discoloured or shows any other signs of deterioration, consult your doctor or pharmacist who will tell you what to do.

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 clear glass ampoules containing a colourless solution, each containing 5 mg of verapamil hydrochloride. Pack size: 5x2ml

**Manufacturer and Product Licence Holder**
Verapamil Hydrochloride 2.5 mg/ml solution for injection

IMPORTANT INFORMATION

Read all of this leaflet carefully before you receive Verapamil Hydrochloride

• Keep this leaflet as you may need to read it again
• This leaflet contains important information on the safety of this medicinal product which should be read by patients before taking Verapamil Hydrochloride, but also by all caregivers
• For further information or advice ask your doctor or pharmacist
• Tell your doctor or pharmacist if you experience any side effects

Your medicine is available using the above name but will be referred to as Verapamil Hydrochloride throughout this leaflet.

Leaflet contents:
1. What is Verapamil Hydrochloride and what is it used for?
2. How will you be given Verapamil Hydrochloride?
3. How will you receive Verapamil Hydrochloride?
4. Possible side effects
5. How should Verapamil Hydrochloride be stored?
6. Further information about Verapamil Hydrochloride

Verapamil Hydrochloride 2.5 mg/ml solution for injection

Patients with atrial flutter/fibrillation in the presence of an accessory pathway (e.g. WPW syndrome) may develop increased conduction across the accessory pathway and ventricular tachycardia may be precipitated.

Combination with ivabradine (see section Interactions with other medicinal products and other forms of interaction).

4.2. POA and MOA of Administration
For slow intravenous injection.

- Adults: 5–10 mg slow intravenous injection over a period of 2 minutes. The patient should be observed continuously, preferably under ECG and blood pressure control. If necessary, e.g. in paroxysmal tachycardia, a further 5 mg may be given after 5 to 10 minutes.

- Children: Verapamil Hydrochloride must always be administered under ECG monitoring in young patients.

0.1–0.2 mg/kg body weight (usual single dose range: 0.75–2 mg); 1–5 years: 0.1–0.3 mg/kg body weight (usual single dose range: 2–5 mg); the dose may be repeated after 30 minutes if necessary. Many cases are controlled by doses at the lower end of the range. The injection should be stopped at the onset of the desired effect.

Elderly: The dosage should be administered over 3 minutes to minimize the risk of adverse effects.

Dosage in impaired liver and renal function: Significant hepatic and renal impairment should not increase the effects of a single intravenous dose but may prolong its duration of action.

Verapamil Hydrochloride 2.5 mg/ml solution for injection

1. What is Verapamil Hydrochloride and what is it used for?

Verapamil Hydrochloride belongs to a group of medicines called calcium channel blockers, its active ingredient is verapamil hydrochloride.

Verapamil hydrochloride is used to treat abnormal heart rhythms such as an irregular or rapid heart rate.

1. What is Verapamil Hydrochloride and what is it used for?

Verapamil Hydrochloride is indicated for the treatment of:

- Hypertension of less than 5 mm Hg in uncompensated patients with a functioning artificial heart.
- Cardiogenic shock.

2. What should you know before receiving Verapamil Hydrochloride?

If this answer to any of the following questions is ‘YES’ please tell your doctor or pharmacist BEFORE receiving Verapamil Hydrochloride:

- Are you allergic (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 abnormal 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 ‘statis’ such as atorvastatin, lovastatin, simvastatin used to lower blood cholesterol and triglycerides.
- Any other medicine for high blood pressure or an abnormal heart beat (arrhythmias) such as quinidine, flecainide, disopyramide, digoxin and digitoxin.

3. How will you be given Verapamil Hydrochloride?

For use with beta-blockers, see ‘Contra-indications’ and ‘Special Warnings and Precautions for Use’.

4.3. Contra-indications

Hypersensitivity to the active substance or to any of the excipients.

Cardiovascular shock; acute myocardial infarction complicated by breafing heart failure, severe second or third degree AV block (except in patients with a functioning artificial ventricular pacemaker); sinusoidal block; sick sinus syndrome (except in patients with a functioning artificial ventricular pacemaker); uncompensated heart failure; bradycardia of less than 50 beats/minute; hypotension. Verapamil is generally contraindicated in patients with unstable angina, and simultaneous administration of intravenous blockers.

Patients with atrial flutter/fibrillation in the presence of an accessory pathway (e.g. WPW syndrome) may develop increased conduction across the accessory pathway and ventricular tachycardia may be precipitated.

Combination with ivabradine (see section Interactions with other medicinal products and other forms of interaction).

4.4. Special Warnings and Precautions for Use

For use during breast feeding:

No data are available on the use of Verapamil Hydrochloride in pregnant women.

Cases of seizures during verapamil hydrochloride injection have been reported.

In rare cases of hypersensitivity, bronchospasm accompanied by pruritis and urticaria has been reported.

Other Reactions from Postmarketing Surveillance or Phase IV Clinical Trials
Other adverse events reported with verapamil have been listed by system organ class.

4.7. Overdose

The usual treatment of overdose includes hypotension, shock, loss of consciousness, first and second degree AV block (frequently as complete heart block), bradycardia up to 60 beats per minute and if required, pacemaker therapy should be considered. If there are signs of myocardial insufficiency, dopamine, dobutamine, calcium glycolates or calcium gluconate (10–20 ml of a 1% solution) can be administered.

In the case of hypotension, after appropriately positioning the patient, dopamine, dobutamine or noradrenaline may be given.

4.6. Special Precautions for Storage

Do not store above 30°C. Protect from light.

Administrative Data

7. Product Licence Holder
Star Pharmaceuticals Ltd, 5 Sandridge Close, Harrow, Middlesex, HA1 1TD

The product is available in 2 ml clear glass ampoules containing a colourless solution, each containing 5 ml of verapamil hydrochloride. Pack size: 5x2ml

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

4. Possible side effects

As with all medicines, Verapamil Hydrochloride can cause side effects. Verapamil Hydrochloride 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 usual. Other side effects with verapamil include flushing of the face or neck, sweating, headaches, tiredness, seizures, 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 Hydrochloride, tell your doctor, nurse or pharmacist.

Reporting of side effects

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If your doctor decides to stop your treatment, return any leftover medicine to your pharmacist.

Only keep the medicine if your doctor tells you to. Do not dispose of left over medicine carelessly (e.g. down the toilet or in with your general rubbish).

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