PATIENT INFORMATION LEAFLET

3019
27.09.25[6]

Securon® IV

(verapamil hydrochloride)

IMPORTANT INFORMATION

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or nurse.
- If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

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

What is in this leaflet

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

Securon IV contains the active substance verapamil hydrochloride. Securon IV belongs to a group of medicines called calcium channel blockers.

Securon IV is used to treat abnormal heart rhythms such as an irregular or rapid heart rate in adults, and children aged 0 to 15 years.

2. What you need to know before you use Securon IV

Do not take Securon IV:
- If you are allergic to verapamil hydrochloride or any of the other ingredients of this medicine (listed in section 6).
- If you have had a heart attack with shock.
- If you had a heart attack, particularly if a slow heartbeat, low blood pressure or a type of heart failure called 'left ventricular failure'.
- If you have an abnormally slow, fast or irregular heartbeat.
- If you have second- or third-degree atrioventricular block or sino-atrial block. This is a disorder where parts of your heart may beat at the wrong time causing it not to pump blood around the body very well (unless a permanent pacemaker is in place).
- If you have a problem where your heart beats very slowly (bradycardia), unless you have been fitted with a pacemaker.
- If you have suffered from heart problems such as heart failure, or the heart condition called Wolff-Parkinson-White syndrome.
- If you are currently being treated with ivabradine (for heart conditions).
- If you have very low blood pressure.
- If you are currently receiving intravenous beta-blockers, e.g. atenolol, propranolol.

Warnings and precautions

Talk to your doctor or nurse before using Securon IV.
- If you are pregnant, planning to become pregnant or breast-feeding.
- If you have liver or kidney problems. If you are currently receiving lipid lowering agents (e.g., simvastatin, atorvastatin or lovastatin).
- If you have a condition where the nerve to muscle transmission is affected e.g. myasthenia gravis, Lambert-Eaton syndrome, advanced Duchenne muscular dystrophy.

Take special care with Securon IV

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

Your doctor may perform ECGs and blood pressure monitoring prior to and during treatment to monitor your individual dose.

Other medicines and Securon IV

Tell your doctor if you are taking, have recently taken or might take any other medicines.
- Beta-blockers such as atenolol, propranolol and metoprolol (used to treat high blood pressure and heart conditions)
- Alpha blockers such as prazosin and terazosin (used to treat high blood pressure and heart conditions)
- Medicines known as 'statins' such as atorvastatin, lovastatin, simvastatin (used to lower cholesterol levels)
- Quinidine, flecainide, disopyramide, digoxin and digitoxin (used to treat high blood pressure or an abnormal heart beat (arrhythmia))
- Dabigatran (medicine to prevent the formation of blood clots) and direct oral anticoagulants (DOACs)
- Ivabradine (used to treat certain heart diseases)
- Medicines used to treat depression, anxiety or psychosis. These include the herbal product St John's Wort or imipramine, buspirone and lithium
- Medicines known as immunosuppressants such as cyclosporine, sirolimus, everolimus and tacrolimus (used to prevent organ transplant rejection)
- Glyburide (Glibenclamide), medicine 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), medicines used as anti-convulsants
- Ritonavir (used to treat HIV)
- Erythromycin, clarithromycin and telithromycin (used to treat types of infection)
- Colchicine or sulfinpyrazone (used to treat gout)
- Metformin. Verapamil may decrease the glucose-lowering effect of metformin.

Securon IV with drink and alcohol
- Do **NOT** drink grapefruit juice whilst taking Securon IV as it can affect the absorption of this medicine. This does not occur with other fruit juices such as orange, apple or tomato juice.
- Before having Securon IV, inform your doctor or nurse if you have recently had alcohol. This is because alcohol can affect how the medicine works.

Sodium:
This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

Driving and using machines

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

This medicine can affect the way the body gets rid of alcohol. This means that you may not have to drink as much for the blood alcohol levels to be above the legal limit to drive. It will also take you longer to sober up.

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

3. How to use 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.
If necessary, an extra 5 mg may be injected after 5 to 10 minutes.

Elderly

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.

Use in children and adolescents

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.

The following information is intended for healthcare professionals only:

Securon® IV

(verapamil hydrochloride)

The following information is intended for healthcare professionals only:

This is an extract from the Summary of Product Characteristics (SmPC) to assist in the administration of Securon IV.

The prescriber should be familiar with the **full SmPC** in order to determine the appropriateness of the use of the product in a particular patient. The full SmPC can be found on the electronic Medicines Compendium (eMC) website: **http://www.medicines.org.uk/emc/**.
The Patient Information Leaflet provided (see other half of this leaflet) should be given to the patient.

1. Trade Name of the Medicinal Product

Securon IV

2. Qualitative and Quantitative Composition

Verapamil Hydrochloride 2.5 mg/ml
For the full list of excipients, see section 6.1.

3. Pharmaceutical Form

Solution for injection.

4. Clinical Particulars

4.1. Therapeutic Indications

Securon IV is indicated for the treatment of paroxysmal supraventricular tachycardia and the reduction of ventricular rate in atrial flutter/fibrillation.

4.2. Posology and Method of Administration

For slow intravenous injection.

Adults: 5-10 mg by 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: Securon IV must always be administered under ECG monitoring in young patients.
0-1 year: 0.1-0.2 mg/kg bodyweight (usual single dose range: 0.75-2 mg).
1-15 years: 0.1-0.3 mg/kg bodyweight (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 minimise 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.

For use with beta-blocker therapy, 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.

Cardiogenic shock; acute myocardial infarction complicated by bradycardia, marked hypotension or left ventricular failure; second or third degree AV block (except in patients with a functioning artificial ventricular pacemaker); sino-atrial block; sick sinus syndrome (except in patients with a functioning artificial ventricular pacemaker); uncompensated heart failure; bradycardia of less than 50 beats/minute; hypotension of less than 90 mmHg systolic; simultaneous administration of intravenous beta-blockers.

Patients with atrial flutter/fibrillation in the presence of an accessory pathway (*e.g.* WPW syndrome) may develop increased conduction across the anomalous 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

Verapamil hydrochloride injection should be given as a slow intravenous injection over at least a two-minute period of time under continuous ECG and blood pressure monitoring.

A small fraction of patients treated with verapamil hydrochloride respond with life-threatening adverse responses including (rapid ventricular rate (in atrial flutter/fibrillation in the presence of an accessory bypass tract), marked hypotension or extreme bradycardia/asystole).

Heart Block/ 1st Degree AV block/ Bradycardia/Asystole

Verapamil hydrochloride affects the AV and SA nodes and prolongs AV conduction time. Use with caution as development of second-or third-degree AV block (contraindication) or unifascicular, bifascicular or trifascicular bundle branch block requires discontinuation in subsequent doses of verapamil hydrochloride and institution of appropriate therapy, if needed.

Verapamil hydrochloride affects the AV and SA nodes and rarely may produce second- or third-degree AV block, bradycardia, and, in extreme cases, asystole. This is more likely to occur in patients with a sick sinus syndrome (SA nodal disease), which is more common in older patients.

Asystole in patients other than those with sick sinus syndrome is usually of short duration (few seconds or less), with spontaneous return to AV nodal or normal sinus rhythm. If this does not occur promptly, appropriate treatment should be initiated immediately. See Undesirable Effects Section.

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 taking an HMG CoA reductase inhibitor (e.g., simvastatin, atorvastatin or lovastatin), refer to advice in the respective statin product information.

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

Sodium:
This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

4.6. Fertility, Pregnancy and lactation

There are no adequate and well-controlled study data in pregnant women. Although animal studies have not shown any teratogenic effects (see section 5.3), verapamil should not be given during the first trimester of pregnancy unless, in the clinician's judgement, it is essential for the welfare of the patient.

Verapamil hydrochloride is excreted in human breast milk. Limited human data from oral administration has shown that the infant relative dose of verapamil is low (0.1 – 1% of the mother's oral dose) and that verapamil use may be compatible with breastfeeding. Due to the potential for serious adverse reactions in nursing infants, 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 headings of frequency, using the following convention: common (>1/100, <1/10), uncommon (>1/1,000, <1/100), rare (>1/10,000, <1/1,000), very rare (<1/10,000), including isolated reports.

System Organ Class	Frequency	Undesirable Effects
Nervous system disorders		
	common	- dizziness - headache
Cardiac disorders/ vascular disorders		
	common	- bradycardia - hypotension
	uncommon	- tachycardia
Gastrointestinal disorders		
	uncommon	- nausea - abdominal pain

Cases of seizures during verapamil hydrochloride injection have been reported.

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

If you use more Securon IV than you should
If you think you have been given too much of his medicine, talk to your doctor or nurse straight away.

If you stop using Securon IV
Your doctor or nurse will let you know when to stop having this medicine. You may need to stop having it gradually.
If you have any further questions on the use of this medicine, ask your doctor or nurse.

4. Possible side effects
Like 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 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 or nurse.

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 or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Securon IV
Do not store above 30°C.
Keep the ampoules in the carton to protect from light.
Keep out of the sight and reach of children.
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 left over 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).
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. Contents of the pack and other information
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 clear, colourless solution, each containing 5 mg of verapamil hydrochloride.
Pack size: 5 x 2ml ampoules.

Manufacturer and Product Licence Holder
Manufactured by Famar Health Care Services Madrid S.A.U., Avda. de Leganés, 62 28923 Alcorcón-Madrid, Spain. Procured from the EU by Product Licence holder Star Pharmaceuticals Ltd, 5 Sandridge Close, Harrow, Middlesex, HA1 1XD. Repackaged by Servipharm Ltd.

POM | PL 20636/3019

Leaflet revision and issue date (Ref.) 27.09.25[6]

Blind or partially sighted?
Is this leaflet hard to see or read?
Call 020 8423 2111 to obtain the leaflet in a format suitable for you.

Other Reactions from Postmarketing Surveillance or Phase IV Clinical Trials
Other adverse events reported with verapamil are listed below by system organ class:

Psychiatric disorders: on rare occasions, nervousness has been reported.

Nervous system disorders: somnolence and extrapyramidal syndrome.

Ear and labyrinth disorders: vertigo.

Cardiac disorders/vascular disorders: decreased myocardial contractility has been reported. On rare occasions, 2nd and 3rd block may occur and in extreme cases, this may lead to asystole. The asystole is usually of short duration and cardiac action returns spontaneously after a few seconds, usually in the form of sinus rhythm. If necessary, the procedures for the treatment of overdosage should be followed as described below. On rare occasions, flushing has been reported.

Gastrointestinal disorders: gingival hyperplasia may occur very rarely when the drug is administered over prolonged periods, and is fully reversible when the drug is discontinued. On rare occasions, vomiting has also been reported.

Skin and subcutaneous tissue disorders: Steven-Johnson syndrome, erythema and hyperhidrosis.

Reproductive system and breast disorders: On very rare occasions, gynaecomastia has been observed in elderly male patients under long-term verapamil treatment; this was fully reversible in all cases when the drug was discontinued.

Investigations: A reversible impairment of liver function characterized by an increase of transaminase and/or alkaline phosphatase may occur on very rare occasions during verapamil treatment and is most probably a hypersensitivity reaction.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

4.9. Overdose
The symptoms of overdosage include hypotension, shock, loss of consciousness, first and second degree AV block (frequently as Wenckebach's phenomenon with or without escape rhythms), total AV block with total AV dissociation, escape rhythm, asystole, bradycardia up to high degree AV block and, sinus arrest, hyperglycaemia, stupor and metabolic acidosis and acute respiratory distress syndrome. Fatalities have occurred as a result of overdose.

Treatment of overdosage depends on the type and severity of symptoms. The specific antidote is calcium, *e.g.* 10-20 ml of 10% calcium gluconate solution i.v. (2.25-4.5 mmol) if necessary by repeated injection or continuous infusion (*e.g.* 5 mmol/hour). The usual emergency measures for acute cardiovascular collapse should be applied and followed by intensive care. Verapamil hydrochloride cannot be removed by haemodialysis. Similarly, in the case of second or third degree AV block, atropine, orciprenaline, isoprenaline and if required, pacemaker therapy should be considered. If there are signs of myocardial insufficiency, dopamine, dobutamine, cardiac glycosides or calcium gluconate (10-20 ml of a 10% solution) can be administered.
In the case of hypotension, after appropriately positioning the patient, dopamine, dobutamine or noradrenaline may be given.

6.4. Special Precautions for Storage
Do not store above 30°C.
Keep the ampoules in the carton to protect from light.

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

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

Leaflet revision and issue date (Ref.) 27.09.25[6]

PATIENT INFORMATION LEAFLET

3019
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Verapamil Hydrochloride 2.5 mg/ml solution for injection

IMPORTANT INFORMATION

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or nurse.
- If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

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

What is in this leaflet

1. What is Verapamil Injection and what is it used for
Verapamil Injection contains the active substance verapamil hydrochloride. Verapamil Injection belongs to a group of medicines called calcium channel blockers.

Verapamil Injection is used to treat abnormal heart rhythms such as an irregular or rapid heart rate in adults, and children aged 0 to 15 years.

2. What you need to know before you use Verapamil Injection
Do not take Verapamil Injection:
- If you are allergic to verapamil hydrochloride or any of the other ingredients of this medicine (listed in section 6).
- If you have had a heart attack with shock.
- If you had a heart attack, particularly if a slow heartbeat, low blood pressure or a type of heart failure called 'left ventricular failure'.
- If you have an abnormally slow, fast or irregular heartbeat.
- If you have second- or third-degree atrioventricular block or sino-atrial block. This is a disorder where parts of your heart may beat at the wrong time causing it not to pump blood around the body very well (unless a permanent pacemaker is in place).
- If you have a problem where your heart beats very slowly (bradycardia), unless you have been fitted with a pacemaker.
- If you have suffered from heart problems such as heart failure, or the heart condition called Wolff-Parkinson-White syndrome.
- If you are currently being treated with ivabradine (for heart conditions).
- If you have very low blood pressure.
- If you are currently receiving intravenous beta-blockers, e.g. atenolol, propranolol.

Warnings and precautions
Talk to your doctor or nurse before using Verapamil Injection.
- If you are pregnant, planning to become pregnant or breast-feeding.
- If you have liver or kidney problems. If you are currently receiving lipid lowering agents (e.g., simvastatin, atorvastatin or lovastatin).
- If you have a condition where the nerve to muscle transmission is affected e.g. myasthenia gravis, Lambert-Eaton syndrome, advanced Duchenne muscular dystrophy.

Take special care with Verapamil Injection
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

Your doctor may perform ECGs and blood pressure monitoring prior to and during treatment to monitor your individual dose.

Other medicines and Verapamil Injection
Tell your doctor if you are taking, have recently taken or might take any other medicines.
- Beta-blockers such as atenolol, propranolol and metoprolol (used to treat high blood pressure and heart conditions)
- Alpha blockers such as prazosin and terazosin (used to treat high blood pressure and heart conditions)
- Medicines known as 'statins' such as atorvastatin, lovastatin, simvastatin (used to lower cholesterol levels)
- Quinidine, flecainide, disopyramide, digoxin and digitoxin (used to treat high blood pressure or an abnormal heart beat (arrhythmia))
- Dabigatran (medicine to prevent the formation of blood clots) and direct oral anticoagulants (DOACs)
- Ivabradine (used to treat certain heart diseases)
- Medicines used to treat depression, anxiety or psychosis. These include the herbal product St John's Wort or imipramine, buspirone and lithium
- Medicines known as immunosuppressants such as cyclosporine, sirolimus, everolimus and tacrolimus (used to prevent organ transplant rejection)
- Glyburide (Glibenclamide), medicine 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), medicines used as anti-convulsants
- Ritonavir (used to treat HIV)
- Erythromycin, clarithromycin and telithromycin (used to treat types of infection)
- Colchicine or sulfinpyrazone (used to treat gout)
- Metformin. Verapamil may decrease the glucose-lowering effect of metformin.

Verapamil Injection with drink and alcohol
- Do **NOT** drink grapefruit juice whilst taking Verapamil Injection as it can affect the absorption of this medicine. This does not occur with other fruit juices such as orange, apple or tomato juice.
- Before having Verapamil Injection, inform your doctor or nurse if you have recently had alcohol. This is because alcohol can affect how the medicine works.

Sodium:
This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

Pregnancy, breast-feeding and fertility
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

Driving and using machines

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

This medicine can affect the way the body gets rid of alcohol. This means that you may not have to drink as much for the blood alcohol levels to be above the legal limit to drive. It will also take you longer to sober up.

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

3. How to use Verapamil Injection
Verapamil Injection 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.
If necessary, an extra 5 mg may be injected after 5 to 10 minutes.

Elderly
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.

Use in children and adolescents
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.

The following information is intended for healthcare professionals only:

Verapamil Hydrochloride 2.5 mg/ml solution for injection

The following information is intended for healthcare professionals only:

This is an extract from the Summary of Product Characteristics (SmPC) to assist in the administration of Verapamil Injection.

The prescriber should be familiar with the **full SmPC** in order to determine the appropriateness of the use of the product in a particular patient. The full SmPC can be found on the electronic Medicines Compendium (eMC) website: **http://www.medicines.org.uk/emc/**.
The Patient Information Leaflet provided (see other half of this leaflet) should be given to the patient.

1. Trade Name of the Medicinal Product
Verapamil Hydrochloride 2.5 mg/ml solution for injection

2. Qualitative and Quantitative Composition
Verapamil Hydrochloride 2.5 mg/ml
For the full list of excipients, see section 6.1.

3. Pharmaceutical Form
Solution for injection.

4. Clinical Particulars
4.1. Therapeutic Indications
Verapamil Injection is indicated for the treatment of paroxysmal supraventricular tachycardia and the reduction of ventricular rate in atrial flutter/fibrillation.

4.2. Posology and Method of Administration
For slow intravenous injection.

Adults: 5-10 mg by 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 Injection must always be administered under ECG monitoring in young patients.
0-1 year: 0.1-0.2 mg/kg bodyweight (usual single dose range: 0.75-2 mg).
1-15 years: 0.1-0.3 mg/kg bodyweight (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 minimise 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.

For use with beta-blocker therapy, 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.

Cardiogenic shock; acute myocardial infarction complicated by bradycardia, marked hypotension or left ventricular failure; second or third degree AV block (except in patients with a functioning artificial ventricular pacemaker); sino-atrial block; sick sinus syndrome (except in patients with a functioning artificial ventricular pacemaker); uncompensated heart failure; bradycardia of less than 50 beats/minute; hypotension of less than 90 mmHg systolic; simultaneous administration of intravenous beta-blockers.

Patients with atrial flutter/fibrillation in the presence of an accessory pathway (*e.g.* WPW syndrome) may develop increased conduction across the anomalous 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
Verapamil hydrochloride injection should be given as a slow intravenous injection over at least a two-minute period of time under continuous ECG and blood pressure monitoring.

A small fraction of patients treated with verapamil hydrochloride respond with life-threatening adverse responses including (rapid ventricular rate (in atrial flutter/fibrillation in the presence of an accessory bypass tract), marked hypotension or extreme bradycardia/asystole).

Heart Block/ 1st Degree AV block/ Bradycardia/Asystole
Verapamil hydrochloride affects the AV and SA nodes and prolongs AV conduction time. Use with caution as development of second-or third-degree AV block (contraindication) or unifascicular, bifascicular or trifascicular bundle branch block requires discontinuation in subsequent doses of verapamil hydrochloride and institution of appropriate therapy, if needed.

Verapamil hydrochloride affects the AV and SA nodes and rarely may produce second- or third-degree AV block, bradycardia, and, in extreme cases, asystole. This is more likely to occur in patients with a sick sinus syndrome (SA nodal disease), which is more common in older patients.

Asystole in patients other than those with sick sinus syndrome is usually of short duration (few seconds or less), with spontaneous return to AV nodal or normal sinus rhythm. If this does not occur promptly, appropriate treatment should be initiated immediately. See Undesirable Effects Section.

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 taking an HMG CoA reductase inhibitor (e.g., simvastatin, atorvastatin or lovastatin), refer to advice in the respective statin product information.

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

Sodium:
This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

4.6. Fertility, Pregnancy and lactation
There are no adequate and well-controlled study data in pregnant women. Although animal studies have not shown any teratogenic effects (see section 5.3), verapamil should not be given during the first trimester of pregnancy unless, in the clinician's judgement, it is essential for the welfare of the patient.

Verapamil hydrochloride is excreted in human breast milk. Limited human data from oral administration has shown that the infant relative dose of verapamil is low (0.1 – 1% of the mother's oral dose) and that verapamil use may be compatible with breastfeeding. Due to the potential for serious adverse reactions in nursing infants, 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 headings of frequency, using the following convention: common (>1/100, <1/10), uncommon (>1/1,000, <1/100), rare (>1/10,000, <1/1,000), very rare (<1/10,000), including isolated reports.

System Organ Class	Frequency	Undesirable Effects
Nervous system disorders		
	common	- dizziness - headache
Cardiac disorders/ vascular disorders		
	common	- bradycardia - hypotension
	uncommon	- tachycardia
Gastrointestinal disorders		
	uncommon	- nausea - abdominal pain

Cases of seizures during verapamil hydrochloride injection have been reported.

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

If you use more Verapamil Injection than you should
If you think you have been given too much of his medicine, talk to your doctor or nurse straight away.

If you stop using Verapamil Injection
Your doctor or nurse will let you know when to stop having this medicine. You may need to stop having it gradually.
If you have any further questions on the use of this medicine, ask your doctor or nurse.

4. Possible side effects
Like all medicines, Verapamil Injection can cause side effects. Verapamil Injection 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 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 Verapamil Injection, tell your doctor or nurse.

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 or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Verapamil Injection
Do not store above 30°C.
Keep the ampoules in the carton to protect from light.
Keep out of the sight and reach of children.
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 left over 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).
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. Contents of the pack and other information
What Verapamil Injection 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 Verapamil Injection looks like:
The product is available in 2 ml clear glass ampoules containing a clear, colourless solution, each containing 5 mg of verapamil hydrochloride.
Pack size: 5 x 2ml ampoules.

Manufacturer and Product Licence Holder
Manufactured by Famar Health Care Services Madrid S.A.U., Avda. de Leganés, 62 28923 Alcorcón-Madrid, Spain. Procured from the EU by Product Licence holder Star Pharmaceuticals Ltd, 5 Sandridge Close, Harrow, Middlesex, HA1 1XD. Repackaged by Servipharm Ltd.

POM | PL 20636/3019

Leaflet revision and issue date (Ref.) 27.09.25[6]

Blind or partially sighted?
Is this leaflet hard to see or read?
Call 020 8423 2111 to obtain the leaflet in a format suitable for you.

Other Reactions from Postmarketing Surveillance or Phase IV Clinical Trials
Other adverse events reported with verapamil are listed below by system organ class:

Psychiatric disorders: on rare occasions, nervousness has been reported.

Nervous system disorders: somnolence and extrapyramidal syndrome.

Ear and labyrinth disorders: vertigo.

Cardiac disorders/vascular disorders: decreased myocardial contractility has been reported. On rare occasions, 2nd and 3rd block may occur and in extreme cases, this may lead to asystole. The asystole is usually of short duration and cardiac action returns spontaneously after a few seconds, usually in the form of sinus rhythm. If necessary, the procedures for the treatment of overdosage should be followed as described below. On rare occasions, flushing has been reported.

Gastrointestinal disorders: gingival hyperplasia may occur very rarely when the drug is administered over prolonged periods, and is fully reversible when the drug is discontinued. On rare occasions, vomiting has also been reported.

Skin and subcutaneous tissue disorders: Steven-Johnson syndrome, erythema and hyperhidrosis.

Reproductive system and breast disorders: On very rare occasions, gynaecomastia has been observed in elderly male patients under long-term verapamil treatment; this was fully reversible in all cases when the drug was discontinued.

Investigations: A reversible impairment of liver function characterized by an increase of transaminase and/or alkaline phosphatase may occur on very rare occasions during verapamil treatment and is most probably a hypersensitivity reaction.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

4.9. Overdose
The symptoms of overdosage include hypotension, shock, loss of consciousness, first and second degree AV block (frequently as Wenckebach's phenomenon with or without escape rhythms), total AV block with total AV dissociation, escape rhythm, asystole, bradycardia up to high degree AV block and, sinus arrest, hyperglycaemia, stupor and metabolic acidosis and acute respiratory distress syndrome. Fatalities have occurred as a result of overdose.

Treatment of overdosage depends on the type and severity of symptoms. The specific antidote is calcium, *e.g.* 10-20 ml of 10% calcium gluconate solution i.v. (2.25-4.5 mmol) if necessary by repeated injection or continuous infusion (*e.g.* 5 mmol/hour). The usual emergency measures for acute cardiovascular collapse should be applied and followed by intensive care. Verapamil hydrochloride cannot be removed by haemodialysis. Similarly, in the case of second or third degree AV block, atropine, orciprenaline, isoprenaline and if required, pacemaker therapy should be considered. If there are signs of myocardial insufficiency, dopamine, dobutamine, cardiac glycosides or calcium gluconate (10-20 ml of a 10% solution) can be administered.
In the case of hypotension, after appropriately positioning the patient, dopamine, dobutamine or noradrenaline may be given.

6.4. Special Precautions for Storage
Do not store above 30°C.
Keep the ampoules in the carton to protect from light.

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

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