

Summary of Product Characteristics for Pharmaceutical Products

1. Name of the medicinal product:

KARIN INJECTION

2. Qualitative and quantitative composition

Each mL contains Heparin Sodium BP 5000 IU.

Excipient with known effect: benzyl alcohol.

For full list of excipients, see section 6.1.

3. Pharmaceutical form

Solution for Injection

4. Clinical particulars

4.1 Therapeutic indications

Heparin belongs to a group of drugs that are called anticoagulants. These help to stop blood clotting. Heparin injection is used in conditions where blood vessels may become blocked by blood clots.

Heparin 5000 IU/mL is used to treat and prevent:

- Blood clots in leg veins (deep vein thrombosis)
- Blood clots in the lung (pulmonary embolism)

as well as for:

- the treatment of chest pains resulting from disease of the heart arteries (unstable angina pectoris)
- the treatment of severe blockages affecting arteries in the legs (acute peripheral arterial occlusion)
- the prevention of blood clots in the heart following a heart attack (mural thrombosis).

It is also used during heart and lung operations and during kidney dialysis.

4.2 Posology and method of administration

Your doctor or nurse will inject your dose of heparin into a vein either all at once or over a longer period of time (usually via a drip).

Alternatively they may inject your heparin underneath your skin.

The amount injected all at once into a vein should not be greater than 15mL.

You may need to have blood tests if you are receiving higher doses of heparin or if you are pregnant to check on the effects of your heparin treatment.

Heparin injection must not be given to premature or newborn babies.

You may require a lower dose if you have kidney or liver disease.

To prevent blood clots in leg veins (deep vein thrombosis) and blood clots in the lung (pulmonary embolism)

Adults

The usual dose of heparin injection in adults is 5,000 units injected under the skin 2 hours before your operation, followed by 5,000 units injected under the skin every 8-12 hours, for 7-10 days or until you are fully able to move about.

Elderly

Lower doses may be used in the elderly. You may need to have blood tests if you are elderly, to check on the effects of your heparin treatment.

Children

No specific doses are recommended.

To treat blood clots in leg veins (deep vein thrombosis) and blood clots in the lung (pulmonary embolism).

Adults

The usual dose in adults is 5000 units injected into a vein. This is followed by:

- 1,000-2,000 units/hour injected slowly into a vein or
- 10,000-20,000 units 12 hourly injected under the skin or
- 5,000-10,000 units 4-hourly injected all at once into a vein.

Elderly

Lower doses may be used in the elderly.

Small adults and children

Small adult and children will be given 50 units/kg body weight injected into a vein followed by:

- 15-25 units/kg bodyweight/hour injected slowly into a vein or
- 250 units/kg bodyweight 12 hourly injected under the skin or
- 100 units/kg bodyweight 4-hourly injected all at once into a vein.

To treat chest pains (unstable angina pectoris) and severe blood clots in the arteries (acute peripheral arterial occlusion).

Adults

The usual dose in adults is 5,000 units injected into a vein.

This is followed by:

1,000-2,000 units/hour injected slowly into a vein or
5,000-10,000 units 4 hourly injected all at once into a vein.

Elderly

Lower doses may be used in the elderly

Small adults and children

Small adults and children will be given 50 units/kg body weight injected into a vein followed by:

- 15-25 units/kg body weight/hour injected slowly into a vein or
 - 100 units/kg body weight 4 hourly injected all at once into a vein
- You will have blood tests every day to check the effects of your heparin

To prevent a blood clot in the heart following a heart attack

Adults

The usual dose for adults is 12,500 units 12 hourly injected under the skin for at least 10days.

Elderly

A lower dose may be needed.

During heart and lung surgery (Adults)

Initially you will be given 300 units/kg body weight. This will be changed according to the results of your blood tests.

During kidney dialysis (Adults)

Initially you will be given 1,000-5,000 units per hour. This will be changed according to the results of your blood tests.

If you think you have been given too much heparin injection

Your doctor will decide which dose is best for you. Too much heparin can cause bleeding. Slight bleeding can be stopped by stopping your heparin treatment. However if you have more severe bleeding you may need blood tests and an injection of a medicine called protamine sulfate. If you think too much medicine has been given to you contact your doctor or nurse.

4.3 Contraindications

Heparin injection should not be given if you:

- are allergic to heparin or any of the other ingredients of this medicine
- are pregnant
- Bleed or bruise easily
- Have had severe skin problems resulting from previous heparin treatment.
- are about to have surgery of the brain, spine or eye, a lumbar puncture or local anaesthetic nerve block or other some other procedure where bleeding could be a problem.
- Heparin 5000 IU/ml must not be given to premature or newborn babies or children up to 3 years of age.

4.4 Special warnings and precautions for use

Warnings and Precautions

Talk to your doctor or nurse before receiving Heparin injection 5000 IU/ML. Particularly careful medical supervision is required if you:

- are over 60 years of age
- have any condition which makes you likely to bleed more easily. If you are unsure, ask your doctor or nurse.
- are diabetic
- have high levels of potassium in your blood or are taking a medicine that may increase the potassium level in your blood (e.g. amiloride, triamterene, eplerenone or spironolactone).
- have kidney or liver disease. Your doctor may decide that a lower dose is necessary
- suffer from allergies or have previously had an allergic reaction to heparin. Your doctor will check your blood if you receive treatment for longer than five days and may do other blood tests if you have major surgery.

Children

Heparin 5000 IU/ML must not be given to premature or newborn babies or children up to 3 years of age.

Other medicines and Heparin 5000 IU/ML.

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Some medicines may affect the way heparin injection works. Taking some medicines at the same time as heparin may mean you may be likely to bleed more.

In particular, tell your doctor if you are taking any of the following:

Aspirin or other non-steroidal anti-inflammatory drugs (e.g. diclofenac or ibuprofen)

- medicines which may interfere with the proper clotting of the blood (e.g. dipyridamole, epoprostenol, clopidogrel or streptokinase)
- Medicines that may increase potassium level in your blood
- Glyceryl trinitrate (for heart disease) If you need one of the above medicines your doctor may decide to alter the dose of heparin injection or the other medication.

If you have any doubts about whether this medicine should be administered then discuss things more fully with your doctor or nurse before Heparin injection 5000 IU/ML is given. Pregnancy and breast-feeding If you are pregnant or breast feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before receiving this medicine. You should not be given Heparin 5000 IU/ML if you are pregnant.

4.5 Interaction with other medicinal products and other forms of interaction

Heparin may prolong the one stage prothrombin time. Accordingly, when Heparin is given with dicoumarol or warfarin sodium, a period of at least 5 hours after the last intravenous dose of heparin should elapse before blood is drawn, if a valid prothrombin time is to be obtained.

The anticoagulant effect of heparin may be enhanced by concomitant medication with other drugs affecting platelet function or the coagulation

system, e.g. platelet aggregation inhibitors, thrombolytic agents, salicylates, non-steroidal anti-inflammatory drugs, vitamin K antagonists, dextrans, activated protein C. Where such combination cannot be avoided, careful clinical and biological monitoring is required. Combined use with ACE inhibitors or angiotensin II antagonists may increase the risk of hyperkalaemia.

4.6 Pregnancy and Lactation

If you are pregnant or breast feeding, think may be pregnant or are planning to to have a baby, ask your doctor or pharmacist for advice before receiving this medicine. You should not be given heparin 5000 IU/ML if you are pregnant.

4.7 Effects on ability to drive and use machines

Heparin injection has not been reported to affect ability to drive or operate machines. Heparin 5000IU/ML contains benzyl alcohol. Heparin 5000IU/ML contains benzyl alcohol which may cause toxic and allergic reactions (possibly delayed) and exceptionally bronchospasm.

4.8 Undesirable effects

Like all medicines, heparin injection can cause side effects in some patients, although not everybody gets them. These are most likely to occur when treatment is first started. You should inform your doctor or nurse immediately if you feel unwell.

Important side effects to look out for:

• Severe allergic reactions

- Heparin can cause a severe allergic reaction with wheezing, difficulty breathing, a blue tinge to the lips, fever, chills, swelling of the eyes and lips, and shock.

If you think you are having a severe allergic reaction you must stop receiving heparin and tell your doctor or nurse immediately.

Bleeding and Bruising

Sign that you are bleeding more easily include:

- unusual bruising or purple spots on your skin
- unusual bleeding from your gums
- unusual nose bleeds
- blood in your urine (which may cause this to go dark)
- black, tarry-looking stools
- bleeding that will not stop from any operation site or other injury

If you are concerned about unusual bleeding you must tell your doctor or nurse immediately as you may need to stop your heparin.

Other side effects include:

- red lumps or red, itchy patches like eczema often develop 3-21 days after the start of heparin treatment, where injections have been given under the skin.
- sloughing of skin may occur around the injection site.
- persistent erection of the penis
- abnormal results for blood tests that report on how the liver is working.
- high level of blood fats after stopping heparin

- high or low blood potassium. If affected you may feel tired and weak.
- If Heparin injection is given over many months then the following may occur:
- loss of hair
 - thinning of the bones (osteoporosis)

Reporting of suspected adverse reactions: Healthcare professionals are requested to report any suspected adverse reactions via National Pharmacovigilance Electronic Reporting Systems' to the respective National Regulatory Authorities.

4.9 Overdose

Bleeding is the main sign of overdose with Heparin injection.

As Heparin Injection is eliminated quickly, a discontinuation of treatment is sufficient in case of minor haemorrhages. In case of severe haemorrhages heparin may be neutralized protamine sulphate injected slowly intravenously. One mg of protamine sulphate neutralises approximately 100 IU of heparin. Nevertheless, the required protamine sulphate dose varies according to the time of heparin administration and the dose administered.

It is important to avoid overdosage of protamine sulphate because protamine itself has anticoagulant properties.

A single dose of protamine sulphate should never exceed 50 mg. Intravenous injection of protamine may cause a sudden fall in blood pressure, bradycardia, dyspnoea and transitory flushing, but these may be avoided or diminished by slow and careful administration.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Antithrombotic agents, ATC code: B01AB01
Heparin prevents the coagulation of blood in-vivo and in-vitro. It potentiates the inhibition of several activated coagulation factors, including thrombin and factor X

5.2 Pharmacokinetic properties

Absorption

Heparin is not absorbed from the gastrointestinal tract. Heparin is administered by injection.

Distribution

Heparin binds extensively to plasma proteins.

Elimination

Heparin and its metabolites are excreted in the urine. The half-life of heparin depends on the dose administered, the route of administration and is subject to wide inter- and intra-individual variation.

5.3 Preclinical safety data

Not available

6. Pharmaceutical Particulars

6.1 List of Excipients

Following excipients are used in the formulation of KARIN (Heparin Injection BP5000IU/ML).

Benzyl alcohol BP

Sodium Chloride BP

Hydrochloric Acid BP

Water for Injections BP

6.2 Incompatibilities

NA

6.3 Shelf-Life

24 Months from the date of manufacture.

6.4 Special Precautions for storage

Store in a cool and dry place below 30°C. Protect from light and freezing.

6.5 Nature and Content of container

Each 5 ml flint USP type I glass vial is filled, plugged with GBBR plugs and sealed with violet coloured flip off aluminium seal and labeled. One such vial to be packed in a monocarton along with Leaflet.

6.6 Special precautions for disposal and other handling

Keep out of reach of children.

7. Marketing Authorization Holder

Kilitch Drugs (India) Ltd

C-301/2 M.I.D.C T.T.C Industrial Area, Pawane village, Navi Mumbai-400 075, Maharashtra, India

8. Marketing Authorization Number

H2022/CTD9247/20027

9. Date of first authorization/renewal of the authorization

2022 November 19

10. Date of revision of the text

2022 November 19