

Protamine Sulfate®

Injection 1%

CONSUMER MEDICINE INFORMATION

What is in this leaflet

This leaflet answers some common questions about PROTAMINE SULFATE. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor or pharmacist has weighed the risks of giving you PROTAMINE SULFATE against the benefits they expect it will have for you.

If you have any concerns about receiving this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What PROTAMINE SULFATE is used for

The active ingredient of PROTAMINE SULFATE is the protein protamine sulfate. Protamine sulfate is used in hospitals to counteract the effect of heparin given before and

after surgery and after dialysis. Heparin is used to prevent blood clots from forming. Protamine sulfate is given when there is excessive bleeding from heparin administration.

Your doctor may have prescribed PROTAMINE SULFATE for another reason. Ask your doctor if you have any questions about why

PROTAMINE SULFATE has been prescribed for you.

This medicine is available only with a doctor's prescription.

PROTAMINE SULFATE is not recommended for use in children.

Before you are given PROTAMINE SULFATE

When you must not be given it

You must not receive PROTAMINE SULFATE if you have a severe allergy to PROTAMINE SULFATE or an allergy to any of the ingredients listed at the end of this leaflet under Product Description.

Your doctor, nurse and pharmacist will ensure that you are not given PROTAMINE SULFATE after the expiry date (EXP) printed on the pack.

If you are given this medicine after the expiry date has passed, it may not work as well.

Your doctor, nurse and pharmacist will ensure that you are not given PROTAMINE SULFATE if the packaging is torn or shows signs of tampering.

If you are not sure whether you should start being given PROTAMINE SULFATE, contact your doctor or pharmacist.

Before you are given it

Tell your doctor, nurse or pharmacist if you have allergies to:

- any other medicines
- any other substances, such as foods, in particular fish, preservatives or dyes

Tell your doctor, nurse or pharmacist if you are pregnant or intend to become pregnant.

Your doctor or pharmacist will discuss the possible risks and benefits of using PROTAMINE SULFATE during pregnancy.

Tell your doctor, nurse or pharmacist if you are breast-feeding or plan to breast-feed.

Your doctor or pharmacist will discuss the possible risks and benefits of using PROTAMINE SULFATE during breast-feeding.

Tell your doctor, nurse or pharmacist if you have or have had any medical conditions, especially the following:

- Heart surgery
- Diabetes and you have received protamine insulin
- You are male and have had a vasectomy or are infertile.

Taking other medicines

Tell your doctor, nurse or pharmacist if you are taking any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food shop.

How PROTAMINE SULFATE is given

PROTAMINE SULFATE is injected or infused into a blood vessel. The dose your doctor gives you of PROTAMINE SULFATE will depend on the amount of heparin that needs to be neutralised

While you are receiving PROTAMINE SULFATE

Things you must do

If you develop itching with swelling or skin rash, difficulty breathing, dizziness or abnormal heart beats while you are receiving PROTAMINE SULFATE tell your doctor or nurse immediately.

Side effects

Tell your doctor, nurse or pharmacist as soon as possible if you do not feel well while receiving PROTAMINE SULFATE.

All medicines have side effects. Sometimes they may be serious, most of the time they are not. You may need urgent treatment if you get some of the side effects.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or nurse immediately if you notice any of the following:

- Red or itchy skin with swelling, skin rash or difficulty breathing.

Tell your doctor or nurse if you notice any of the following and they worry you:

- Abnormal heart beats
- Dizziness
- Flushing and/or a feeling of warmth
- Back pain
- Stomach disturbances
- Weakness or generally feeling unwell

Other side effects not listed above may occur in some patients. Tell your doctor, nurse or pharmacist if you notice anything that is making you feel unwell.

Do not be alarmed by the list of possible side effects.

You may not experience any of them.

After using PROTAMINE SULFATE

Storage

PROTAMINE SULFATE should be stored in the pharmacy or on the ward. The injection should be kept where the temperature stays below 25°C.

Product description

What it looks like

A clear, colourless solution in a clear glass ampoule.

Ingredients

Each 5mL ampoule contains protamine sulfate 50mg, sodium chloride, hydrochloric acid, sodium hydroxide and water for injections.

Distributor

sanofi-aventis australia pty ltd

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Australia

Australian registration number:

AUST R 27971

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