

FISONS PROTAMINE SULFATE®

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I being given FISONS PROTAMINE SULFATE?

FISONS PROTAMINE SULFATE contains the active ingredient protamine sulfate. FISONS PROTAMINE SULFATE is used to counteract the effect of heparin. It is given when there is excessive bleeding from heparin administration.

For more information, see Section [1. Why am I being given FISONS PROTAMINE SULFATE?](#) in the full CMI.

2. What should I know before being given FISONS PROTAMINE SULFATE?

Do not use if you have ever had an allergic reaction to protamine sulfate or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before being given FISONS PROTAMINE SULFATE?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with FISONS PROTAMINE SULFATE and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How is FISONS PROTAMINE SULFATE given?

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

More instructions can be found in Section [4. How is FISONS PROTAMINE SULFATE given?](#) in the full CMI.

5. What should I know while being given FISONS PROTAMINE SULFATE?

Things you should do	<ul style="list-style-type: none">• Tell your doctor or nurse straight away if you develop itching with swelling or skin rash, difficulty breathing, dizziness or abnormal heart beats while you are receiving FISONS PROTAMINE SULFATE.
Driving or using machines	<ul style="list-style-type: none">• Be careful before you drive or use any machines or tools until you know how FISONS PROTAMINE SULFATE affects you.
Looking after your medicine	<ul style="list-style-type: none">• FISONS PROTAMINE SULFATE will be stored in the hospital or clinic pharmacy.

For more information, see Section [5. What should I know while being given FISONS PROTAMINE SULFATE?](#) in the full CMI.

6. Are there any side effects?

Less serious side effects include bleeding and bruising, dizziness, flushing and/or a feeling of warmth, back pain, nausea, vomiting, weakness or generally feeling unwell. Serious side effects include signs of allergic reaction (e.g. shortness of breath, wheezing or difficulty breathing, swelling of the face, lips, tongue or other parts of the body, rash, itching or hives on the skin), bleeding, coughing up blood, slow or abnormal heartbeats.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

FISONS PROTAMINE SULFATE

Active ingredient(s): *protamine sulfate*

Consumer Medicine Information (CMI)

This leaflet provides important information about using FISONS PROTAMINE SULFATE. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using FISONS PROTAMINE SULFATE.**

Where to find information in this leaflet:

1. [Why am I being given FISONS PROTAMINE SULFATE?](#)
2. [What should I know before I am given FISONS PROTAMINE SULFATE?](#)
3. [What if I am taking other medicines?](#)
4. [How is FISONS PROTAMINE SULFATE given?](#)
5. [What should I know while being given FISONS PROTAMINE SULFATE?](#)
6. [Are there any side effects?](#)
7. [Product details](#)

1. Why am I being given FISONS PROTAMINE SULFATE?

FISONS PROTAMINE SULFATE contains the active ingredient **protamine sulfate**. Protamine sulfate is a protein used to counteract the effect of heparin. Heparin is used to prevent blood clots from forming.

FISONS PROTAMINE SULFATE is given in hospitals when there is excessive bleeding from heparin administration before and after surgery or after dialysis.

2. What should I know before I being given FISONS PROTAMINE SULFATE?

Warnings

You should not be given FISONS PROTAMINE SULFATE if:

- you are allergic to protamine sulfate, protamine contained in insulin NPH (Neutral Protamine Hagedorn), or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.

Check with your doctor if you:

- are allergic to any other medicines, or substances, such as foods, in particular fish, preservatives or dyes
- take any medicines for any other condition
- have or have had diabetes and you have received protamine insulin
- have any other medical conditions.

Tell your doctor if you:

- have had heart surgery
- are male and have had a vasectomy or are infertile.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

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

Talk to your doctor if you are breastfeeding or intend to breastfeed.

It is not known whether FISONS PROTAMINE SULFATE passes into breast milk. Therefore, it should not be given during breastfeeding.

Children

FISONS PROTAMINE SULFATE is not recommended for use in children.

3. What if I am taking other medicines?

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

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect FISONS PROTAMINE SULFATE.

4. How is FISONS PROTAMINE SULFATE given?

How much is given

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

If you are given too much FISONS PROTAMINE SULFATE

As FISONS PROTAMINE SULFATE is given to you in hospital under the supervision of a healthcare professional, it is very unlikely that you will receive an overdose. Symptoms of a protamine sulfate overdose include low blood pressure, slow heartbeat, nausea, vomiting, fatigue, temporary flushing, and difficulty breathing with a sensation of warmth. If you think that you have been given much FISONS PROTAMINE SULFATE, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or

- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using FISONS PROTAMINE SULFATE?

Things you should do

Tell your doctor or nurse straight away if you:

- develop itching with swelling or skin rash, difficulty breathing, dizziness or abnormal heart beats while you are receiving FISONS PROTAMINE SULFATE.

Looking after your medicine

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

It will be kept where young children cannot reach it.

The expiry date will be checked by your doctor, nurse or pharmacist that it has not passed.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
Alertness and sleep-related: <ul style="list-style-type: none"> • dizziness. Skin and muscle-related: <ul style="list-style-type: none"> • flushing and/or a feeling of warmth • back pain. Stomach-related: <ul style="list-style-type: none"> • stomach disturbances. Other: <ul style="list-style-type: none"> • weakness or generally feeling unwell. 	Speak to your doctor or nurse if you have any of these less serious side effects and they worry you.

Serious side effects

Serious side effects	What to do
Allergy-related: <ul style="list-style-type: none"> • signs of an allergic reaction, such as shortness of breath, wheezing or difficulty breathing, swelling of the face, lips, tongue or other 	Tell your doctor or nurse straight away if you notice any

Serious side effects	What to do
parts of the body, rash, itching or hives on the skin. Heart-related: <ul style="list-style-type: none"> • Abnormal heart beats. 	of these serious side effects.

Tell your doctor, nurse or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

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

What FISONS PROTAMINE SULFATE contains

Active ingredient (main ingredient)	Each 5 mL ampoule contains protamine sulfate 50 mg
Other ingredients (inactive ingredients)	<ul style="list-style-type: none"> • sodium chloride • hydrochloric acid • sodium hydroxide • water for injections

Do not receive this medicine if you are allergic to any of these ingredients.

What FISONS PROTAMINE SULFATE looks like

FISONS PROTAMINE SULFATE is a clear, colourless solution in a clear glass ampoule (Aust R 27971).

Who distributes FISONS PROTAMINE SULFATE

Distributed by:

sanofi-aventis australia pty ltd

12-24 Talavera Road

Macquarie Park NSW 2113

Freecall: 1800 818 806

Email: medinfo.australia@sanofi.com

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