

[GlaxoSmithKline Logo]

Package Leaflet: Information for the User

Pentostam[®] Injection **sodium stibogluconate**

Read all of this leaflet carefully before you are given 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, pharmacist or nurse.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Pentostam is and what it is used for
2. What you need to know before you have Pentostam
3. How Pentostam is given
4. Possible side effects
5. How to store Pentostam
6. Contents of the pack and other information

1 What Pentostam is and what it is used for

The name of your injection is Pentostam. It contains a medicine called sodium stibogluconate.

Pentostam kills parasites, which cause a disease called leishmaniasis. These parasites are spread by bites from sand flies.

There are 3 main ways in which leishmaniasis can show itself:

- by sores on your skin (cutaneous)
- by sores in your nose, mouth and throat (mucocutaneous)
- by affecting your internal organs like the liver (visceral).

2 What you need to know before you have Pentostam

You should not have Pentostam if you:

- are allergic to sodium stibogluconate or any of the other ingredients of this medicine (listed in section 6)
- have serious kidney disease.

Do not have Pentostam if any of the above apply to you. If you are not sure, talk to your doctor, pharmacist or nurse before having Pentostam.

Warnings and precautions

Take special care with Pentostam if you have:

- liver problems
- heart problems, an unusual heart rhythm or beat
- been treated for leishmaniasis disease before
- sores in your nose, mouth or throat.

If you are not sure if any of the above apply to you, talk to your doctor, pharmacist or nurse before you have Pentostam.

Your doctor or nurse will normally check your heart rhythm and beat before and during your Pentostam treatment. The doctor or nurse will use an electrocardiogram (ECG) to check how well your heart works.

If you are having blood tests to check for changes to the blood, pancreas or liver function, let your doctor, pharmacist or nurse know that you are on Pentostam. This is because Pentostam can affect the results of these types of tests.

Other medicines and Pentostam

Please tell your doctor, pharmacist or nurse if you are taking, have recently taken or might use any other medicines, including medicines obtained without a prescription.

Your doctor, pharmacist or nurse will take special care if you have medicines for an unusual heart rhythm or beat (anti-arrhythmics), like amiodarone and sotalol. This is because Pentostam can change your heart rhythm and increase the effects of these medicines.

If your doctor recommends that you take amphotericin B they may wish to delay starting this treatment and check your electrolyte levels before use. This is because amphotericin B given shortly after Pentostam can cause abnormal heart beats.

Pregnancy and breast-feeding

Talk to your doctor, pharmacist or nurse before having this medicine if you are pregnant, planning to get pregnant or breast-feeding. If you are, you should not have Pentostam.

3 How Pentostam is given

You will never give yourself this medicine. A qualified person, like a doctor or a nurse, will give you this medicine.

Pentostam can be given as an injection into a vein (intravenous) or a muscle (intramuscular). Your doctor will decide which one is best for you.

The dose and how long you will have this treatment

- The dose that you will have is different for each type of leishmaniasis. Your doctor will decide the dose and how long your treatment will last.
- Treatment is usually one injection daily for 30 days.

It is recommended that you return to your doctor after 2 months and again after 6 months so that your condition can be assessed.

If more Pentostam is given to you than recommended

If you think you have been given too much Pentostam, **tell your doctor immediately**.

You may get the following symptoms:

- feeling sick (nausea), being sick (vomiting), severe diarrhoea
- your skin or the whites of your eyes may turn yellow (jaundice)
- your urine may become darker or your stools may become paler.

Your doctor may give you another medicine to help your recovery.

If you have any further questions about how this product is given, ask your doctor, pharmacist or nurse.

4 Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Very rarely, a sudden and severe allergic reaction to Pentostam can occur. If you get any of the following symptoms **tell your doctor, pharmacist or nurse immediately**:

- Rash, itching or hives on the skin.
- Swelling of the face, lips, tongue or other parts of the body.
- Shortness of breath, wheezing or trouble breathing.

Some patients can get pneumonia. If you get any of the following **tell your doctor, pharmacist or nurse as soon as possible**:

- Fever and chills.
- Cough with phlegm or blood.

The pneumonia may be caused by Pentostam or the leishmaniasis disease itself.

Other side effects include:

Common (may affect up to 1 in 10 patients)

- Feeling sick (nausea), being sick (vomiting), diarrhoea or stomach pain.
- General feeling of tiredness, drowsiness or lack of energy.
- Muscle pain.

- Joint pains.
- Headache.
- Weight loss or lack of appetite.

Rare (may affect up to 1 in 1,000 patients)

- Your skin or the whites of your eyes may turn yellow.
- High temperature, sweating and flushing of your face.
- Bleeding from your nose or gum.
- Dizziness or a spinning feeling, also called vertigo.
- Rash or worsening of your sores.
- Chest pain.

The following side effects may occur but the frequency with which these may occur is not known:

- Pain where you had the injection. If you have the injections into your vein (intravenous) you may feel brief pain along the vein or get a blood clot in the vein due to the injection (thrombosis).
- Coughing straight after you have the injection.
- Severe stomach pain, which may spread to the back (associated with the inflammation of the pancreas), often with feeling sick (nausea) and being sick (vomiting).
- Short term changes in blood chemistry. Please also see section 2.

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 to store Pentostam

- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date which is printed on the carton and the bottle label. This expiry date (Exp.) refers to the last day of that month.
- Store below 25°C and do not freeze.
- Pentostam should be stored in the carton to protect from light.

6 Contents of the pack and other information

What Pentostam contains

- The active substance is sodium stibogluconate.
- The other ingredients are chlorocresol, glucono-delta-lactone and Water for Injections.

What Pentostam looks like and contents of the pack

Each carton contains an amber glass bottle containing 100 ml of solution.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder: The Wellcome Foundation Ltd, Stockley Park West, Uxbridge, Middlesex UB11 1BT.

Manufacturer: Glaxo Wellcome Operations, Barnard Castle, Durham DL12 8DT.

Other formats:

To listen to or request a copy of this leaflet in Braille, large print or audio please call, free of charge:

0800 198 5000 (UK Only)

Please be ready to give the following information:

Product name	Pentostam Injection
Reference number	00003/5105R

This is a service provided by the Royal National Institute of Blind People.

Leaflet date: February 2014

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