

Pentostam® Injection

sodium stibogluconate

Please read this leaflet carefully. Keep it safe, as you may want to read it again.

This leaflet is a summary of information about your Pentostam Injection. If you want to know more about your illness or your medicine, please ask your doctor.

What is in Pentostam Injection ?

Each vial contains:

- the active ingredient - sodium stibogluconate (equivalent to 100 mg of pentavalent antimony per ml)
- other inactive ingredients - chlorocresol 0.1% (as a preservative), glucono-delta-lactone and Water for Injections.

Pentostam Injection is supplied in vials of 100 ml.

Who makes Pentostam Injection ?

Product licence held by The Wellcome Foundation Ltd., trading as GlaxoSmithKline UK, Stockley Park West, Uxbridge, Middlesex UB11 1BT.

Manufactured by Glaxo Wellcome Operations, Greenford, Middlesex UB6 0NN.

What is Pentostam Injection for ?

Pentostam belongs to a group of drugs called anti-parasitics. It is used to treat various types of leishmaniasis, an infection which may result from the bites of sandflies.

Before being given Pentostam Injection

This medicine suits most people, but there are a few people who should not be given it.

Tell your doctor **before** you are given the injection:

- if you have ever had an allergy (rash, itching, shortness of breath) or bad reaction to Pentostam, sodium stibogluconate, antimony or any of the inactive ingredients
- if you suffer from kidney or liver disease
- if you suffer from heart disease or irregular heartbeat
- if you are pregnant or trying to become pregnant
- if you are breast-feeding
- if you are taking any other medicines which contain antimony, or any other medications for your heart.

How is Pentostam Injection given ?

You will never be expected to give yourself this medicine. It will always be given to you by a person qualified to do so. The injection should be given intravenously (into a vein) or intramuscularly (into a muscle).

The dose of Pentostam will vary depending on the type of leishmaniasis that you have. Your doctor will decide on a dose and duration of Pentostam therapy that is right for you.

Treatment is usually once daily for 20 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 you have any concerns about the dosage of your medicine and its frequency of administration, ask your doctor for clarification.

Does Pentostam Injection have side effects ?

Medicines can, in rare cases, cause a severe allergic reaction. If you experience any of the following symptoms while using Pentostam, tell your doctor **immediately**:

- sudden difficulty in breathing, speaking and swallowing; swelling of the lips, face and neck; extreme dizziness or collapse; itchy, raised skin rash.

This medicine may cause the following side effects in some people:

- swelling and redness around the site of injection
- changes to the normal heartbeat
- stomach upsets such as feeling sick, vomiting, diarrhoea or stomach pains
- short-term changes in blood chemistry
- severe upper abdominal pain which may spread to the back (associated with inflammation of the pancreas)
- weight loss or loss of appetite
- a general feeling of being tired and unwell
- muscle pains; pain in the joints; stiffness
- high temperature, sweating and facial flushing
- worsening of cheek lesions
- chest pains
- bleeding from the nose or gums
- jaundice or rash
- dizziness
- headache
- pneumonia
- coughing immediately following injection
- pain and thrombosis at the injection site, following injection.

Tell your doctor if you notice any side effects from your medicine, even if they are not mentioned here.

Pentostam has been observed to cause ECG (electrocardiogram) changes in some patients and this appears to be dose-related. You may not notice any change in your heartbeat but your doctor may recommend that you have an ECG before and during therapy with Pentostam.

Pentostam can cause abnormal liver function tests. This is a blood test that lets your doctor know how well your liver is working. If there are any changes due to Pentostam, do not worry, as they will go back to normal once you have stopped using Pentostam.

Storing Pentostam Injection

Pentostam Injection should be protected from light. Do not store above 25°C. Do not freeze. Pentostam Injection should be stored where children cannot see or reach it.

Pentostam Injection should not be used after the expiry date on the pack.

The contents of the bottle should not be used more than 1 month after removing the first dose.

Further information

Date leaflet last revised: October 2004

The information provided applies only to Pentostam Injection

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