

PATENT INFORMATION LEAFLET

PATIENT INFORMATION LEAFLET: INFORMATION FOR THE USER

Streptomycin (as sulfate) 1 g powder for injection ¹

Read all of this leaflet carefully before you start using 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 health care provider.
- This medicine has been prescribed for you or your child only. Do not pass it on to others. It may harm them, even if the signs of their illness are the same as yours.
- **If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your health care provider.**

What is in this leaflet:

1. What Streptomycin (as sulfate) 1 g powder for injection is and what it is used for
2. What you need to know before you are given Streptomycin (as sulfate) 1 g powder for injection
3. How you are given Streptomycin (as sulfate) 1 g powder for injection
4. Possible side effects
5. How to store Streptomycin (as sulfate) 1 g powder for injection
6. Further information

1. WHAT STREPTOMYCIN (AS SULFATE) 1 G POWDER FOR INJECTION IS AND WHAT IT IS USED FOR

Streptomycin (as sulfate) 1 g powder for injection contains the active ingredient streptomycin. Streptomycin is an antibiotic which is used to treat tuberculosis (TB) together with other medicines.

2. WHAT YOU NEED TO KNOW BEFORE YOU ARE GIVEN STREPTOMYCIN (AS SULFATE) 1 G POWDER FOR INJECTION

Do not take Streptomycin (as sulfate) 1 g powder for injection if:

- you are allergic (hypersensitive) to streptomycin. An allergic reaction may include rash, itching, difficulty breathing or swelling of the face, lips, throat or tongue
- you are pregnant

Take special care with Streptomycin (as sulfate) 1 g powder for injection if:

- you have kidney problems
- you have hearing or balance problems. Your health care provider may want to test your hearing and balance before you have Streptomycin (as sulfate) 1 g powder for injection
- you have a history of allergies, especially to a class of antibiotics known as aminoglycosides

If any of the above apply to you, tell your health care provider.

Taking other medicines with Streptomycin (as sulfate) 1 g powder for injection

You should tell your health care provider if you are taking or have taken any medicines, including medicines obtained without a prescription. In particular, talk to your health care provider if you are taking any of the following medicines:

¹ Trade names are not prequalified by WHO. This is the national medicines regulatory authority's (NMRA) responsibility. Throughout this WHOPAR the proprietary name is given as an example only.

- capreomycin, viomycin (other treatments for tuberculosis [TB])
- other aminoglycoside antibiotics (e.g. gentamicin), amphotericin B, cephalosporins, ciclosporin, cisplatin, vancomycin and diuretics (e.g. furosemide and etacrynic acid).

It may still be alright for you to be given Streptomycin (as sulfate) 1 g powder for injection and your health care provider will be able to decide what is suitable for you.

Pregnancy and breastfeeding

If you are pregnant, think you might be pregnant, or planning to become pregnant you should not take Streptomycin (as sulfate) 1 g powder for injection.

Streptomycin (as sulfate) 1 g powder for injection can be used while breast-feeding.

Ask your health care provider for advice before taking any medicine.

Driving and using machines

Streptomycin may make you feel dizzy or experience problems with your balance. If they affect you in this way do not drive, operate machinery or do anything that requires you to be alert. Remember that if you are unwell your ability to drive or operate machinery may be affected.

3. HOW YOU ARE GIVEN STREPTOMYCIN (AS SULFATE) 1 G POWDER FOR INJECTION

Dose

You will be given other TB antibiotic medicines while you are having Streptomycin (as sulfate) 1 g powder for injection.

Streptomycin is usually given by injecting it into a large muscle (deep intramuscular injection). It will usually be given by a health care provider. In certain rare circumstances it may need to be given into your vein.

Adults

The usual dose is 15 mg/kg every day, 5 or 7 times a week, up to a maximum of 1 g daily. Your health care provider may adjust this dose according to your circumstances (e.g. because you are very overweight).

If you are older than 59 years or if you have kidney problems your health care provider may reduce your dose.

Children

The dose of streptomycin for a child is calculated according to the child's body weight. The recommended dose in children is 20–40 mg/kg every day, 5 or 7 times a week, up to a maximum of 1 g daily.

If you have any further questions on the use of this medicine, ask your health care provider.

4. POSSIBLE SIDE EFFECTS

Like all medicines, streptomycin can cause side effects, but not everybody gets them. Tell your health care provider about any change in your health.

Very serious side effects

All medicines can cause allergic reactions but serious allergic reactions are very rare. Tell your health care provider straightaway if you get any sudden wheeziness, difficulty in breathing, swelling of the eyelids, face or lips, rash or itching (especially affecting your whole body).

The following side effects can occur with streptomycin:

- kidney problems
- hearing or balance may get worse and you may hear noises in your ears or feel dizzy
- numbness and tingling around the mouth occur immediately after injection.
- the amount of potassium, calcium and magnesium in your blood may decrease (symptoms are muscle weakness, muscle cramps, feeling thirsty all the time, drinking all the time, passing urine frequently, vomiting and, possibly, having a fit)
- changes in the number of different types of blood cells (a blood test arranged by a health care provider will detect these). You may notice that you bruise easily (caused by low platelets) or you cannot fight off infections
- rash (without other symptoms)
- itching
- fever
- injection-site pain; rash, induration, or sterile abscesses can form at injection sites.

If any side effects gets serious or if you notice any side effects not listed in this leaflet, please tell your health care provider.

5. HOW TO STORE STREPTOMYCIN (AS SULFATE) 1 G POWDER FOR INJECTION

Your health care provider knows how to store Streptomycin (as sulfate) 1 g powder for injection.

Keep out of the sight and reach of children.

Do not store above 30°C. Protect from light and humidity.

After reconstitution:

Chemical and physical in-use stability has been demonstrated for 24 hours at 2-8°C.

From a microbiological point of view, the product should be used immediately after it has been reconstituted. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at 2 to 8 C, unless it has been reconstituted or diluted in controlled and validated aseptic conditions.

Do not use Streptomycin (as sulfate) 1 g powder for injection after the expiry date stated on the vial or carton.

The expiry date refers to the last day of that month.

Medicines should not be disposed of in wastewater or household waste. Ask your health care provider how to dispose of medicines you no longer use. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Streptomycin (as sulfate) 1 g powder for injection contains

Each vial contains 1 g of the active substance streptomycin.

What Streptomycin (as sulfate) 1 g powder for injection looks like and contents of the pack

Streptomycin (as sulfate) 1 g powder for injection is a white or almost white powder, filled in type III glass vial closed with chlorobutyl rubber stopper and sealed with flip-off aluminium cap. 10 vials are provided in a carton box.

Supplier

NCPC International Corp.
217-1 East Heping Road
Shijiazhuang, Hebei
P.R. China, 050011
Tel: 0086-311-85528596
Fax: 0086-311-85051711
Email: mayanzi@ncpc.biz

Manufacturer

NCPC New Preparation Branch Factory
No.115 Hainan Road
Shijiazhuang Economic & Technological
Development Zone
Hebei
China
Tel: 0086-311-67269099
Fax: 0086-311-67269081
Email: npfqazc@163.com

For any information about this medicine, contact the supplier.

This leaflet was last approved in January 2018

Detailed information on this medicine is available on the World Health Organization (WHO) web site:
<https://extranet.who.int/prequal>

This information is intended for medical or healthcare professionals only:

INFORMATION FOR HEALTHCARE PROFESSIONALS

Streptomycin (as sulfate) 1g powder for injection

Please refer to the Summary of Product Characteristics for full prescribing information.

Posology and method of administration

Dose:

Adults

The usual dose is 15 mg/kg once daily on 5–7 days each week up to a maximum daily dose of 1 g.

Please see section 4.2 of the Summary of Product Characteristics for dosing information related to obese individuals, adults aged over 59 years and patients with renal impairment.

Children

The recommended dose in children is 20–40 mg/kg/day, 5–7 days per week, up to a maximum daily dose of 1 g.

Preparation

Intravenous injection or infusion

After reconstitution chemical and physical in-use stability has been demonstrated for 24 hours at 2-8°C.

From a microbiological point of view, the product should be used immediately. If not used immediately, in-use storage times and conditions of the reconstituted infusion fluid prior to use are the responsibility of the user and would normally not be longer than 24 hours at 2 to 8 C, unless reconstitution / dilution has taken place in controlled and validated aseptic conditions.

Intramuscular injection

Adults: The preferred site is the upper outer quadrant of the buttock, (i.e., gluteus maximus), or the mid-lateral thigh. The deltoid area should be used only if well-developed such as in certain adults and older children, and then only with caution to avoid radial nerve injury. Intramuscular injections should not be made into the lower and mid-third of the upper arm.

Children: It is recommended that intramuscular injections be given preferably in the mid-lateral muscles of the thigh. In infants and small children the periphery of the upper outer quadrant of the gluteal region should be used only when necessary, in order to minimize the possibility of damage to the sciatic nerve.

Reconstitution of the streptomycin solution

The product is reconstituted by adding 4.2 mL of water for injection into the vial, which results in a solution of 200 mg of streptomycin activity per mL.

Shake the vial to mix well until the powder is completely dissolved and the solution is clear. If the solution appears cloudy or a precipitate is present, it should be discarded.