APPROVED PATIENT INFORMATION LEAFLET

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SRATOP 250 mg (Powder for injection)

SRATOP 500 mg (Powder for injection)

SRATOP 1 g (Powder for injection)

Cefazolin sodium

Read all of this leaflet carefully before you start taking SRATOP.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- **SRATOP** has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

1. WHAT SRATOP CONTAINS:

The active substance is cefazolin.

SRATOP 250 mg:

Each vial contains sterile cefazolin sodium equivalent to cefazolin 250 mg.

SRATOP 500 mg:

Each vial contains sterile cefazolin sodium equivalent to cefazolin 500 mg.

SRATOP 1 g:

Each vial contains sterile cefazolin sodium equivalent to cefazolin 1 g.

2. WHAT SRATOP IS USED FOR:

SRATOP is a cephalosporin antibiotic, used to treat many kinds of infections, including lung, skin, bone, joint, stomach, blood, heart valve and urinary tract infections, caused by bacteria sensitive to **SRATOP.**

3. BEFORE YOU RECEIVE SRATOP:

Do not take SRATOP:

If you have ever had an unusual or allergic reaction to cefazolin, any other cephalosporin or penicillins, and any of the other ingredients of **SRATOP.**

Take special care with SRATOP:

- Tell your doctor is you have a history of gastrointestinal disease, particularly colitis. Mild diarrhoea is common with antibiotic use. However, a more serious form of diarrhoea (pseudomembranous colitis) may occur less frequently. This may develop while you use the antibiotic or within several months after you stop using it. Contact your doctor right away if stomach pain or cramps, severe diarrhoea, or bloody stools occur. Do not treat diarrhoea without first checking with your doctor.
- Tell your doctor if you are penicillin sensitive.
- Tell your doctor immediately if you develop an allergic reaction to **SRATOP**.
- Tell your doctor if you are have or have ever had kidney disease. Your dosage may need to be adjusted.
- The safety and effectiveness for the use of cefazolin in children younger than one month old, has not been confirmed.
- If you have diabetes and regularly check your urine for sugar, use Clinistix or Tes-Tape. Do not use Clinitest tablets because cefazolin may cause false positive results.
- **SRATOP** may interfere with certain laboratory tests. Be sure your doctor and laboratory personnel know you are using **SRATOP.**

Pregnancy and Breast-feeding:

The safety of **SRATOP** in pregnancy and breast-feeding has not been established. Tell your doctor if you are pregnant, plan to become pregnant, or are breast-feeding. If you become pregnant while taking **SRATOP**, call your doctor.

If you are pregnant or breast feeding your baby while taking **SRATOP**, please consult your doctor, pharmacist or other health care professional for advice before taking **SRATOP**.

Driving and using machinery:

SRATOP is presumed to be safe or unlikely to produce an effect on the ability to drive and use machines.

Taking other medicines with SRATOP:

Some medicines may interact with cefazolin. Before taking **SRATOP**, tell your doctor if you are using any of the following medicines:

- Probenecid - the amount of **SRATOP** in your blood may be increased.
- Oral contraceptives – Your oral contraceptive may not work properly.
- Aminoglycoside antibiotics – there is an increased risk of kidney damage.

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines).

4. HOW TO RECEIVE SRATOP:

SRATOP will be given to you, by injection, by your doctor or another health care professional. You should check with your doctor or pharmacist if you are unsure. If you have the impression that the effect of **SRATOP** is too strong or too weak, talk to your doctor or pharmacist.

- **SRATOP** is administered as an injection at your doctor's office, hospital, or clinic. **SRATOP** will be either injected into a large muscle (such as your buttock or hip) or added to an intravenous fluid that will drip through a needle or catheter placed in your vein.
- Your doctor will prescribe an appropriate dose according to your condition.

If you receive more SRATOP than you should:

Large doses of **SRATOP** may cause dizziness; numbness, tingling, pins and needles; and headache. Seizures may occur, particularly in patients with impaired kidney function.

Since a healthcare professional will be administering **SRATOP**, he/she will control the dosage.

However, in the event of an overdosage, your doctor will manage the overdosage.

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

5. POSSIBLE SIDE EFFECTS:

SRATOP can have side-effects.

- Get emergency medical help if you have any of these **signs of an allergic reaction:**
  - Hives, difficulty breathing, swelling of your face, lips, tongue, or throat.

- Call your doctor at once if you have any of these serious side-effects:
  - Severe diarrhoea,
  - severe nausea or vomiting,
  - severe stomach pain/cramps
  - unusual bleeding or bruising,
  - bloody stools,
  - vaginal irritation or discharge,
  - white spots in the mouth,
  - yellowing of the eyes and skin.

- Tell your doctor if any of the side-effects below are severe, bothersome, do not go away or about any concerns you have while taking **SRATOP**.
  - Fever, flu-like symptoms,
  - diarrhoea, stomach pain, vomiting, loss of appetite,
  - skin rash, itching,
  - swollen eyes and mouth.

Not all side-effects reported for **SRATOP** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking **SRATOP**, please consult your doctor, pharmacist or other health care professional for advice.

6. STORING AND DISPOSING OF SRATOP:

Store at or below 25 °C (room temperature).

Once reconstituted, the solution is to be used within 24 hours if stored below 25 °C (room temperature) and within 96 hours if stored at 2 – 8 °C (in the refrigerator).

SRATOP is usually stored and handled by a healthcare provider. If you are using **SRATOP** at home, store **SRATOP** as directed by your pharmacist or healthcare provider.

Store all medicines out of reach of children.

7. PRESENTATION OF SRATOP:

SRATOP 250 mg:

10 ml clear transparent type I glass vials with grey bromo butyl rubber stoppers sealed with maroon coloured aluminium flip off seals.

Pack size: Single vial packed in printed carton with a package insert.

SRATOP 500 mg:

10 ml clear transparent type I glass vials with grey bromo butyl rubber stoppers sealed with light rose coloured aluminium flip off seals.

Pack size: Single vial packed in printed carton with a package insert.

SRATOP 1 g:

10 ml clear transparent type I glass vials with grey bromo butyl rubber stoppers sealed with violet coloured aluminium flip off seals.

Pack size: Single vial packed in printed carton with a package insert.

8. IDENTIFICATION OF SRATOP:

A white or almost white powder. When reconstituted, a pale yellow to intense yellow, clear liquid is formed.

9. REGISTRATION NUMBER/REFERENCE NUMBER:

SRATOP 250 mg: **43/20.1.1/0637**

SRATOP 500 mg: **43/20.1.1/0638**

SRATOP 1 g: **43/20.1.1/0639**

10. NAME AND ADDRESS OF REGISTRATION HOLDER:

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11. DATE OF PUBLICATION

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