

PATIENT INFORMATION LEAFLET

TREGS 0.5 g IM powder for injection

For intramuscular use.

Active ingredient:

Each vial contains: 500 mg ceftriaxone as 596.45 mg ceftriaxone sodium.

Each ampoule contains: 2 ml 1% lidocaine hydrochloride solution as solvent

Excipients:

Each ampoule contains: water for injection and sodium hydroxide.

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 doctor or pharmacist.
- This medicine has been prescribed for you only, do not pass it on to others.
- Tell your doctor that you are using this medicine when you visit your doctor or a hospital.
- Always follow the instructions in this leaflet. Do not use lower or higher doses than prescribed.

What is in this leaflet:

- 1. What TREGS is and what it is used for**
- 2. What you need to know before you use TREGS**
- 3. How to use TREGS**
- 4. Possible side effects**
- 5. How to store TREGS**

1. What TREGS is and what it is used for

TREGS is a crystalline powder and ranges from white to yellowish in color.

TREGS is supplied in packs of one vial containing powder for injection and one ampoule containing 2 ml of 1% lidocaine solution for injection. Each ampoule contains; 20 mg anhydrous lidocaine hydrochloride as 21.3 mg lidocaine hydrochloride monohydrate and water for injection.

TREGS contains ceftriaxone which belongs to a group of medicines called antibiotics. Ceftriaxone kills bacteria and it is used to treat infections in different parts of the body caused by bacteria.

TREGS can be used to treat following infections:

- Sepsis (blood infection caused by bacteria accompanied by fever and chills)
- Meningitis (inflammation of the protective membranes of the brain)
- Early and late stages of *Lyme borreliosis*, an infectious disease caused by ticks
- Abdominal infections (infection of the inner wall of the abdomen, gallbladder and gastrointestinal tract infections)
- Bone, joint, skin and soft tissue infections, wound infections
- Infections due to immune system disorders
- Kidney and urinary tract infections
- Respiratory tract infections including pneumonia (a type of lung infection), ear-nose and throat infections, uncomplicated otitis media with sudden onset (infection of the middle ear)
- Genital infections including a sexually transmitted disease called gonorrhea
- To prevent infections associated with surgery

2. What you need to know before you use TREGS

Do not use TREGS injection:

- If you are hypersensitive (allergic) to ceftriaxone (active ingredient in TREGS).
If you are hypersensitive to antibiotics called cephalosporins. These include ceftriaxone as well as cefalexin, cefaclor and cefuroxime.
- If you have had a sudden and severe allergic reaction to penicillins or similar antibiotics. The signs include sudden swelling of the throat or face which might make it difficult to breathe or swallow, sudden swelling of the hands, feet and ankles and a severe rash that develops quickly.
- If you are hypersensitive (allergic) to lidocaine (Contents of TREGS vial is dissolved in lidocaine solution before intramuscular administration)

TREGS must not be given to newborn babies if:

- The newborn baby is less than 28 days old and require or expected to require treatment with calcium containing intravenous solutions
- The baby is premature (born before 37 weeks)
- The newborn develop jaundice

Take special care with TREGS injection

Tell your doctor if;

- You have recently received or are about to receive a medicine containing calcium
- You have a history of gastrointestinal problems, in particular colitis (inflammation of the bowel)
- You have liver or kidney problems
- You have other illnesses such as blood problems
- You have gallbladder disease or any sign of gallstones seen as shadowing in your sonographic report
- You have asthma
- You are pregnant
- You are breast-feeding

Tell your doctor if any of the above apply to you, even for a period in the past.

TREGS with food and drink

There is no interaction with food and drink due to the route of administration. TREGS can be used without regard to meals.

Pregnancy

Ask your doctor or pharmacist for advice before taking this medicine.

Safety of TREGS during pregnancy has not been established. If you are pregnant or intend to become pregnant or are breast-feeding you must tell your doctor before using this medicine.

Tell your doctor or pharmacist if you become pregnant during treatment with TREGS.

Breast-feeding

Ask your doctor or pharmacist for advice before using this medicine.

A small amount of ceftriaxone (active ingredient of TREGS) is excreted in breast milk. This should be taken into consideration for breast-feeding mothers.

If you are breast-feeding or plan to breast-feed, talk to your doctor or pharmacist before using this medicine.

Driving and using machines

There is no evidence of negative effects of TREGS while driving or operating machinery. Since TREGS may cause dizziness, talk to your doctor before using this medicine, driving or operating machinery.

Important information about the excipients of TREGS

Each vial of TREGS contains 41.47 mg sodium. This should be taken into consideration for patients on a controlled sodium diet.

Taking other medicines

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines including medicines obtained with or without a prescription and herbal medicines.

This is because TREGS and some medicines may interfere with each other and can affect the way they work.

Tell your doctor if you are taking any of the following medicines:

- Oral contraceptives (birth control pills). TREGS may reduce the affect of contraceptive pills when used concomitantly, therefore you should use an additional method of contraception (e.g. condoms) while using TREGS and for the following one month after the treatment ends
- Chloramphenicol (used to treat infections, particularly of the eyes)
- Anticoagulants (medicines used to thin blood)
- Probenecid (used to treat gout)
- Amsacrine (an anti-cancer medicine)
- Fluconazole (an anti-fungal medicine)
- Vancomycin or other antibiotics (used to treat infections)

3. How to use TREGS

• Instructions for administration and dose/frequency of administration

The correct dose of your medicine will be decided by your doctor depending on your infection.

The usual dose of TREGS is 1-2 g daily. Your doctor may prescribe higher doses depending on the type of infection you have and how severe it is (up to 4 g daily).

If you are going to have an operation, you may be given a single dose of 1-2 g, 30-90 minutes before the operation.

The length of treatment varies according to the course of the disease. As with all antibiotic therapies in general, administration of TREGS should be continued for a minimum of 48-72

hours after the patient has become afebrile or evidence of bacterial eradication has been obtained.

- **Route of administration**

TREGS IM is administered by intramuscular injection by a doctor or a nurse. It is not recommended to inject more than 1 gram to one site.

- **Special age groups:**

Infants and children:

The doctor will decide the dose depending on the weight of your child. For newborns, infants and children up to 12 years of age, the following doses are given as a single daily dose.

Newborns (up to 14 days): a single daily dose of 20-50 mg per kg of body weight, daily dose should not exceed 50 mg/kg.

Infants and children (from 15 days up to 12 years of age) : A single daily dose of 20-80 mg per kg of body weight.

For children with body weights of 50 kg or more, the usual adult dose should be used.

For the treatment of acute otitis media (infection of the middle ear), a single dose of 50 mg/kg (should not exceed 1 g daily) is recommended.

Elderly patients:

Usual adult doses are used for elderly patients.

- **Special patients:**

Reduced kidney/liver functions:

If you have problems with your liver and kidneys, you may be given a lower dose. You may need to have blood tests to check that you are getting the dose you need.

If you have the impression that the effect of TREGS is too strong or too weak, you should tell your doctor or pharmacist.

If you used more TREGS than you should

If you think you have been given more TREGS than you should, tell your doctor or pharmacist.

If you forget to use TREGS

Do not take a double dose to make up for a forgotten dose.

If you forget to use a dose of TREGS, use the next dose as soon as you remember. But if it is nearly time for the next dose, skip the forgotten dose.

If you stop using TREGS

Do not stop using TREGS without talking to your doctor.

4. Possible side effects

Like all medicines, TREGS may cause side effects in patients who are sensitive to any of the ingredients of this medicine.

If any of the following side effects happen, stop using this medicine and tell you doctor immediately or go to the emergency service at your nearest hospital.

- Severe allergic reactions (uncommon, affect less than 1 in 100 people)

Sudden swelling of the face, throat, lips and mouth. This can make it difficult to breathe and swallow.

- Sudden swelling of the hands, feet and ankles.
- Severe skin rashes (very rare, affect less than 1 in 10.000 people).

If you get a severe skin rash, tell your doctor immediately. The signs may include a severe rash that develops quickly, with blisters or peeling of the skin and possibly blisters in the mouth.

Other possible side effects

Common (affect less than 1 in 10 people)

- Loose stools or diarrhoea
- Feeling sick or being sick

Uncommon (affect less than 1 in 100 people)

- Other skin reactions. These include a rash which may cover almost all your body, a lumpy rash, itching, and swelling.

Rare (affect less than 1 in 1.000 people)

- Other types of infection, such as those caused by fungi and yeasts (for example, thrush)
- Blood problems. The signs include feeling tired, bruising easily, being short of breath and nose bleeds.
- Headache
- Feeling dizzy
- Sore mouth
- Inflammation of the tongue (glossitis). The signs include swelling, redness, and soreness of the tongue.
- Liver problems (shown in a blood test).
- Problems with your gallbladder which may cause pain, feeling sick and being sick.
- Kidney problems. These may reduce the volume of urine produced. Some people pass more urine than usual. Very rarely, people stop passing urine completely.
- Blood or sugar in your urine

- Pain or a burning feeling along the vein where TREGS has been injected.
- Pain at the injection site.
- High fever or shivering.

Very rare (affect less than 1 out of 10.000)

- Positive results in a Coombs test (a test for some blood problems).
- Problems with blood clotting. The signs include bruising easily, pain and swelling of your joints.
- Changes in the number of white cells in the blood. The signs include sudden onset of high fever, shivering and sore throat.
- Inflammation of the pancreas (pancreatitis). The signs include severe pain in the abdomen which spreads to your back.
- Inflammation of the large bowel (colon). The signs include diarrhoea, usually with blood and mucus, stomach pain, and fever.

Tell your doctor or pharmacist if you notice any side effects not listed in this leaflet.

5. How to store TREGS

Keep TREGS out of the sight and reach of children.

Unopened vial; should be stored below 25°C. Keep TREGS in the outer carton in order to protect from light.

Chemical and physical stability has been demonstrated for 6 hours at room temperature (25°C) and for 24 hours at refrigerator (2-8 °C) after reconstitution.

Use the medicine in conformity with the expiry date.

Do not use this medicine after the expiry date printed on the pack.

Do not use TREGS if you notice that the medicine or the packaging is damaged.

Marketing Authorisation Holder:

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THE FOLLOWING INFORMATION IS INTENDED FOR MEDICAL AND OR HEALTHCARE PROFESSIONALS WHO WILL ADMINISTER THE MEDICINE.

“TREGS 0.5 g IM Powder for injection” consists of a vial containing powder for injection and an ampoule containing 2 ml 1% lidocaine hydrochloride solution

Mode of administration

Intramuscular administration:

TREGS 0.5 g IM vial should be dissolved in 2 ml 1% lidocaine hydrochloride solution and is administered the by deep intragluteal injection. It is not recommended to inject more than 1 g to one site. Dosages higher than 1 g should be divided and injected at two sites (gluteus). Intramuscular dose of ceftriaxone should not exceed 2 grams daily.

When lidocaine hydrochloride solution is used as solvent, solutions should only be used for intramuscular (never used for intravenous injection) injection.

Chemical and physical stability has been demonstrated for 6 hours at room temperature (25°C), for 24 hours at refrigerator (2-8 °C) after reconstitution.

After reconstitution, parenteral drugs should be shaken thoroughly before administration and should be inspected for particulate matter. Do not use if particles are present.

The color of reconstituted solutions range from honey to light yellow, depending on the concentration and length of storage time. Variations in the color of solutions do not indicate a change in potency or safety.

From a microbiological point of view, reconstituted solutions should be used immediately. If not, in-use storage times and conditions are the responsibility of the user.