

Patient Information Leaflet

Mesporin 2 g powder for solution for I.V. infusion 2000 mg powder for solution for infusion

Ceftriaxone (in the form of ceftriaxone sodium)

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. Do not pass it on to others. It may harm them, even if their symptoms 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 doctor or pharmacist.

What is in this leaflet

1. What Mesporin is and what it is used for
2. Before you use Mesporin
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1. What Mesporin is and what it is used for

Mesporin is an antibiotic for adults and children (including newborn babies). This medicine works by killing bacteria that cause infections. It belongs to a group of medicines called cephalosporins.

Mesporin is used to treat infections of:

- the brain (meningitis),
- the lungs,
- the middle ear,
- the abdomen and abdominal wall (peritonitis),
- the urinary tract and kidneys,
- the bones and joints,
- the skin and soft tissues,
- the blood,
- the heart.

It can be given to:

- treat specific sexually transmitted infections (gonorrhoea and syphilis),
- treat patients with a low white blood cell count (neutropenia) who have fever due to bacterial infection,
- treat chest infections in adults with chronic bronchitis,
- treat Lyme disease (caused by tick bites) in adults and children including newborn babies from 15 days of age,

- prevent infections during surgery.

2. What you need to know before you use Mespurin

a. Don't use Mespurin if:

- you are allergic to ceftriaxone or any of the other ingredients of this medicine (listed in section 6).
- you have had a sudden or severe allergic reaction to penicillin or similar antibiotics (such as cephalosporins, carbapenems or monobactams). The signs include sudden swelling of the throat or face which may make it difficult to breathe or swallow, sudden swelling of the hands, feet and heels, and a severe skin rash that develops quickly.
- you are allergic to lidocaine and if Mespurin is to be given as an injection into a muscle.

Mespurin cannot be given to babies if:

- the baby is premature.
- the baby is newborn (up to 28 days of age) and has certain blood problems or jaundice (yellowing of the skin or whites of the eyes) or if the baby is to be given a product that contains calcium into a vein.

b. Take special care with Mespurin

Talk to your doctor, pharmacist or nurse before you are given Mespurin if:

- you have recently received or are about to receive products that contain calcium.
- you have recently had diarrhoea after taking an antibiotic, or if you have ever had problems with your intestine, in particular colitis (inflammation of the intestine).
- you have liver or kidney problems.
- you have gallstones or kidney stones.
- you have other illnesses, such as haemolytic anaemia (a reduction in the red blood cells that may make your skin pale yellow and cause weakness or difficulty breathing).
- you are on a low sodium diet.

If you need a blood or urine test

If you are given Mespurin for a long time, you may need to have regular blood tests. Mespurin may affect the results of urine tests for sugar and a blood test known as the Coombs' test. If you are having tests:

- tell the person taking the blood sample that you have been given Mespurin.

Children

Talk to your doctor, pharmacist or nurse before Mespurin is given to your child if:

- he/she has recently received or is to be given a product that contains calcium into a vein.

c. Taking other medicines, herbal or dietary supplements

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

In particular, tell your doctor or pharmacist if you are taking any of the following medicines:

- A type of antibiotic called an aminoglycoside.
- An antibiotic called chloramphenicol (used to treat infections, especially eye infections).

d. Pregnancy, breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

Your doctor will consider the benefit of treatment with Mespurin in relation to the risk to your baby.

e. Driving and using machines

Mespurin can cause dizziness. If you feel dizzy, do not drive or use tools or machines. Talk to your doctor if you get these symptoms.

3. How to use Mespurin

Mespurin is normally given by a doctor or nurse. It can be given by a drip (intravenous infusion) system or as an injection directly into a vein or muscle. Mespurin is prepared by the doctor, pharmacist or nurse and will not be mixed with or given at the same time as injections that contain calcium.

Usual dose

Your doctor will decide the correct dose of Mespurin for you. The dose will depend on the severity and type of infection, on whether you are taking other antibiotics, on your weight and age, and on your kidney and liver function. The number of days or weeks that you are given Mespurin depends on the type of infection that you have.

Adults, the elderly and children over 12 years of age with a body weight \geq 50 kilograms (kg):

- 1 to 2 g once a day, depending on the severity and type of infection. If you have a severe infection, your doctor will give you a higher dose (up to 4 g once a day). If your daily dose is higher than 2 g, you may receive it as a single dose once a day or as two separate doses.

Newborn babies, infants and children between 15 days and 12 years of age with a body weight < 50 kg:

- 50-80 mg of Mespurin per kg of body weight once a day, depending on the severity and type of infection. If you have a severe infection, your doctor will give you a daily dose of up to 100 mg per kg of body weight up to a maximum of 4 g once a day. If your daily dose is higher than 2 g, you may receive it as a single dose once a day or as two separate doses.
- Children with a body weight of 50 kg or more should receive the usual adult dose.

Newborn babies (0-14 days)

- 20-50 mg of Mespurin per kg of body weight once a day, depending on the severity and type of infection.
- The maximum daily dose should not exceed 50 mg per kg of the baby's body weight.

People with liver and kidney problems

You may receive a different dose from the usual dose. Your doctor will decide how much Mespurin you will need and will monitor your condition closely, depending on the severity of the liver or kidney disease.

a. If you use more Mespurin than you should

If you accidentally receive a dose higher than your prescribed dose, contact your doctor or the nearest hospital immediately.

b. If you forget to use Mespurin

If you miss an injection, it should be given to you as quickly as possible. However, if it is nearly time to receive your next injection, skip the injection that you missed. Do not take a double dose (two injections at the same time) to make up for a missed dose.

c. If you stop using Mespurin

Do not stop using Mespurin unless your doctor tells you to. If you have any further questions on the use of this medicine, ask your doctor or nurse.

4. Possible side effects

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

The following side effects may occur with this medicine:

Severe allergic reactions (not known, frequency cannot be estimated from the available data)

If you have a severe allergic reaction, tell a doctor immediately.

The signs may include:

- Sudden swelling of the face, throat, lips and mouth. This may make it difficult to breathe or swallow.
- Sudden swelling of the hands, feet and heels.

Severe skin rashes (not known, frequency cannot be estimated from the available data)

If you have a severe skin rash, tell a doctor immediately.

- The signs may include a severe skin rash that develops quickly, with blisters or peeling of the skin and possibly blisters in the mouth.

Other possible side effects:

Common (may affect up to 1 in 10 people)

- Abnormalities in blood levels of white blood cells (such as a decrease in leucocytes and an increase in eosinophils) and platelets (decrease in thrombocytes).
- Loose stools or diarrhoea.
- Changes in the results of blood tests for liver function.
- Skin rash.

Uncommon (may affect up to 1 in 100 people)

- Fungal infections (e.g. candidiasis).
- A decrease in the number of white blood cells (granulocytopenia).
- A reduction in the number of red blood cells (anaemia).

- Problems with blood clotting. The signs may include easy bruising, and pain and swelling of the joints.
- Headache.
- Dizziness.
- Feeling sick or being sick.
- Pruritus (itching).
- Pain or a burning sensation along the vein where Mespurin has been given. Pain at the injection site.
- A high temperature (fever).
- Abnormal kidney function test (increase in blood creatinine).

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

- Inflammation of the large intestine (colon). The signs include diarrhoea, usually with blood and mucus, stomach pain and fever.
- Difficulty breathing (bronchospasm).
- A lumpy skin rash (urticaria) that may cover a lot of your body, an itching sensation and swelling.
- Blood or sugar in the urine.
- Oedema (accumulation of fluid).
- Shivers.

Not known (frequency cannot be estimated from the available data)

- A secondary infection that may not respond to the antibiotics previously prescribed.
- A form of anaemia where red blood cells are destroyed (haemolytic anaemia).
- Severe decrease in white blood cells (agranulocytosis).
- Convulsions.
- Vertigo (spinning sensation).
- Inflammation of the pancreas (pancreatitis). The signs include severe stomach pain which spreads to your back.
- Inflammation of the mucous lining of the mouth (stomatitis).
- Inflammation of the tongue (glossitis). The signs include a swollen, red and sore tongue.
- Problems with the bladder, which may cause pain, feeling sick and being sick.
- A neurological condition that may occur in newborn babies with severe jaundice (kernicterus).
- Kidney problems caused by deposits of ceftriaxone-calcium. There may be pain when urinating or low output of urine.
- A false positive result in the Coombs' test (a test for some blood problems).
- A false positive result for galactosaemia (abnormal accumulation of galactose in the blood).
- Mespurin may interfere with some types of blood glucose tests – please check with your doctor.

5. How to store Mespurin

Keep this medicine out of the sight & reach of children.

Do not use Mespurin after the expiry date which is stated on the carton and bottle. The expiry date refers to the last day of that month.

Do not store above 30 °C. Store in the original package in order to protect from moisture and light.

It is recommended to use each reconstituted solution freshly.
Its effectiveness remains for up to 6 hours at room temperature (15-25 °C) and up to 24 hours under refrigeration (2-8 °C).

Any unused solutions for infusion should be discarded.
Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines you no longer require. These measures will help protect the environment.

6. Further Information

a. What Mespurin contains

The active substance is ceftriaxone in the form of sodium salt. Each bottle contains 250 mg, 500 mg or 1000 mg of ceftriaxone.

The other ingredient is water for injections.

b. What Mespurin looks like and contents of the pack

Mespurin is a white or almost white crystalline powder with a characteristic odour. The ready-to-use solutions are colourless.
Packs of 1, 2 and 4 units are available.

Not all pack sizes may be marketed.

c. Marketing Authorisation Holder and Manufacture

Marketing Authorization Holder:

Acino AG
Am Windfeld 35, D-83714 Miesbach
Germany

Manufacturer:

Labesfal - Laboratórios Almiro, S.A.
Zona Industrial do Lagedo
3465-157 Santiago de Besteiros
Portugal

d. This leaflet was last revised in June 2018

e. To report any side effects:

- ***Saudi Arabia:***

- The National Pharmacovigilance and Drug Safety Centre (NPC)
 - Fax: +966-11-205-7662
 - Call NPC at +966-11-2038222, Exts: 2317-2356-2353-2354-2334-2340.
 - Toll free phone: 8002490000
 - E-mail: npc.drug@sfda.gov.sa
 - Website: www.sfda.gov.sa/npc

- ***Other GCC States:***

- Please contact the relevant competent authority.

f. Council of Arab Health Ministers

This is a Medicament

- Medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are the experts in medicines, their benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed.
- Do not repeat the same prescription without consulting your doctor.
- Keep all medicaments out of reach of children.

Council of Arab Health Ministers

Union of Arab Pharmacists

g. This patient information leaflet is approved by the Saudi Food and Drug Authority