

Ceftriaxone (as Sodium) 1g  
Powder for Solution for Injection and Infusion  
(Sinopharm Zhijun (Shenzhen) Pharmaceutical Co., Ltd), HA622

WHOPAR part 3

January 2017

## **PATIENT INFORMATION LEAFLET**

## PATIENT INFORMATION LEAFLET: INFORMATION FOR THE USER

### 达力嗪<sup>R</sup> (DALIQIN)\*

**Read all of this leaflet carefully before you start taking 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 healthcare provider.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your healthcare provider. This includes any possible side effects not listed in this leaflet.

#### **What is in this leaflet:**

1. What 达力嗪<sup>R</sup> (DALIQIN) is and what it is used for.
2. What you need to know before you are given 达力嗪<sup>R</sup> (DALIQIN).
3. How 达力嗪<sup>R</sup> (DALIQIN) is given.
4. Possible side effects.
5. How to store 达力嗪<sup>R</sup> (DALIQIN).
6. Contents of the pack and other information.

#### **1. WHAT 达力嗪<sup>R</sup> (DALIQIN) IS AND WHAT IT IS USED FOR**

达力嗪<sup>R</sup> (DALIQIN) is an antibiotic used for the treatment of the following bacterial infections in Human Immunodeficiency Virus (HIV)/AIDS patients.

达力嗪<sup>R</sup> (DALIQIN) 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
- bones and joints
- the skin or soft tissues
- the blood
- the heart

It can be given:

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

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

days of age

- to prevent infections during surgery

## 2. WHAT YOU NEED TO KNOW BEFORE YOU ARE GIVEN 达力嗪<sup>R</sup>(DALIQIN)

### You must not be given 达力嗪<sup>R</sup> (DALIQIN) if:

- you are hypersensitive (allergic) to ceftriaxone or any of the other ingredients of 达力嗪<sup>R</sup> (DALIQIN) (see section 6. What 达力嗪<sup>R</sup> (DALIQIN) contains),
- you have had a sudden or severe allergic reaction to penicillin or similar antibiotic medicines ( such as cephalosporins, carbapenems or monobactams). 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
- you are allergic to lidocaine and you are to be given 达力嗪<sup>R</sup> (DALIQIN) as an injection into a muscle.

### 达力嗪<sup>R</sup> (DALIQIN) must not 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 the whites of the eyes) or is to be given a product that contains calcium into their vein.

### Warnings and precautions:

Talk to your healthcare provider before you are given 达力嗪<sup>R</sup> (DALIQIN) if:

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

### If you need a blood or urine test

If you are given 达力嗪<sup>R</sup> (DALIQIN) for a long time, you may need to have regular blood tests. 达力嗪<sup>R</sup> (DALIQIN) can 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 sample that you have been given 达力嗪<sup>R</sup> (DALIQIN).

### Children

Talk to your healthcare provider before your child is given 达力嗪<sup>R</sup> (DALIQIN) if:

- Your child has recently been given or is to be given a product that contains calcium into their vein.

### Other medicines and 达力嗪<sup>R</sup> (DALIQIN)

Tell your healthcare provider if you are taking, have recently taken or might take any other medicines. In particular, tell your healthcare provider if you are taking any of the following medicines:

- A type of antibiotic called an aminoglycoside.
- An antibiotic called chloramphenicol (used to treat infections, particularly of the eyes).

### **Pregnancy, breastfeeding and fertility**

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your healthcare provider for advice before taking this medicine.

The healthcare provider will consider the benefit of treating you with 达力嗪<sup>R</sup> (DALIQIN) against the risk to your baby.

### **Driving and using machines**

达力嗪<sup>R</sup> (DALIQIN) can cause dizziness. If you feel dizzy, do not drive or use any tools or machines.

Talk to your healthcare provider if you experience these symptoms.

## **3. HOW 达力嗪<sup>R</sup> (DALIQIN) IS GIVEN**

达力嗪<sup>R</sup> (DALIQIN) is usually given by a healthcare provider. It can be given as a drip (intravenous infusion) or as an injection directly into a vein or into a muscle. 达力嗪<sup>R</sup> (DALIQIN) is made up by the healthcare provider and will not be mixed with or given to you at the same time as calcium-containing injections.

### **The usual dose**

Your healthcare provider will decide the correct dose of 达力嗪<sup>R</sup> (DALIQIN) for you. The dose will depend on the severity and type of infection; whether you are on any other antibiotics; your weight and age; how well your kidneys and liver are working. The number of days or weeks that you are given 达力嗪<sup>R</sup> (DALIQIN) depends on what sort of infection you have.

### **Adults, older people and children aged 12 years and over with a body weight greater than or equal to 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 healthcare provider 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 aged 15 days to 12 years with a body weight of less than 50 kg:**

- 50-80 mg 达力嗪<sup>R</sup> (DALIQIN) for each kg of the child's body weight once a day depending on the severity and type of infection. If you have a severe infection, your healthcare provider will give you a higher dose up to 100 mg for each kg of body weight 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 be given the usual adult dose.

**Newborn babies (0-14 days)**

- 20 – 50 mg 达力嗪<sup>R</sup> (DALIQIN) for each kg of the child's body weight once a day depending on the severity and type of infection.
- The maximum daily dose is not to be more than 50 mg for each kg of the baby's weight.

**People with liver and kidney problems**

You may be given a different dose to the usual dose. Your healthcare provider will decide how much 达力嗪<sup>R</sup> (DALIQIN) you will need and will check you closely depending on the severity of the liver and kidney disease.

**If you are given more 达力嗪<sup>R</sup> (DALIQIN) than you should**

If you accidentally receive more than your prescribed dose, contact your healthcare provider or nearest hospital straight away.

**If you forget to use 达力嗪<sup>R</sup> (DALIQIN)**

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

**If you stop using 达力嗪<sup>R</sup> (DALIQIN)**

Do not stop taking 达力嗪<sup>R</sup> (DALIQIN) unless your healthcare provider tells you to. If you have any further questions on the use of this medicine, ask your healthcare provider.

**4. POSSIBLE SIDE EFFECTS**

Like all medicines, 达力嗪<sup>R</sup> (DALIQIN) can cause side effects, although not everybody gets them. The following side effects may happen with this medicine:

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

If you have a severe allergic reaction, tell your healthcare provider straight away.

The signs may include:

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

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

If you get a severe skin rash, tell your healthcare provider straight away.

- 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 (may affect up to 1 in 10 people)**

- Abnormalities with your white blood cells (such as a decrease of leucocytes and an increase of eosinophils) and platelets (decrease of thrombocytes).
- Loose stools or diarrhoea.
- Changes in the results of blood tests for liver functions.
- Rash.

**Uncommon (may affect up to 1 in 100 people)**

- Fungal infections (for example, thrush).
- A decrease in the number of white blood cells (granulocytopenia).
- Reduction in number of red blood cells (anaemia).
- Problems with the way your blood clots. The signs may include bruising easily and pain and swelling of your joints.
- Headache.
- Dizziness.
- Feeling sick or being sick.
- Pruritis (itching).
- Pain or a burning feeling along the vein where 达力嗪<sup>R</sup> (DALIQIN) has been given. Pain where the injection was given.
- A high temperature (fever).
- Abnormal kidney function test (blood creatinine increased).

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

- Inflammation of the large bowel (colon). The signs include diarrhoea, usually with blood and mucus, stomach pain and fever.
- Difficulty in breathing (bronchospasm).
- A lumpy rash (hives) that may cover a lot of your body, feeling itchy and swelling.
- Blood or sugar in your urine.
- Oedema (fluid build-up).
- Shivering.

**Not known (Frequency cannot be estimated from the available data)**

- A secondary infection that may not respond to the antibiotic previously prescribed
- 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 pain in the stomach which spreads to your back.
- Inflammation of the mucus lining of the mouth (stomatitis).
- Inflammation of the tongue (glossitis). The signs include swelling, redness and soreness of the tongue.
- Problems with your gallbladder, which may cause pain, feeling sick and being sick.
- A neurological condition that may occur in neonates with severe jaundice (kernicterus).
- Kidney problems caused by deposits of calcium ceftriaxone. There may be pain when passing water (urine) or low output of urine.
- A false positive result in a Coombs' test (a test for some blood problems).
- A false positive result for galactosaemia (an abnormal buildup of the sugar galactose).
- 达力嗪<sup>R</sup> (DALIQIN) may interfere with some types of blood glucose tests - please check with your healthcare provider.

**Reporting of side effects**

If you get any side effects, talk to your healthcare provider. This includes any possible side effects not listed in

this leaflet. By reporting side effects, you can help provide more information on the safety of this medicine.

## 5. HOW TO STORE 达力嗪<sup>R</sup> (DALIQIN)

### Unopened vials:

Do not store above 30°C. Keep the container in the outer carton in order to protect from light.

### After reconstitution:

The constituted product as well as further diluted product should be used immediately after preparation. If not used immediately, the solutions in glass bottles or PVC bags should be used within 6 hours when stored at 30°C and 24 hours when stored at 2-8°C.

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

Do not use 达力嗪<sup>R</sup> (DALIQIN) after the expiry date which is stated on the label after {EXP}. The expiry date refers to the last day of that month.

## 6. CONTENTS OF THE PACK AND OTHER INFORMATION

### What 达力嗪<sup>R</sup> (DALIQIN) contains

Each vial contains 1 g of the active substance ceftriaxone.

### What 达力嗪<sup>R</sup> (DALIQIN) looks like and contents of the pack

达力嗪<sup>R</sup> (DALIQIN) is provided as a sterile white or yellowish crystalline powder in a Type I glass vial (30 ml) closed with bromobutyl rubber stoppers and aluminium caps.

达力嗪<sup>R</sup> (DALIQIN) is packed in boxes of 10 vials.

### Supplier and Manufacturer

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**For any information about this medicinal product, please contact the supplier.**

**This leaflet was last approved in January 2017.**

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