

# Colistimethate Sodium 1 million I.U./ 2 million I.U./ 3 million I.U./ 4.5 million I.U. powder for solution for Injection/Inhalation

## PATIENT INFORMATION LEAFLET

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 further questions, please ask your doctor, nurse or pharmacist.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

### In this leaflet:

1. What Colistimethate is and what it is used for
2. What you need to know before you are given Colistimethate
3. How Colistimethate is given
4. Possible side-effects
5. How to store Colistimethate
6. Contents of the pack and other information

## 1. What colistimethate is and what it is used for

Colistimethate is given by injection to treat some types of serious infections caused by certain bacteria. Colistimethate is used when other antibiotics are not suitable.

## 2. What you need to know before you are given colistimethate

Colistimethate is not suitable for everyone. Some people **must not** have this injection. Do not have the injection:

If you are allergic (hypersensitive) to colistimethate, colistin or to other polymyxins. If you are unsure about anything, ask your doctor before you have the injection.

### **Warnings and precautions**

Talk to your doctor, pharmacist or nurse before using Colistimethate

- If you have or have had kidney problems.
- If you suffer from myasthenia gravis
- If you suffer from porphyria

In premature and new-born babies, special care should be taken when using Colistimethate as the kidneys are not yet fully developed.

### **Other medicines and Colistimethate**

Colistimethate may not be suitable if you are also taking the following medications. These medications may need to be stopped, you may need a lower dose of Colistimethate or monitoring may be required while taking Colistimethate. Colistimethate levels in blood may need to be monitored to ensure the correct dose is given.

Aminoglycoside antibiotics (including netilmicin, gentamicin, amikacin and tobramycin) and cephalosporins taken concurrently with Colistimethate can affect kidney function and increase the risk of side effects and damage to the kidneys, ears and parts of the nervous system.

Colistimethate can increase the effects of muscle relaxant medications used in general anaesthesia. Anaesthetist should be made aware if you are taking Colistimethate.

If you are taking macrolides for myasthenia gravis (including azithromycin, clarithromycin or

erythromycin) or fluoroquinolone antibiotics (including ofloxacin, norfloxacin and ciprofloxacin), taking Colistimethate further increases the risk of muscle weakness and breathing difficulties.

Taking any other colistimethate products as an inhalation at the same time as receiving Colistimethate as an infusion can increase the risk of side effects.

Make sure the doctor knows about any other medicines that you are taking, including medicines that you obtained without a prescription.

Each vial of Colistimethate contains about 5mg of sodium. This means that you could receive up to 60mg sodium each day if you are having the maximum adult dose. This medicine contains less than 1 mmol sodium (23 mg) per vial.

### **Pregnancy and breastfeeding**

- Colistimethate is not known to harm the unborn child but, like all medicines, it will only be given to a pregnant woman if it is really needed.
- Small amounts of Colistimethate enter the milk. If you cannot stop breastfeeding while you have the injections, you should watch your baby carefully for any signs of illness and tell your doctor if you notice anything wrong.

### **Driving and operating machinery**

Some people have reported side effects such as dizziness, confusion or problems with vision. If you are affected do not drive or operate machinery.

## 3. How colistimethate is given

Colistimethate Sodium is given to you by your doctor as an infusion into a vein over 30 – 60 minutes.

The usual daily dose in adults is 9 million units, divided into two or three doses. If you are quite unwell, you will be given a higher dose of 9 million units once at the start of treatment.

In some cases, your doctor may decide to give a higher daily dose of up to 12 million units.

## 4. Possible side effects

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

### **Some side effects can be serious**

**Tell the doctor or nurse immediately if you notice any of the following symptoms:**

- Wheezing or breathing difficulties which can lead to collapse, a rash, itching or hives on the skin, or sudden swelling of the face, throat or lips. These can be signs of a severe allergic reaction.

### **The following side effects have also been reported:**

- Reactions, such as irritation, at the injection site.
- Kidney problems. These are more likely in patients who already have poor kidneys, or who are given Colistimethate at the same time as other medicines that can affect the kidneys, or who are given a dose that is too high. These problems will normally get better if treatment is stopped, or the dose of Colistimethate is reduced.
- Neurological problems such as inability to breathe because of paralysis of the chest muscles, numbness or tingling (especially around the face), dizziness or loss of balance, rapid changes in blood pressure or blood flow (including faintness and flushing), slurred speech, problems with vision, confusion and mental problems (including

loss of sense of reality). Side effects that affect the nervous system are more likely to occur when the dose of Colistimethate is too high, in people who have poor kidneys or in those who are also receiving muscle relaxants or other medicines with a similar effect on how the nerves work.

#### **Reporting of side effects**

If you get any side effects, talk to your doctor, nurse or pharmacist. This includes any possible side effects not listed in this leaflet.

### **5. How to store colistimethate**

Keep this medicine out of the sight and reach of children. The vials of powder must not be stored above 25°C. The vials must be protected from light by storing in the outer carton. The vials must not be used after the expiry date printed on the carton and vial label. Do not freeze.

The solution of Colistimethate should be used immediately, or within 8 hours when stored at temperatures not exceeding 25°C or 24 hours in the refrigerator (2 to 8°C). The vials are for single use. Any unused solution should be discarded.

Colistimethate should not be used if there is any discoloration or cloudiness of the solution.

### **6. Contents of the pack and other information**

Colistimethate is a creamy white powder for solution for injection in single dose 7ml glass vials. Each carton contains 1 or 10 vials. Each vial contains the active ingredient, Colistimethate (also called colistin) as an amount of powder equivalent to one million international units. There are no other ingredients. The sodium content is 0.228 mMol per vial.

### **7. Manufactured By:**

**Taj Pharmaceuticals Ltd.**

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Industrial Estate, At & Post-Moraiya,  
Tal-Sanand, Dist- Ahmedabad Gujarat (India)