

**COLISTIMETHATE
SODIUM POWDER FOR
INJECTION
1 MIU, 2 MIU, 4.5 MIU
(COLISTIN)**

Package leaflet:

Information for the patient

Colistimethate Sodium Powder For Injection

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 doctor or pharmacist.
- 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 doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

The name of your medicine is Colistimethate sodium Powder for Solution for Injection. It is referred to as Colistimethate in this leaflet.

What is in this leaflet

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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 take 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

- medicines which can affect how your kidneys function. Taking such medicines at the same time as Colistimethate can increase the risk of damage to the kidneys
- medicines which can affect your nervous system. Taking such medicines at the same time as Colistimethate can increase the risk of side effects in your nervous system
- medicines called muscle relaxants, often used during general anaesthesia. Colistimethate can increase the effects of these medicines. If you have a general anaesthetic, let your anaesthetist know that you are having Colistimethate.

If you suffer from myasthenia gravis and are also taking other antibiotics called macrolides (such as azithromycin, clarithromycin or erythromycin) or antibiotics called fluoroquinolones (such as ofloxacin, norfloxacin

and ciprofloxacin), taking Colistimethate further increases the risk of muscle weakness and breathing difficulties.

Having Colistimethate as an infusion at the same time as receiving colistimethate as an inhalation can increase your 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. Please take this into account if you are on a low sodium (salt) diet and let your doctor or pharmacist know about this.

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 to take Colistimethate

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.

The usual daily dose in children weighing up to 40 kg is 75,000 to 150,000 units per kilogram body weight, divided into three doses. Higher doses have occasionally been given in cystic fibrosis.

Children and adults with kidney problems, including those on dialysis, are usually given lower doses.

Your doctor will monitor your kidney function regularly while you receive Colistimethate

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. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard. By reporting side effects you can help provide more information on the safety of this medicine.

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. Further 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 or two million international units. There are no other ingredients. The sodium content is 0.228 mMol per vial.

Manufactured by:

Taj Pharmaceuticals Limited
220, Mahagujarat Ind. Estate,
Moraiya, Tal. Sanand, Dist.
Ahmedabad, Gujarat, INDIA

Marketing Authorization

Holder:

Regal sun co., Ltd.Myanmar