COLISTIN®

MOST TRUSTED BRAND OF INDIA

Colistimethate Sodium for Injection USP 1/2/3/4/4.5 & 5 Million I.U.

POWDER FOR SOLUTION FOR INJECTION

The name of your medicine is Colistimethate sodium 1 Million I.U. Powder for Solution for Injection.
It is referred to as Colistimethate in this leaflet.

Keep this leaflet. You may need to read it again.
If you have further questions, please ask your doctor, nurse or pharmacist.
If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell the doctor, nurse or pharmacist.

In this leaflet:

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
- 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.

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PATIENT INFORMATION LEAFLET
COLISTIMETHATE SODIUM 1 MILLION I.U.
POWDER FOR SOLUTION FOR INJECTION
1 million international units/vial

Information for the Healthcare Professional

COLISTIMETHATE SODIUM 1 MILLION I.U. POWDER FOR SOLUTION FOR INJECTION

Please read this information carefully before using Colistimethate Sodium. Further information is contained in the Summary of Product Characteristics.

PRESENTATION

Colistimethate Sodium is a white lyophilised powder in a 7ml glass vial. Each vial contains 1 Million I.U. (International Units) of Colistimethate Sodium.

DOSAGE AND METHOD OF ADMINISTRATION

Colistimethate Sodium is administered intravenously as a slow infusion over 30 – 60 minutes.

Dilution/flush solution:
For bolus injection:
Reconstitute the contents of the vial with not more than 7ml water for injection or 0.9% sodium chloride.
For infusion:
The contents of the reconstituted vial may be diluted, usually with 50ml 0.9% sodium chloride. During reconstitution swirl gently to avoid frothing.
Reconstituted Colistimethate Sodium is a clear solution.

Dosage (adjustment required in renal impairment):
Adults and adolescents
Maintenance dose 9MIU/day in 2-3 divided doses
In patients who are critically ill, a loading dose of 9 MIU should be administered.
The most appropriate time interval to the first maintenance dose has not been established.
Loading and maintenance doses of up to 12 MIU may be required in patients with good renal function in some cases.
The loading dose applies to patients with normal and impaired renal functions including those on renal replacement therapy.

Renal impairment
Dose adjustments in renal impairment are necessary.
The following dose adjustments are suggested as guidance.
Dose reductions are recommended for patients with creatinine clearance < 50 ml/min:
Twice daily dosing is recommended.
Paediatric population
The data supporting the dose regimen in paediatric patients are very limited. Renal maturity should be taken into consideration when selecting the dose.
The dose should be based on lean body weight.
Children ≤ 40kg
75,000-150,000 IU/kg/day divided into 3 doses.
For children with a body weight above 40 kg, use

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.

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. Storing 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. There are no other ingredients. The sodium content is 0.228 mMol per vial.
Marketed by:
TAJ PHARMA INDIA LTD.
15-6-108 Afzal Gunj, Hyderabad TS 500 012, India.
Manufactured in India by:
TAJ PHARMACEUTICALS LTD.
at : Dedhrota,Himatnagar-Vijapur Highway,
Dist : Sabarkantha, Gujarat - INDIA.
WHO-cGMP & ISO 9001:2015
Certified Company

If you find this leaflet difficult to read or understand, please speak to the doctor or nurse or contact the marketing authorisation holder at the above address.

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of the dosing recommendation for adults should be considered.
The use of doses >150,000 IU/kg/day has been reported in children with cystic fibrosis.

Incompatibilities with commonly used mixtures:
Do not mix reconstituted solution with other medicinal products.
Special handling information:
Solutions below 80,000 IU/ml should be used immediately. For solutions for bolus injection the chemical and physical in-use stability of reconstituted solution in the original vial, with a concentration ≥ 80,000 IU/ml has been demonstrated for 24 hours at 2 to 8°C.
Solutions for infusion, which have been diluted beyond the original vial volume and/or with a concentration < 80,000 IU/ml should be used immediately.
For single use only. Discard any remaining solution.
The outer surface of the primary container is non-sterile.

Contraindications

Do not use in patients with known hypersensitivity to Colistimethate Sodium or polymyxin B.

Interactions with other Medicinal Products and other Forms of Interaction

Colistimethate Sodium may interact with aminoglycoside and cephalosporin antibiotics, neuromuscular blocking drugs or ether.

Pharmaceutical Information

Excipients: There are no other excipients

Shelf-life: 3 years

Storage Precautions

Do not store above 25°C. Store the vial in the outer carton in order to protect from light.
Do not freeze.
From a microbiological point of view, unless the method of opening/ reconstitution/ dilution precludes the risk of microbial contamination, the product should be used immediately.
If not used immediately, in-use storage times and conditions are the responsibility of user.

Nature of Container
7ml Type I glass vials with rubber stoppers and aluminium crimp seals. Each carton contains 1 or 10 vials.

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