

Package leaflet: Information for the user

COLOMYCIN 1 million or 2 million International Units (IU) Powder for solution for injection, infusion or inhalation

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

What is in this leaflet

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2. What you need to know before you use Colomycin
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1. What Colomycin is and what it is used for

Colomycin contains the active substance colistimethate sodium. Colistimethate sodium is an antibiotic. It belongs to a group of antibiotics that are called polymyxins.

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

Colomycin is given as an inhalation to treat chronic chest infections in patients with cystic fibrosis. Colomycin is used when these infections are caused by specific bacteria called *Pseudomonas aeruginosa*.

2. What you need to know before you use Colomycin

Do not use Colomycin

- If you are allergic (hypersensitive) to colistimethate sodium, colistin or to other polymyxins.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before using Colomycin

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

If you experience muscle spasm, fatigue or increased urine output at any time, tell your doctor immediately as these events may be related to a condition known as pseudo-Bartter syndrome.

Some people may experience a feeling of tightness in the chest due to narrowing of the airways when inhaling Colomycin. Your doctor may prescribe other medicines for inhalation directly before or after using Colomycin; in order to prevent or treat this.

Children

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

Other medicines and Colomycin

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

If you are taking any of the following medicines, you may or may not be able to take Colomycin. Sometimes the other medicines must be stopped (if only for a while) or you may need a lower dose of Colomycin or you may need to be monitored while you are taking Colomycin. In some cases, the level of Colomycin in your blood may have to be measured from time to time to make sure that you are having the right dose.

- medicines like antibiotics called aminoglycosides (which include gentamicin, tobramycin, amikacin and netilmicin) and cephalosporins which can affect how your kidneys function. Taking such medicines at the same time as Colomycin can increase the risk of damage to the kidneys (see section 4 of this leaflet).
- medicines like antibiotics called aminoglycosides (which include gentamicin, tobramycin, amikacin and netilmicin) which can affect your nervous system. Taking such medicines at the same time as Colomycin can increase the risk of side effects in the ears and other parts of your nervous system (see section 4 of this leaflet).
- medicines called muscle relaxants, often used during general anaesthesia. Colomycin can increase the effects of these medicines. If you have a general anaesthetic, let your anaesthetist know that you are having Colomycin.

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 Colomycin further increases the risk of muscle weakness and breathing difficulties.

Having Colomycin as an infusion at the same time as receiving Colomycin as an inhalation can increase your risk of side effects.

Pregnancy and breast-feeding

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

Colomycin 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.

Are you breast-feeding? Small amounts of Colomycin enter the milk. If you cannot stop breast-feeding while you take Colomycin, you should watch your baby carefully for any signs of illness and tell your doctor if you notice anything wrong.

Driving and using machines

When Colomycin is given into a vein there may be side effects such as dizziness, confusion or problems with vision. If these occur, you should not drive or operate machinery.

Colomycin contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per vial, that is to say essentially 'sodium-free'.

3. How to use Colomycin

Depending on the reason (see section 1 of this leaflet), Colomycin may be given by fast injection (over 5 minutes into a special kind of tube in a vein) or slow injection (infusion over about 30 to 60 minutes) into a vein. Colomycin may occasionally be given by injection into the brain or the spine. Colomycin can also be breathed into the lungs as a fine spray made using a machine called a nebuliser. The droplets of the spray produced by the nebuliser are small enough to enter the lungs so that Colomycin can reach the site of the bacterial infection.

Always use Colomycin exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

For use by infusion or injection:

Colomycin 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 Colomycin.

Method of administration

Colomycin is given by injection mainly in hospitals. If you are to treat yourself at home, your doctor, pharmacist or nurse will show you how to dissolve the powder and inject the right dose of solution.

Duration of treatment

Your doctor will decide how long your treatment should last depending of the severity of the infection. When treating bacterial infections it is important to complete the full course of treatment so as to prevent worsening of the existing infection.

For use in a nebuliser:

The usual dose for adults, adolescents and children aged 2 years or older is 1-2 million units two to three times per day (maximum 6 million units per day).

The usual dose for children less than 2 years old is 0.5-1 million units twice daily (maximum 2 million units per day).

Your doctor may decide to adjust the dose depending on your circumstances. If you also take other inhaled medicines, your doctor will tell you which order to taken them in.

Method of administration

If you are treating yourself at home, your doctor, pharmacist or nurse will show you how to use Colomycin in your nebuliser when you first start the treatment. You should sit upright and breathe normally during inhalation. The following are general instructions.

Preparation for inhalation treatment

Before Colomycin can be used it must be dissolved in **isotonic saline solution** (salt water).

To start your treatment, you will need the following:

- **One clear-glass vial of Colomycin 1 Million IU**
- **The solvent for dissolving the powder (3 ml of isotonic saline solution)**
- **A nebuliser appropriate for inhalation use of Colomycin 1 Million IU (e.g. PARI LC PLUS, PARI LC SPRINT, or eFlow rapid)**

To start your treatment, you will need the following:

- **One clear-glass vial of Colomycin 2 Million IU**
- **The solvent for dissolving the powder (4 ml of isotonic saline solution)**
- **A nebuliser appropriate for inhalation use of Colomycin 2 Million IU (e.g. PARI LC PLUS, PARI LC SPRINT, or eFlow rapid)**

It is important that your nebuliser system functions properly before starting your treatment with Colomycin. **Read carefully the instructions for use of the nebuliser for further information on handling the nebuliser system.**

Place the components of your nebuliser on a clean flat surface and follow the manufacturer's instructions for use.

Preparing your Colomycin for inhalation

Colomycin must be used immediately after dissolution. Do not dissolve Colomycin until ready to administer a dose (see also section 5).

Step 1: Take one vial of Colomycin and gently tap the glass vial so that the powder settles to the bottom. This helps ensure you get the proper dose of medication. Open the drug vial by lifting up the plastic overcap on the top (Figure 1).

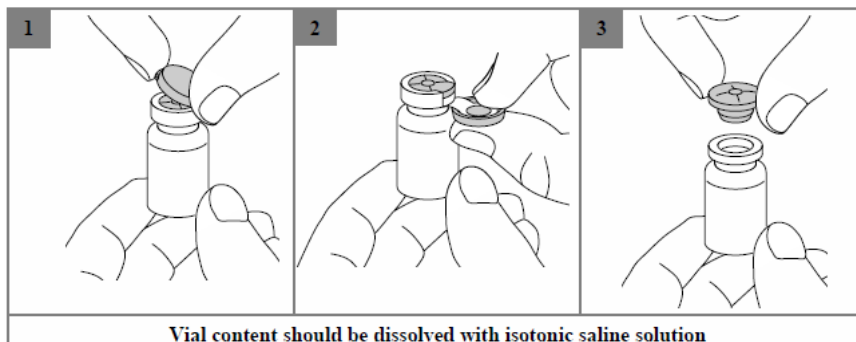
Step 2: Pull down to carefully remove the entire plastic overcap together with metal ring from the vial (Figure 2). Safely dispose of the ring and overcap.

Step 3: Carefully remove the rubber stopper (Figure 3).

Colomycin 1 Million IU: Add the solvent (**3 ml of isotonic saline solution**) to the corresponding vial to dissolve the powder:

Colomycin 2 Million IU: Add the solvent (**4 ml of isotonic saline solution**) to the corresponding vial to dissolve the powder:

In order to avoid foaming, shake the vial gently until all powder is dissolved. Pour the solution into the nebuliser. Do not use Colomycin if you notice visible particles in the solution after dissolution. Once prepared Colomycin should be used immediately. Any unused solution should be disposed of.



Using your Colomycin

Colomycin is for inhalation use with an appropriate nebuliser (*e.g.* PARI LC PLUS, PARI LC SPRINT or eFlow rapid).

For more detailed information on correct use of the selected nebuliser follow the instruction manual of the nebuliser.

Inhalation should take place in a well ventilated room.

After inhalation of Colomycin

Please refer to the manufacturer's instructions for use of the nebuliser for cleaning and disinfecting instructions.

IMPORTANT: Do not mix Colomycin with any other product for nebulisation at the same time.

Duration of treatment

For nebulised use your doctor will advise on the course of the treatment.

If you use more Colomycin than you should

If you think that you have given yourself too much Colomycin, you should contact your doctor or nurse immediately for advice or, if they are not available, contact or go to your nearest hospital accident and emergency department. If too much Colomycin is accidentally given, the side effects can be serious and can include kidney problems, muscle weakness and difficulty (or even stopping) breathing.

If you are being treated in hospital or at home by a doctor or nurse and think that you may have missed a dose or been given too much Colomycin, please ask your doctor, nurse or pharmacist about this.

If you forget to use Colomycin

If you are treating yourself and have missed any doses, you should give the missed dose as soon as you remember and then give the next dose 8 hours later if using Colomycin three times a day, or 12 hours later if using Colomycin twice a day. Carry on from there as instructed. Do not take a double dose to make up for a forgotten dose.

If you stop using Colomycin

Do not stop your treatment early unless your doctor says you can. Your doctor will decide how long your treatment should last.

If you have any further questions on the use of this medicine, ask your doctor.

4. Possible side effects

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

Allergic reactions

Whether Colomycin is given into a vein or by inhalation, an allergic reaction is possible. Serious allergic reactions can happen even with the very first dose and can include rapid development of rashes, swelling of the face, tongue and neck, inability to breathe due to narrowing of the airways and loss of consciousness.

If you experience signs of an allergic reaction you should seek urgent medical attention.

Less severe allergic reactions include skin rashes that appear later during treatment.

Side effects associated with injecting Colomycin into a vein

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

The most serious of these possible side effects in the nervous system is inability to breathe because of paralysis of the chest muscles. **If you experience any difficulty breathing you should seek urgent medical attention.**

Other possible side effects include 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). There can be reactions at the site of the injection, such as irritation.

Kidney problems may also occur. These are especially likely in people who already have poor kidneys, or who are given Colomycin at the same time as other medicines that can cause side effects in 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 Colomycin is reduced.

You may experience, after intravenous administration, the following symptoms that may be related to a condition known as pseudo-Bartter syndrome (see section 2):

- muscle spasm
- increase in urine output
- fatigue

Side effects associated with inhaling Colomycin (nebulisation)

The risk of side effects is usually much less when it is given by inhalation because very little Colomycin usually reaches the bloodstream when it is given this way.

Possible side effects include coughing, a feeling of tightness in the chest due to narrowing of the airways, sore mouth or throat and thrush (Candida) infections of the mouth or throat.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRAs Pharmacovigilance, Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Colomycin

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

Do not use this medicine after the expiry date which is stated on the vial label and the carton after EXP. The expiry date refers to the last day of that month.

Do not store above 25°C.

Keep the vials in the outer carton in order to protect from light.

Colomycin solutions for injection and for inhalation should be used immediately after preparation.

If this is not possible, talk first to your doctor or pharmacist as the solutions may be stored in a refrigerator for no longer than 24 hours. Any remaining solution should be discarded.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Colomycin contains

The active substance is colistimethate sodium.

Each vial contains either 1 million or 2 million IU colistimethate sodium.

There are no other ingredients.

What Colomycin looks like and contents of the pack

Colomycin, a powder for solution for injection, infusion or inhalation, is supplied as a sterile white powder in single dose vials of either:

- 1 million units of colistimethate sodium per vial: red cap (1.0 MIU)
- 2 million units of colistimethate sodium per vial: lilac cap (2.0 MIU)

Each carton contains 10, 56 or 60 vials.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

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