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 these nebulisers 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 has told you. Check with your doctor 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 use to treat yourself at home, your doctor 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 on 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 take them in.

Method of administration

If you are treating yourself at home, your doctor or nurse will show you how to use Colomycin in your nebuliser when you first start the treatment. The following are general instructions.
The plastic cap is flipped open and the foil seal carefully ripped from around the top of the vial to remove it completely. The rubber bung is aiken out carefully and sterile water or sterile salt water (saline) is added to each vial to dissolve the powder as follows:

1 milliliter unit vial: 2ml sterile water / saline
2 milliliter unit vial: 4ml sterile water / saline

The solution is then poured into the nebuliser.

**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 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 where you have last taken it.

Do not take a double dose to make up for the 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 effect 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 i. 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.

If you get any side effects, talk to your doctor. This includes any possible side effects not listed in his leaflet.

**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 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 Website: 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 COLOMYCIN

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

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

Do not store the vials above 25°C.

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

Colomycin solutions for inhalation and for injection 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**
Each vial contains the active substance cefotiam hydrochloride (also called cefotiam) as an amount of powder equivalent to one million or two million units. There are no other ingredients. This medicinal product contains less than 1 millimoles of sodium (23 milligrams per vial, i.e. essentially sodium free).

**What Colomycin looks like and contents of the pack**
Colomycin, a powder for solution for injection, infusion or inhalation, is supplied as a creamy white powder in single dose vials of either:

- 1 million units of cefotiam hydrochloride per vial; red cap (1.0 MU)
- 2 million units of cefotiam hydrochloride per vial; lilac cap (2.0 MU)

Each box contains ten vials.

**Marketing Authorisation Holder**
TEVA UK Limited, Eastbourne, BN22 9AG, UK

**Manufacturer and site of batch release**
Penn Pharmaceutical Services, Tregaron, Gwent, NP22 3AA, UK.

This leaflet was last revised in February 2018.