

## Package leaflet: Information for the user

**Colistin/Norma<sup>®</sup> 1.000.000 International Units, Powder for solution for injection**  
**Colistin/Norma<sup>®</sup> 1.000.000 International Units, Powder for solution for infusion**  
**Colistin/Norma<sup>®</sup> 1.000.000 International Units, Powder for solution for inhalation with nebuliser**  
**Colistin/Norma<sup>®</sup> 2.000.000 International Units, Powder for solution for injection or infusion**

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

### What is in this leaflet

1. What **Colistin/Norma<sup>®</sup>** is and what it is used for
2. What you need to know before you use **Colistin/Norma<sup>®</sup>**
3. How to use **Colistin/Norma<sup>®</sup>**
4. Possible side effects
5. How to store **Colistin/Norma<sup>®</sup>**
6. Contents of the pack and other information

#### 1. What **Colistin/Norma<sup>®</sup>** is and what it is used for

**Colistin/Norma<sup>®</sup>** contains the active substance colistimethate sodium. Colistimethate sodium is an antibiotic. It belongs to a group of antibiotics that are called polymyxins.

**Colistin/Norma<sup>®</sup>** is given by injection to treat some types of serious infections caused by certain bacteria. **Colistin/Norma<sup>®</sup>** is used when other antibiotics are not suitable.

**Colistin/Norma<sup>®</sup>** is given as an inhalation to treat chronic chest infections in patients with cystic fibrosis. **Colistin/Norma<sup>®</sup>** is used when these infections are caused by specific bacteria called *Pseudomonas aeruginosa*.

#### 2. What you need to know before you use **Colistin/Norma<sup>®</sup>**

##### **Do not use **Colistin/Norma<sup>®</sup>**:**

- 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 **Colistin/Norma<sup>®</sup>**:

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

Some people may experience a feeling of tightness in the chest due to narrowing of the airways when inhaling **Colistin/Norma<sup>®</sup>**. Your doctor may prescribe other medicines for inhalation directly before or after using **Colistin/Norma<sup>®</sup>**; in order to prevent or treat this.

In premature and new-born babies, special care should be taken when using **Colistin/Norma**<sup>®</sup> as the kidneys are not yet fully developed.

#### **Other medicines and Colistin/Norma**<sup>®</sup>

Tell your doctor if you are taking, have recently taken or might take any other medicines including medicines you are taking without a prescription.

If you are taking any of the following medicines, you may or may not be able to take **Colistin/Norma**<sup>®</sup>. Sometimes the other medicines must be stopped (if only for a while) or you may need a lower dose of **Colistin/Norma**<sup>®</sup> or you may need to be monitored while you are taking **Colistin/Norma**<sup>®</sup>. In some cases, the level of medicine 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 **Colistin/Norma**<sup>®</sup> 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 **Colistin/Norma**<sup>®</sup> 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. **Colistin/Norma** can increase the effects of these medicines. If you have a general anaesthetic, let your anaesthetist know that you are having **Colistin/Norma**<sup>®</sup>.

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 **Colistin/Norma**<sup>®</sup> further increases the risk of muscle weakness and breathing difficulties.

Having **Colistin/Norma**<sup>®</sup> as an infusion at the same time as receiving **Colistin/Norma**<sup>®</sup> as an inhalation can increase your risk of side effects.

#### **Pregnancy and breast-feeding**

**Colistin/Norma**<sup>®</sup> 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. If you are pregnant, think you may be pregnant or are planning to have a baby ask your doctor for advice before taking this medicine.

Are you breast-feeding? Small amounts of **Colistin/Norma**<sup>®</sup> enter the milk. If you cannot stop breast-feeding while you take **Colistin/Norma**<sup>®</sup>, 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 **Colistin/Norma**<sup>®</sup> 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.

### **3. How to use Colistin/Norma**<sup>®</sup>

Depending on the reason (see section 1 of this leaflet), **Colistin/Norma**<sup>®</sup> 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. **Colistin/Norma**<sup>®</sup> may occasionally be given by intrathecal or intraventricular administration in the Central Nervous System (CNS). **Colistin/Norma**<sup>®</sup> 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 **Colistin/Norma**<sup>®</sup> can reach the site of the bacterial infection.

#### *Posology*

Always use **Colistin/Norma**<sup>®</sup> exactly as your doctor has told you. Check with your doctor if you are not sure.

For use by infusion or injection:

**Colistin/Norma**<sup>®</sup> 1.000.000 I.U./vial, powder for solution for injection is administered by injection.

**Colistin/Norma**<sup>®</sup> 1.000.000 I.U./vial, powder for solution for infusion and **Colistin/Norma**<sup>®</sup> 2.000.000 I.U./vial, powder for solution for injection or infusion 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 **Colistin/Norma**<sup>®</sup>.

*Method of administration*

**Colistin/Norma**<sup>®</sup> is given by injection mainly in hospitals. If you are 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 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 or nurse will show you how to use **Colistin/Norma**<sup>®</sup> in your nebuliser when you first start the treatment. The following are general instructions.

Flip open the plastic cap and carefully rip the foil seal from around the top of the vial to remove it completely. Take out carefully the rubber bung and add to the vial either water for injection or a 50:50 mixture of water for injection and 0.9% sodium chloride solution or 0.9% sodium chloride. The volume of reconstitution should be according to the instructions for use of nebuliser administration device, and is normally not more than 4ml. Add the diluent slowly to be rolled on the wall of the vial and roll the vial gently between both hands to dissolve all the content of the vial, do not shake the vial too hard.

Pour the solution into the nebuliser.

The solution is for single use only and any remaining solution should be discarded.

**IMPORTANT:** Do not mix **Colistin/Norma**<sup>®</sup> with any other product for nebulisation at the same time.

*Duration of treatment*

Your doctor will advise on the course of the treatment.

**If you take more Colistin/Norma<sup>®</sup> than you should**

If you think that you have taken too much **Colistin/Norma<sup>®</sup>**, 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 **Colistin/Norma<sup>®</sup>** 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 **Colistin/Norma<sup>®</sup>**, please ask your doctor, nurse or pharmacist about this.

**If you forget to take Colistin/Norma<sup>®</sup>**

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 **Colistin/Norma<sup>®</sup>** three times a day, or 12 hours later if using **Colistin/Norma<sup>®</sup>** 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 taking Colistin/Norma<sup>®</sup>**

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

When **Colistin/Norma<sup>®</sup>** is given intravenously or intramuscularly 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 infusion of Colistin/Norma<sup>®</sup>

Side effects that affect the nervous system are more likely to occur when the dose of **Colistin/Norma<sup>®</sup>** 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 **Colistin/Norma<sup>®</sup>** 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 **Colistin/Norma<sup>®</sup>** is reduced.

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

### Side effects associated with inhaling Colistin/Norma<sup>®</sup> (with nebuliser)

The risk of side effects is usually much less when it is given by inhalation because very little Colistin/Norma<sup>®</sup> 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 Candida (thrush) 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 National Organization for Medicines (284 Mesogeion Av., GR-15562 Cholargos, Athens, Greece, Tel.: + 30 21 32040380/337, Fax: + 30 21 06549585, website <http://www.eof.gr>). By reporting side effects you can help provide more information on the safety of this medicine.

## **5. How to store Colistin/Norma<sup>®</sup>**

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

Do not use Colistin/Norma<sup>®</sup> after the expiry date which is stated on the carton and vial label after EXP. The expiry date refers to the last date of that month.

Do not store above 25°C. Keep the vials in the outer carton.

After reconstitution the solutions for injection and inhalation should be used immediately after preparation.

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 Colistin/Norma<sup>®</sup> contains**

The active substance is colistimethate sodium. Each vial contains the active substance colistimethate sodium as an amount of powder equivalent to 1.000.000 or 2.000.000 International Units. There are no other ingredients. This medicinal product contains less than 1mmol sodium (23mg) per vial.

### **What Colistin/Norma<sup>®</sup> looks like and contents of the pack**

#### **Colistin/Norma<sup>®</sup> 1.000.000 I.U./vial, powder for solution for injection**

Carton box that contains a glass vial of 10ml sealed with a rubber stopper and protected by an aluminum cap and a package leaflet.

#### **Colistin/Norma<sup>®</sup> 1.000.000 I.U./vial, powder for solution for infusion**

Carton box that contains one or ten or thirty glass vials of 10ml sealed with flip-off cap and a package leaflet.

#### **Colistin/Norma<sup>®</sup> 1.000.000 I.U./vial, powder for solution for inhalation with nebuliser**

Carton box that contains one or thirty or sixty or ninety glass vials of 10ml sealed with flip-off cap and a package leaflet.

#### **Colistin/Norma<sup>®</sup> 2.000.000 I.U./vial, powder for solution for injection or infusion**

Carton box that contains one or ten or thirty glass vials of 10ml sealed with flip-off cap and a package leaflet.

Not all pack sizes may be marketed.

### **Marketing Authorisation Holder and Manufacturer**

*Marketing Authorisation Holder*

**NORMA HELLAS S.A.**, 54 Menandrou Str., 10431 Athens, Greece, tel: +30 210 52 22 282, fax: +30 210 52 41 368, email: info@normahellas.gr.

*Manufacturer:*

**Colistin/Norma® 1.000.000 I.U./vial, powder for solution for infusion and Colistin/Norma® 2.000.000 I.U./vial, powder for solution for injection or infusion**

Famar S.A. (plant Alimos). 63 Ag. Dimitriou Str., Alimos 17456, Attiki, Greece.

**Colistin/Norma® 1.000.000 I.U./vial, powder for solution for inhalation with nebuliser**

Famar S.A. (plant Alimos). 63 Ag. Dimitriou Str., Alimos 17456, Attiki, Greece.

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