

PACKAGE LEAFLET: INFORMATION FOR THE USER

Promixin **1 million International Units (IU)** **Powder for Nebuliser Solution** colistimethate sodium

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 further questions, please ask your doctor, nurse, physiotherapist 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, nurse, physiotherapist or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Promixin is and what it is used for
2. What you need to know before you take Promixin
3. How to take Promixin
4. Possible side effects
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1. WHAT PROMIXIN IS AND WHAT IT IS USED FOR

Promixin contains the active substance colistimethate sodium, and is given as an inhalation to treat chronic chest infections in patients with cystic fibrosis. Promixin is used when these infections are caused by specific bacteria called *Pseudomonas aeruginosa*.

This is a very common bacteria that infects the lungs of nearly all patients with cystic fibrosis at some time during their lives. If the infection is not properly controlled it will continue to damage the lungs, causing further problems.

In order to administer Promixin the powder contained in its vial should be dissolved with appropriate diluent solution, in sterile saline (salt water) or sterile water and then breathed (inhaled) into the lungs using a suitable nebuliser device so that more of the antibiotic can target the bacteria causing the infection.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE PROMIXIN

In certain circumstances your doctor may decide not to prescribe Promixin.

Do not use Promixin if:

- you are **allergic** (hypersensitive) to colistimethate sodium, colistin or other polymyxins;
- If this applies to you, see your doctor before you start taking Promixin.**

Warnings and precautions with Promixin:

- you have or have had **kidney problems**;

- you suffer from **myasthenia gravis** (a rare disease where your muscles are extremely weak and get tired very quickly);
- you suffer from **porphyria** (a rare metabolic disease that some people are born with);
- you suffer from **asthma**.

If any of these apply to you, tell your doctor.

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

Other medicines and Promixin

Tell your doctor or pharmacist if you are taking or have recently taken or might take any other medicines. **These medicines may interfere with the effect of Promixin.**

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

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

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

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before using this medicine. There is no information about the safety of Promixin in pregnant women. Your doctor should advise you before using Promixin where benefits of the medicine exceed the risk.

Colistimethate sodium may be secreted in the breast milk. Please discuss the use of Promixin with your doctor.

Driving and using machines

Promixin may make you feel dizzy, confused or have problems with your sight, such as blurred vision. If this happens to you, do not drive or use any tools or machines.

3. HOW TO TAKE PROMIXIN

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Tell your doctor if you have **problems with your kidneys** as you may need to take a lower dose of Promixin.

You should take your **first dose** of Promixin when you are with your doctor or nurse.

Take your Promixin **after physiotherapy** (if you have physiotherapy). This will ensure that your lungs are clear so that Promixin can work effectively. If you also take other inhaled medicines, your doctor will tell you which order to take them in.

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

The recommended dose for children less than 2 years old is half to 1 vial (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.

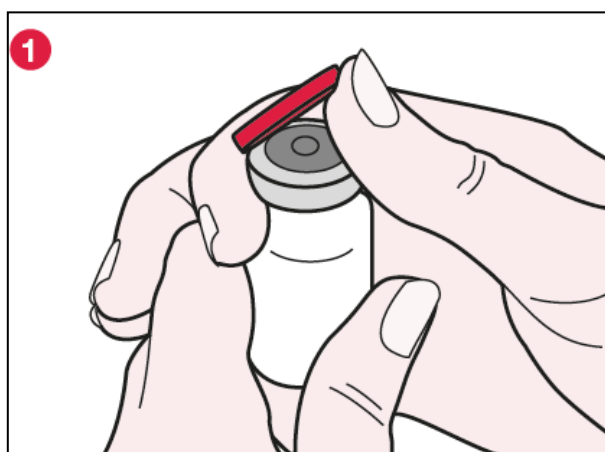
Promixin is inhaled from a device called a nebuliser. Promixin can be taken using any nebuliser system that can be used to deliver antibiotics to the lungs in the form of a mist. In countries where the I-neb AAD is available Promixin comes with a Promixin Disc so that it can be used with the I-neb AAD System. To find out how to use Promixin with the I-neb, see the detailed instructions which come with the device. If you use a different nebuliser you should make sure the room is well ventilated.

How to prepare Promixin

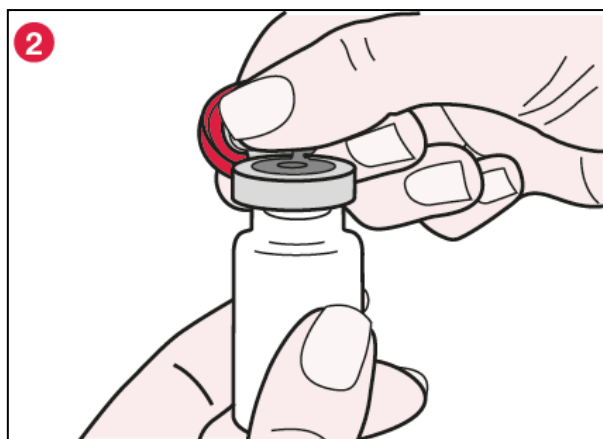
Your doctor or nurse will show you how to prepare and use Promixin with your nebuliser.

Before Promixin can be placed into the nebuliser and inhaled it must first be dissolved with **sterile water, sterile 0.9% saline** (salt water) or a **half and half mixture of sterile water and sterile 0.9% saline** (salt water) as directed below. **Your doctor or nurse will tell you the correct volume of liquid to add to each Promixin vial and how many Promixin vials you need to prepare and use for each dose with your nebuliser.**

- 1) Locate the lip on the red plastic top near the arrow marked “FLIP UP”. Then holding the vial in one hand and the plastic top with the other hand, **turn the top a small amount anti-clockwise**. Place a thumb under the lip and push the top up to about 90° (see diagram 1).



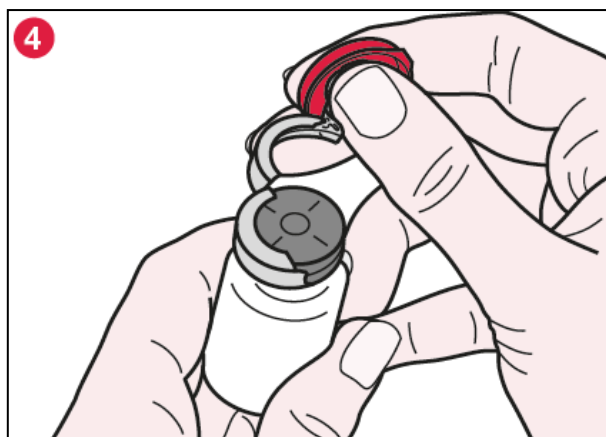
- 2) Grasp the plastic top as shown in diagram 2 and pull open slowly, like a hinge, to almost 180°.



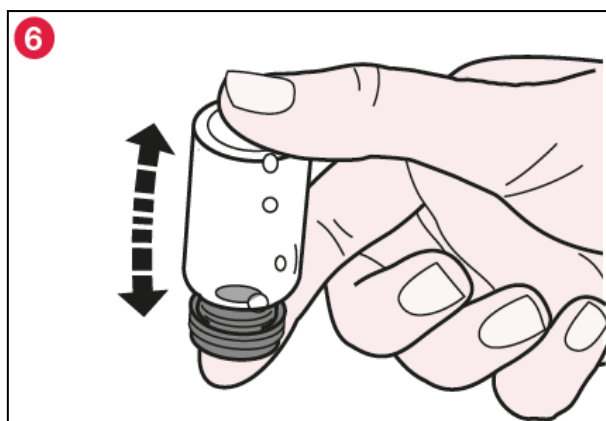
- 3) Turn the vial around so that the plastic top is pointing towards you. Holding the centre of the top as shown, **pull it downwards and twist slightly to either the right (diagram 3a) or the left so that the metal seal is broken on one side only (diagram 3b).**



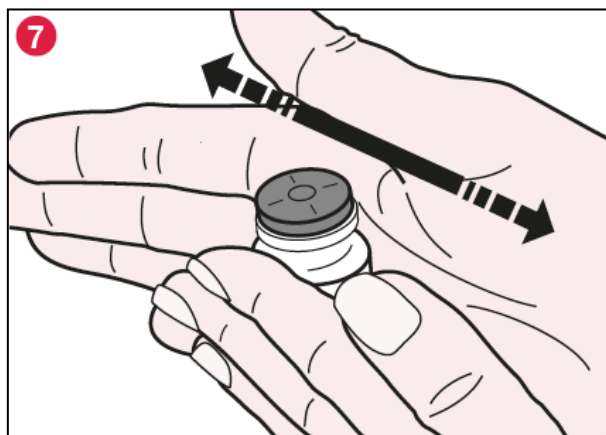
- 4) Once the seal is broken, hold the vial firmly and peel off the metal seal to reveal the whole of the rubber stopper (diagram 4).



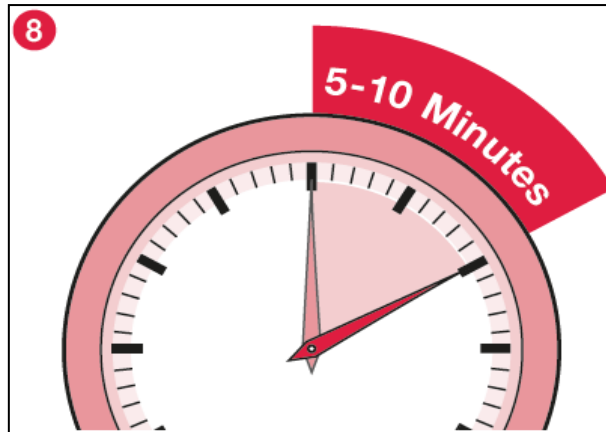
- 5) Remove the rubber stopper from the vial of Promixin by holding the outside edge of the stopper only and place it upside-down on a clean surface. Slowly add sterile water, sterile 0.9% saline, or sterile water and sterile 0.9% saline to the vial, **adding the volume of liquid your doctor or nurse has told you.**
- 6) Replace the rubber stopper and gently turn the vial upside down twice (diagram 6).



- 7) Roll the vial gently between both hands to dissolve all the Promixin powder visible on the base and side of the vial (diagram 7). **Do not shake** the vial too hard as this may make the solution foam.



- 8) Once most of the powder is dissolved leave the vial to stand for 5-10 minutes to let any foam disappear and to allow any remaining powder to dissolve.



Pour the solution into the nebuliser and inhale immediately. If it is not possible to use the solution immediately replace the stopper in the vial and store for no longer than 24 hours in a refrigerator. **Do not use any solutions that have been prepared for more than 24 hours.** See section 5 ‘How to store Promixin’ for instructions on how to store or dispose of any unused Promixin.

If you take more Promixin than you should

If you realise that you have taken more Promixin than your doctor has recommended (or if someone else has taken some of your Promixin), contact your doctor straight away.

The symptoms of taking too much Promixin can include:

- tingling or numbness around the lips and face
- dizziness and spinning sensation (vertigo)
- slurred speech
- visual disturbance
- confusion
- mental disturbance
- flushing (reddening of the face)

If you forget to take Promixin

Take the dose as soon as you remember, unless it is near the time for your next dose. Do not take a double dose to make up for a forgotten dose.

If you stop taking Promixin

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

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

4. POSSIBLE SIDE EFFECTS

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

Promixin can sometimes cause **allergic reactions** like **skin rash**. If this happens you should **stop taking Promixin** and tell your doctor immediately.

Breathing in Promixin through a nebuliser can make some people notice **tightness in their chest, feel wheezy, cough** or become **breathless** (sometimes described as choking sensation). For this reason the first dose should be taken when you are with your doctor or

nurse. Your doctor may also advise you to take a medicine to help prevent any breathlessness. Your doctor may check your breathing at your clinic visits.

Promixin might also affect your **kidneys**, usually if the dose is high or you are taking other medicines that may affect your kidneys.

Promixin may sometimes cause you to have a **sore mouth** or **sore 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 (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

United Kingdom

Yellow Card Scheme

Website: www.mhra.gov.uk/yellowcard

Ireland

HPRA Pharmacovigilance

Earlsfort Terrace

IRL - Dublin 2

Tel: +353 1 6764971

Fax: +353 1 6762517

Website: www.hpra.ie

E-mail: medsafety@hpra.ie

5. HOW TO STORE PROMIXIN

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 and carton. The expiry date refers to the last day of that month.

Unopened Promixin vials do not require any special storage conditions.

Promixin contains no preservatives. Once prepared, Promixin solutions should preferably be used immediately. If this is not possible, solutions should be stored for no longer than 24 hours in a refrigerator. **Do not use any solutions that have been prepared for more than 24 hours.**

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 to protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Promixin contains

The **active substance** is colistimethate sodium.

Each vial contains 1 million International Units (IU) of colistimethate sodium, which weighs about 80 milligrams (mg). There are no other ingredients.

What Promixin looks like and contents of the pack

Promixin is a powder for nebuliser solution, supplied as a white to off-white powder in a glass vial.

Promixin is supplied in packs containing 30 vials. In countries where the I-neb AAD is available, each pack also contains a Promixin Disc for use with the I-neb AAD system.

Marketing Authorisation Holder

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Email: info.zambonspa@zambongroup.com

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Xellia Pharmaceuticals ApS
Dalslandsgade 11
DK- 2300, Copenhagen S
Denmark

Distributor

Zambon UK Limited
UK
Tel: +44 (0) 800 0288 942

Other formats:

To listen to or request a copy of this leaflet in Braille, large print or audio please call, free of charge:

0800 198 5000 (UK Only)

Please be ready to give the following information:

Product name: Promixin 1 million international unit powder for nebuliser solution.
Reference number: 31654/0008

This is a service provided by the Royal National Institute of Blind People.

PA 1441/003/001 (Ireland)

This medicine is authorised in the Member States of the European Economic Area and in the United Kingdom (Northern Ireland) under the following names:

Austria, Netherlands, Sweden, France: Tadim
Germany, Denmark, Norway, United Kingdom (Northern Ireland), Italy, Spain, Portugal:
Promixin

This leaflet was last revised in June 2022