Colistimethate sodium Accord 1 million IU powder for solution for injection/infusion
Colistimethate sodium Accord 2 million IU powder for solution for injection/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, 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:

1. What is Colistimethate sodium Accord and what it is used for

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

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

2. What you need to know before you use Colistimethate sodium Accord

Do not use Colistimethate sodium Accord
- 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 Colistimethate sodium Accord
- if you have or have had kidney problems.
- if you suffer from myasthenia gravis
- if you suffer from porphyria
- 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.

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

Other medicine and Colistimethate sodium Accord
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 Colistimethate sodium Accord. Sometimes the other medicines must be stopped (if only for a while) or you may need a lower dose of Colistimethate sodium Accord or you may need to be monitored while you are taking

Colistimethate sodium Accord. In some cases, the level of Colistimethate sodium Accord 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 Colistimethate sodium Accord 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 Colistimethate sodium Accord 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. Colistimethate sodium Accord can increase the effects of these medicines. If you have a general anaesthetic, let your anaesthetist know that you are having Colistimethate sodium Accord.

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 sodium Accord further increases the risk of muscle weakness and breathing difficulties.

Pregnancy and breast-feeding
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 taking this medicine.

Pregnancy
There are no adequate data from the use in pregnant women. Your doctor will give you this medicine if the possible benefit outweighs the possible risk to the fetus.

Breast-feeding
Small amounts of Colistimethate sodium Accord enter the milk. Breast feeding is not recommended during therapy.

Driving and using machines
When Colistimethate sodium Accord 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.

Colistimethate sodium Accord 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** Colistimethate sodium Accord

Depending on the reason (see section 1 of this leaflet), Colistimethate sodium Accord 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. Colistimethate sodium Accord may occasionally be given by injection into the brain or the spine.

Always use Colistimethate sodium Accord 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:

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.

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 sodium Accord.

Method of administration
Colistimethate sodium Accord is given by injection mainly in hospitals. Colistimethate sodium Accord is given to you by your doctor as an infusion into a vein over 30 – 60 minutes. 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.

If you use more Colistimethate sodium Accord than you should
If you think that you have given yourself too much Colistimethate sodium Accord, 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 Colistimethate sodium Accord 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 Colistimethate sodium Accord, please ask your doctor, nurse or pharmacist about this.

If you forget to use Colistimethate sodium Accord
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 Colistimethate sodium Accord three times a day, or 12 hours later if using Colistimethate sodium Accord 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 Colistimethate sodium Accord
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 or pharmacist.

4. Possible side effects

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

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

<u>Allergic reactions</u>

Whether Colistimethate sodium Accord is given into a vein, 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 Colistimethate sodium Accord into a vein
Side effects that affect the nervous system are more likely to occur when the dose of Colistimethate sodium Accord 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 Colistimethate sodium Accord 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 Colistimethate sodium Accord is reduced.

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
HPRA 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 Colistimethate sodium Accord

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

This medicine does not require any special storage conditions.

Diluted solutions of this medicine should be used immediately, or within 24 hours when stored in the refrigerator (2 to 8°C), depending on the concentration and how the medicine is used.

If not used immediately, in-use storage times and conditions are the responsibility of user.

The appearance of the solution should be a clear colourless to pale yellow solution free from visible particulate matter.

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 Colistimethate sodium Accord 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 Colistimethate sodium Accord looks like and contents of the pack

Colistimethate sodium Accord 1 million international units is a white lyophilised powder available in 10 ml clear glass vial
Colistimethate sodium Accord 2 million international units is a white lyophilised powder available in 10 ml clear glass vial

Pack sizes
1 x 1 vial
1 x 10 vials

Not all pack sizes may be marketed

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:
Accord Healthcare Ireland Ltd
Euro House
Euro Business Park
Little Island
Cork T45 K857
Ireland

Manufacturer:
Accord Healthcare Polska Sp.z o.o.
ul. Lutomierska 50,
95-200 Pabianice, Poland

Or
Laboratori Fundació Dau
C/ C, 12-14 Pol. Ind.
Zona Franca, Barcelona, 08040,
Spain

Accord Healthcare Single Member S.A.
64th Km National Road Athens,
Lamia, Schimatari, 32009, Greece

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder

This medicine is authorised in the member states of the European Economic Area (EEA) under the following names:

Name of the Member State	Name of the medicine
The Netherlands	Colistimethaatnatrium Accord 1 miljoen IE, poeder voor oplossing voor injectie / infusie Colistimethaatnatrium Accord 2 miljoen IE, poeder voor oplossing voor injectie / infusie
Austria	Colistimethat-Natrium Accord 1 Mio. I.E. Pulver zur Herstellung einer Injektions-/Infusionslösung Colistimethat-Natrium Accord 2 Mio. I.E. Pulver zur Herstellung einer Injektions-/Infusionslösung
Belgium	NL : Colistimethaat Accord 1 miljoen Internationale Eenheden (IE) poeder voor oplossing voor injectie/infusie FR : Colistimethaat Accord 1 million (UI) poudre pour solution injectable/pour perfusion DE : Colistimethaat Accord 1 Million (IE) Pulver zur Herstellung einer Injektions-/Infusionslösung
Denmark	Kolistimetatnatrium Accord 1 million IE, pulver til opløsning til injektion/infusion
Estonia	Colistimethate sodium Accord
Germany	Colistimethat-Natrium Accord 1 Million I.E. Pulver zur Herstellung einer Injektions-/Infusionslösung Colistimethat-Natrium Accord 2 Millionen I.E. Pulver zur Herstellung einer Injektions-/Infusionslösung
Lithuania	Colistimethate sodium Accord 1 000 000 TV milteliai injekciniam ar infuziniam tirpalui
Sweden	Kolistimetatnatrium Accord 1 miljon IE pulver till injektions-/infusionsvätska, lösning
Bulgaria	Colistimethate sodium Accord 1 million IU powder for solution for injection/infusion
Czechia	Colistimethate Accord
Croatia	Kolistimetatnatrij Accord 1 milijun IU prašak za otopinu za injekciju/infuziju Kolistimetatnatrij Accord 2 milijuna IU prašak za otopinu za injekciju/infuziju.
Hungary	Colistimethate sodium Accord 1 000 000 NE por oldatos injekcióhoz/infúzióhoz
Romania	Colistimetat de sodiu Accord 1000000 UI pulbere pentru soluţie injectabilă/ perfuzabilă
Slovenia	Natrijev kolistimetat Accord 1 milijon IE prašek za raztopino za injiciranje / infundiranje
France	COLISTIMETHATE SODIQUE ACCORD 1 000 000 UI, poudre pour solution injectable/pour perfusion COLISTIMETHATE SODIQUE ACCORD 2 000 000 UI, poudre pour solution injectable/pour perfusion
Spain	Colistimetato de sodio Accordpharma 1 millón de UI polvo para solución inyectable y para perfusión EFG Colistimetato de sodio Accordpharma 2 millones de UI polvo para solución inyectable y para perfusión EFG
Cyprus	Colistimethate sodium Accord 1 million IU powder for solution for injection/infusion

Poland	Colistimethate Accord
Portugal	Colistimetato Accordpharma 1 million IU Colistimetato Accordpharma 2 million IU
Ireland	Colistimethate sodium Accord 1 million IU powder for solution for injection/infusion Colistimethate sodium Accord 2 million IU powder for solution for injection/infusion

This leaflet was last revised in March 2026

Detailed information on this medicine is available on the website of HPRA

The following information is intended for healthcare professionals only:

Special precaution for disposal and other handling

For bolus injection:
Reconstitute the contents of the vial with not more than 10 ml water for injection or 0.9% sodium chloride.

For infusion:
The contents of the reconstituted vial may be diluted, usually with 50 ml 0.9% sodium chloride.

When the intrathecal and Intracerebroventricular routes of administration are used, the volume administered should not exceed 1 ml (reconstituted concentration 125,000 IU/ml).

Any unused medicinal product or waste material should be disposed of in accordance with local requirements

The appearance of solution after reconstitution should be clear colourless to pale yellow solution free from visible particulate matter. The reconstitution is completed in less than 3 minutes.

Solutions are for single use only and any remaining solution should be discarded.