Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Colistin Link. It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you being given Colistin Link against the benefits they expect it will have for you.

If you have any concerns about being given this medicine, ask your doctor or pharmacist.

Keep this leaflet.

You may need to read it again.

What is Colistin Link used for

Colistin Link is used to treat bacterial infections in different parts of the body.

This medicine will not work against infections caused by viruses such as colds or the flu.

Colistin Link is an antibiotic that belongs to a group of medicines called polymixins.

These antibiotics work by killing bacteria causing your infection.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

This medicine is not addictive.

Colistin Link is available only with a doctor's prescription.

Before you are given Colistin Link

When you must not be given it You must not be given Colistin Link if you have an allergy to:

- any medicine containing the active ingredient colistin.
- any of the ingredients listed at the end of this leaflet
- any other similar medicines (such as other polymixin antibiotics).

Some of the symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.

Colistin Link must not be given after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If you are given this medicine after this date, it may not work.

If you are not sure whether you should be given Colistin Link talk to your doctor.

Before you are given it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any medical conditions such as:

kidney disease

Tell your doctor if you are not passing urine as frequently as normal, whilst you are being given Colistin Link.

Tell your doctor if you are pregnant or plan to become pregnant.

It may affect your developing baby if you are given Colistin Link during pregnancy. Your doctor can discuss with you the risks and benefits involved.

Tell your doctor if you are breastfeeding or plan to breastfeed.

Your doctor can discuss with you the risks and benefits involved.

If you have not told your doctor about any of the above, tell him/her before you have Colistin Link.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and Colistin Link may interfere with each other.

These include:

- certain other antibiotics such as Gentamicin
- particular types of muscle relaxants called 'curariform' muscle relaxants.

These medicines may be affected by Colistin Link or may affect how well it works. You may need different amounts of your medicines, or you may need to use different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while being given this medicine.

How Colistin Link is given

How much is given

The amount of Colistin Link given will depend on the severity of your infection, your body weight and kidney function.

Your doctor will work out how much of this medicine you need.

The usual dose in adults and children who have normal kidney function is 2.5 mg to 5.0 mg per kilogram of body weight.

How it is given

This medicine is given by injection into a vein or muscle by your doctor or nurse.

Colistin Link may be given to you in one of 2 ways:

1. Intermittently

Two injections will be given 12 hours apart. Each injection will take between 3 and 5 minutes.

2. Continuously

Two injections will be given. The first injection will take between 3 and 5 minutes and the second injection will be given slowly over 1 to 2 hours in a drip.

Your doctor will decide whether you receive two injections 12 hours apart or in a drip.

If you have reduced kidney function your doctor will give you the injections more slowly.

Colistin Link is a powder. Your hospital pharmacist will reconstitute the powder by mixing it with water for injections before it is used.

How long it is given for

The length of time you are given Colistin Link will depend on the sort of infection you have.

You may be switched from the injection to an oral antibiotic once your condition improves.

If a dose is missed

Colistin Link will be given to you under close medical supervision; it is unlikely that a dose would be missed. However, tell your doctor if you think a dose has been forgotten.

If too much is given (overdose)

As Colistin Link is given to you under the supervision of your doctor, it is very unlikely that you will receive too much.

Symptoms of overdose include:

- · passing urine a lot less frequently
- · muscle weakness
- · difficulty in breathing.

While you are receiving Colistin Link

Things you must do

If the symptoms of your infection do not improve within a few days, or if they become worse, tell your doctor.

If you get a sore white mouth or tongue while receiving or soon after stopping Colistin Link, tell your doctor. Also tell your doctor if you get vaginal itching or discharge. This may mean you have a fungal infection called thrush. Sometimes the use of Colistin Link allows fungi to grow and the above symptoms to occur. This medicine does not work against fungi.

If you are about to start taking any new medicines, remind your doctor and pharmacist that you are receiving Colistin Link.

Tell any other doctors, dentists, and pharmacists who treat you that you are being given this medicine.

If you are going to have surgery, tell the surgeon or anaesthetist that you are being given this medicine.

It may affect other medicines used during surgery.

If you become pregnant while being given this medicine, tell your doctor immediately.

Things to be careful of

Be careful driving or operating machinery until you know how Colistin Link affects

This medicine may cause temporary numbness and/or tingling in the fingers and toes, dizziness and/or slurred speech in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

Be careful when drinking alcohol while you are being given this medicine.

If you drink alcohol symptoms such as dizziness and slurred speech may be worse.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are receiving Colistin Link.

This medicine helps most people with bacterial infections, but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

If you are over 65 years of age you may have an increased chance of getting side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- · dizziness
- tingling or numbness of the mouth or tongue
- · general itching
- · upset tummy
- slurred speech.

The above list includes the more common side effects of your medicine. They are usually short lived.

Tell your doctor as soon as possible if you notice any of the following:

- · fever and chills
- · difficulty in breathing
- muscle weakness
- difficulty in passing urine or noticeably not passing as much urine.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

 allergic reactions including fever, rash, swelling of the face, lips, mouth or sore throat that may cause difficulty in swallowing or breathing, shortness of breath, swelling of the hands, feet or ankles.

These are serious side effects that may require medical attention.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people. Some of these side effects (for example, changes in kidney function) can only be found when your doctor does tests from time to time to check your progress.

Ask your doctor or nurse if you do not understand anything in this list.

After being given Colistin Link

Storage

Colistin Link vials should be kept in a cool dry place below 25°C.

Prepared solution should be stored in the refrigerator at a temperature of 2° C to 8° C for up to 24 hours.

The hospital pharmacy will store Colistin Link. It will be stored where children cannot reach it, usually in a locked cupboard at least one-and-a-half metres above the ground.

Disposal

The hospital staff will dispose of any left over or expired medicine.

Product description

What it looks like

Colistin Link is a white to slightly yellow powder in a clear glass vial. The powder is reconstituted with Water for Injections to give a clear solution before being used.

Ingredients

Once reconstituted each vial of Colistin Link contains colistimethate sodium equivalent to colistin 150 mg) in 2 mL (equivalent to 4,500,000 units activity) as the active ingredient. It does not contain any other ingredients.

This medicine does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes or preservatives.

Supplier

Colistin Link is supplied in Australia by:

Link Medical Products Pty. Ltd.

5 Apollo Street

Warriewood, NSW 2102

Australia

Colistin Link is supplied in New Zealand by:

Link Pharmaceuticals Ltd.

Suite 32

Level 26, PwC Tower

188 Quay Street

Auckland 1010

New Zealand

Australian Registration Number:

AUST R 14667

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