Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using COLISTIN LINK?

COLISTIN LINK contains the active ingredient colistimethate sodium. COLISTIN LINK is used to treat certain types of bacterial infections.

For more information, see Section 1. Why am I using COLISTIN LINK? in the full CMI.

2. What should I know before I use COLISTIN LINK?

Do not use if you have ever had an allergic reaction to COLISTIN LINK or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section 2. What should I know before I use COLISTIN LINK? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with COLISTIN LINK and affect how it works.

A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How do I use COLISTIN LINK?

• COLISTIN LINK is given as an injection by a doctor or other healthcare professional into a vein or muscle. You may receive doses of this medicine as injections, or infusions (via drip).

More instructions can be found in Section 4. How do I use COLISTIN LINK? in the full CMI.

5. What should I know while using COLISTIN LINK?

Things you should do	 Remind any doctor, dentist or pharmacist you visit that you are using COLISTIN LINK. Tell your doctor if symptoms of your infection do not improve within a few days, or they become worse.
Driving or using machines	 Be careful driving or operating machinery until you know how this medicine affects you. This medicine may cause temporary numbness, tingling in the fingers and toes, and dizziness. If you have any of these symptoms, do not drive, or operate machinery.
Drinking alcohol	Be careful when drinking alcohol whilst being given this medicine.
Looking after your medicine	 COLISTIN LINK vials should be kept in a cool dry place below 25°C. Once the vial is opened, the prepared solution should be stored in the refrigerator between 2°C-8°C for a maximum of 24 hours.

For more information, see Section 5. What should I know while using COLISTIN LINK? in the full CMI.

6. Are there any side effects?

Side effects that require urgent medical attention include: difficulty breathing; decreased urine output or difficulty passing urine. Other possible side effects include dizziness, tingling or numbness of the mouth or tongue, itching, upset tummy, slurred speech, fever.

For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

COLISTIN LINK®

Active ingredient(s): colistimethate sodium

Consumer Medicine Information (CMI)

This leaflet provides important information about using COLISTIN LINK. You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using COLISTIN LINK.

Where to find information in this leaflet:

- 1. Why am I using COLISTIN LINK?
- 2. What should I know before I use COLISTIN LINK?
- 3. What if I am taking other medicines?
- 4. How do I use COLISTIN LINK?
- 5. What should I know while using COLISTIN LINK?
- 6. Are there any side effects?
- 7. Product details

1. Why am I using COLISTIN LINK?

COLISTIN LINK contains the active ingredient colistin (as colistimethate sodium). COLISTIN LINK is an antibiotic that belongs to a group of medicines called polymixins. These antibiotics work by killing a type of bacteria that causes infections.

COLISTIN LINK is used to treat some types of bacterial infection.

2. What should I know before I use COLISTIN LINK?

Warnings

Do not use COLISTIN LINK if:

 you are allergic to colistin, colistimethate sodium, or similar medicines (other polymyxin antibiotics).

Check with your doctor if you:

- have any other medical conditions
- have kidney problems
- take any medicines for any other condition

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section <u>6</u>. Are there any side effects?

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant. Your doctor will discuss with you the risks and benefits involved.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

3. What if I am taking other medicines?

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

Some medicines may interfere with COLISTIN LINK and affect how it works.

These medicines include:

- Certain antibiotics (kanamycin, streptomycin, dihydrostreptomycin, polymyxin, neomycin.
- A particular type of muscle relaxant (curariform muscle relaxants)
- Fthe
- Tubocurarine succinylcholine
- Gallamine
- Decamethonium
- Sodium citrate

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect COLISTIN LINK.

4. How do I use COLISTIN LINK?

How much is given

Your doctor will determine the amount of medicine you need based on

- the severity of your infection,
- your body weight, and
- your kidney function

The usual dose in adults and children who have normal kidney function is 2.5 mg to 5 mg per kilogram of body weight per day, given in 2 to 4 divided doses.

How the medicine is given

This medicine is given by injection into a vein or muscle by your doctor or nurse. This medicine may be given to you in one of two ways as decided by your doctor:

Intermittently:

As two injections given 12 hours apart. Each injection will take between 3 and 5 minutes.

Continuous infusion: One injection which will take between 3 and 5 minutes, followed 1 to 2 hours later by a slow infusion where medicine is given in a drip.

If you have reduced kidney function, your doctor may decide to give you these injections more slowly, or less frequently.

COLISTIN LINK is a powder. Your hospital pharmacist or nurse will reconstitute the powder by mixing it with water for injection before it is used.

If you forget to use COLISTIN LINK

COLISTIN LINK will be given to you under close medical supervision. It is unlikely that a dose will be missed. However, tell your doctor or nurse if you think a dose has been forgotten.

If you use too much COLISTIN LINK

COLISTIN LINK will be given to you under close medical supervision and it is unlikely that you will receive too much.

Symptoms of overdose include:

- passing urine a lot less frequently
- muscle weakness
- difficulty breathing

If you have any concerns about how much COLISTIN LINK you are being given, speak to your doctor.

5. What should I know while using COLISTIN LINK?

Things you should do

Tell your doctor straight away if:

- The symptoms of your infection do not improve within a few days, or if they become worse.
- You are about to start taking any new medications, be given any new treatments, or are going to have surgery, remind your doctor and pharmacist that you are taking COLISTIN LINK

Remind any doctor, dentist or pharmacist you visit that you are using COLISTIN LINK.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how COLISTIN LINK affects you.

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

Drinking alcohol

Tell your doctor if you drink alcohol.

Looking after your medicine

- It is unlikely that you will be asked to store COLISTIN LINK yourself. It will usually be stored by your doctor or pharmacist.
- Keep COLISTIN LINK a cool dry place below 25°C
- A prepared solution of COLISTIN LINK should be stored in the refrigerator between 2°C and 8°C and used within 24 hours.

Follow the instructions in the carton on how to take care of your medicine properly.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
 Dizziness Tingling or numbness of the mouth or tongue Slurred speech Upset tummy Generalised itching Fever 	Speak to your doctor if you have any of these less serious side effects and they worry you.

Serious side effects

Serious side effects	What to do
Signs of kidney problems such as: • Swelling of the hands, ankles, or feet • Changes to the frequency of urination • Absence of urination	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you
Signs of lung problems such as: • Difficulty breathing	notice any of these serious side effects.

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What COLISTIN LINK contains

Active ingredient (main ingredient)	Colistimethate sodium
Other ingredients (inactive ingredients)	COLISTIN LINK does not contain any ingredients, other than the active ingredient colistimethate sodium.
Potential allergens	COLISTIN LINK does not contain any ingredients, other than the active ingredient colistimethate sodium.

Do not take this medicine if you are allergic to any of these ingredients.

What COLISTIN LINK looks like

COLISTIN LINK is a white to slightly yellow powder in a clear glass vial. The powder is reconstituted with Water for Injection to give a clear solution before being used.

Each vial contains colistimethate sodium equivalent to colistin 150 mg, or 4,500,000 IU antibiotic activity. (Aust R 14667).

Who distributes COLISTIN LINK

Link Medical Products Pty Ltd 5 Apollo Street Warriewood, NSW 2102 Australia

Ph: 1800 181 060 linkhealthcare.com.au

Link Pharmaceuticals Ltd Suite 32, Level 26 188 Quay Street Auckland 1010 New Zealand

Ph: +64(9) 358 7146

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