

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.

▼ This medicine is new or being used differently. Please report side effects. See the [full CMI](#) for further details.

1. Why am I using Korsuva?

Korsuva contains the active ingredient difelikefalin. Korsuva is used to treat itchy skin in adults with chronic kidney disease who need dialysis to clean their blood.

For more information, see Section [1. Why am I using Korsuva?](#) in the full CMI.

2. What should I know before I use Korsuva?

Do not use if you have ever had an allergic reaction to difelikefalin 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 Korsuva?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Korsuva 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 Korsuva?

- The doctor will determine the recommended dose for Korsuva based on your body weight. It will be given as an injection into a vein by a doctor or nurse at the end of your dialysis treatment through the tube that connects you to the dialysis machine.

More instructions can be found in Section [4. How do I use Korsuva?](#) in the full CMI.

5. What should I know while using Korsuva?

| | |
|------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Things you should do | <ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using Korsuva. |
| Things you should not do | NA |
| Driving or using machines | <ul style="list-style-type: none">• Be careful before you drive or use any machines or tools until you know how Korsuva affects you. Certain symptoms such as dizziness and drowsiness may affect your ability to drive or operate machinery. |
| Drinking alcohol | <ul style="list-style-type: none">• Tell your doctor if you drink alcohol |
| Looking after your medicine | <ul style="list-style-type: none">• Do not use this medicine if you notice particles or colour changes.• Korsuva will normally be stored for you by your doctor or the hospital.• Korsuva is for single use in one patient only. Discard any residue |

For more information, see Section [5. What should I know while using Korsuva?](#) in the full CMI.

6. Are there any side effects?

Tell your doctor or pharmacist if you notice any of the following and they worry you: drowsiness. This is the more common side effect of your medicine.

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.



This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. You can report side effects to your doctor, or directly at www.tga.gov.au/reporting-problems.

Korsuva

Active ingredient(s): *difelikefalin (dye fel i kef a lin)*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Korsuva. **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 Korsuva.**

Where to find information in this leaflet:

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

1. Why am I using Korsuva?

Korsuva contains the active ingredient difelikefalin. Korsuva works by activating kappa-opioid receptors outside of the brain.

Korsuva is used to treat itchy skin in adults with chronic kidney disease who need haemodialysis to clean their blood.

2. What should I know before I use Korsuva?

Warnings

Do not use Korsuva if:

- you are allergic to difelikefalin, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.

Check with your doctor if you:

- have any other medical conditions
- take any medicines for any other condition
- have a reduced function of the blood-brain barrier
- (such as cancer in the brain or the central nervous system, or a disease of the central nervous system like multiple sclerosis or dementia) as this might increase your risk of side effects
- are 65 years of age or older, as you may be more likely to be made drowsy by the medicine
- are using medicines that could increase the risk of drowsiness or dizziness, such as:

- medicines that slow down brain activity such as those that help with sleep disturbances and anxiety
 - medicines to treat allergies, cold, nausea and/or vomiting called sedating antihistamines
 - strong painkillers, called opioid analgesics
- Talk to your doctor if you take any of these medicines.

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 [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Korsuva has not been studied in pregnant women. It is unknown whether Korsuva can harm the unborn baby. Your doctor will decide if you should use Korsuva during pregnancy.

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

Korsuva is likely to be present in human breast milk at very low levels. Your doctor will decide whether you should use Korsuva while breastfeeding. After three dialysis cycles Korsuva is not detectable in blood.

Children and adolescents

It is not known whether Korsuva is safe and effective in children under 18 years. It has not been studied in these patients.

3. What if I am taking other medicines?

Tell your doctor 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 Korsuva and affect how it works.

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

4. How do I use Korsuva?

How much to use

- Your doctor will determine the recommended dose for Korsuva based on your body weight. It will be given as an injection into a vein under a healthcare provider (HCP) supervision or care at the end of your dialysis treatment through the tube that connects you to the dialysis machine.

When to use Korsuva

- Korsuva will be given 3 times per week after your scheduled dialysis. This can increase to 4 times per week in case of a fourth dialysis. No more than 4 doses are recommended even if the number of dialyses in a week exceeds 4.

If you use too much Korsuva

As Korsuva will be given to you under HCP supervision or care, it is unlikely that you will be given an overdose.

However, if you believe that you have been given too much Korsuva:

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using Korsuva?

Things you should do

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

Driving or using machines

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

Korsuva can cause drowsiness and dizziness which may affect your ability to react. Do not drive or use machines if your ability to react is reduced or you do not know the effect of Korsuva on your ability to react.

Drinking alcohol

Tell your doctor if you drink alcohol.

Looking after your medicine

- Korsuva will normally be stored for you by your doctor or the hospital.
- Store below 30°C. Do not freeze.
- Do not use this medicine if you notice particles or colour changes.

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

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

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 |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------|
| Head related: <ul style="list-style-type: none">HeadacheDizzinessConfusion and mental status changesDrowsiness Stomach related: <ul style="list-style-type: none">NauseaDiarrhoea | Speak to your doctor if you have any of these less serious side effects and they worry you. |

Frequently conducted blood tests by your doctor may show an increase in the blood potassium level.

In patients receiving difelikefalin, Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS) (symptoms may include fever, rash, and enlarged lymph nodes), has been reported in only one individual case report, but a causal relationship is yet to be established.

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 Korsuva contains

| | |
|-----------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------|
| Active ingredient (main ingredient) | Difelikefalin |
| Other ingredients (inactive ingredients) | Acetic acid Sodium acetate trihydrate Water for Injection |
| Potential allergens | Sodium chloride* This medicine contains less than 1 mmol sodium (23 mg) per vial, that is to say essentially 'sodium-free'. |

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

What Korsuva looks like

Korsuva is a clear and colourless solution. It is supplied in a glass vial with rubber stopper, an aluminium seal and a blue flip-off plastic cap. (Aust R 374062).

Korsuva is provided in pack sizes of 3 and 12 vials containing 1 mL of solution for injection.

Korsuva is for single use in one patient only. Discard any residue.

Not all pack sizes may be marketed.

Who distributes Korsuva

Distributed in Australia by:

CSL Seqirus
655 Elizabeth Street,
Melbourne, VIC 3000
Australia

1800 642 865 (Within Australia)

Sponsor

Seqirus Pty Ltd
63 Poplar Rd,
Parkville VIC 3052
Australia

This leaflet was prepared in January 2024.