PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986

The medicine is dispensed with a doctor's prescription only

Korsuva

Solution for injection 50 micrograms/ 1 ml

Active ingredient and its concentration:

Each 1 ml of solution contains 50 mcg of difelikefalin.

Inactive and allergenic ingredients in the preparation – for the list of inactive and allergenic ingredients in the preparation - see Section 6.

Read the leaflet carefully in its entirety before using the medicine.

This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar.

1. What is the medicine intended for?

Korsuva is used to treat moderate to severe itching related to chronic kidney disease in adults who undergo hemodialysis.

Therapeutic group: All other therapeutic products

Korsuva contains the active substance difelikefalin.

Korsuva acts on targets in the body called kappa-opioid receptors, which are involved in controlling the perception of itching. By stimulating these receptors on nerve and immune cells outside the brain, Korsuva relieves the itching sensation caused by chronic kidney disease.

The active substance difelikefalin does not cross the blood-brain barrier (a natural barrier between blood vessels and the brain), reducing the risk of side effects.

2. Before using this medicine:

Do not use this medicine if:

- You are sensitive (allergic) to difelikefalin, or to any of the other ingredients contained in the medicine (see Section 6).

Special warnings regarding the use of this medicine:

Before the treatment with Korsuva, tell the doctor or nurse if:

- you have an increased level of potassium in your blood
- you have or have had heart weakness or arrhythmia (irregular heartbeat)
- you have reduced function of the blood-brain barrier (for example, due to cancer in the brain or the central nervous system, or a disease of the central nervous system such as multiple sclerosis or dementia), as this might increase the risk of side effects
- you are 65 or older, as you may be more likely to become drowsy from the medicine
- you are using medicines that may increase the risk of drowsiness or dizziness, such as:
  - medicines that slow down brain activity like those that help with sleep disorders and anxiety
  - medicines that treat allergy, common cold, nausea and/or vomiting called antihistamines with a sedative effect
  - strong painkillers called opioid analgesics

  Tell your doctor if you take any of the abovementioned medicines.

Children and adolescents

Korsuva is not recommended for children and adolescents under the age of 18.
There is no information on its use in children and adolescents under the age of 18.

Drug interactions:

If you are taking, or have recently taken other medicines including non-prescription medicines and nutritional supplements, tell your doctor or pharmacist.

Pregnancy and breastfeeding
If you are pregnant or breastfeeding, if you might be pregnant or are planning to have a baby, consult your doctor or pharmacist before beginning treatment with this medicine.

Korsuva has not been tested on pregnant women. It is not known whether Korsuva can harm the unborn baby. Your doctor will discuss with you whether you should use Korsuva during pregnancy.

It is not known whether Korsuva can pass into breast milk. If you are breastfeeding, your doctor will advise you regarding whether you should stop breastfeeding or discontinue treatment with Korsuva, considering the benefits of nursing your baby and giving Korsuva to you, the mother.

Driving and using machines

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

Important information about some of the medicine's ingredients

This medicine contains less than 23 mg of sodium per ml and is therefore considered sodium-free.

3. How should you use the medicine?

Always use this preparation in accordance with the doctor's instructions. Check with the doctor or pharmacist if you are not sure about the dosage and treatment regimen of the preparation. The dosage and treatment regimen will be determined by the doctor only.

Your doctor will determine the Korsuva dosage that is right for you based on your body weight. The medicine will be given by intravenous injection by a doctor or nurse at the end of your dialysis treatment through the tube that connects you to the dialysis machine.

Do not exceed the recommended dose.

Duration of treatment

Korsuva will be given to you three times per week. This number will increase to 4 times per week if you undergo dialysis four times a week. No more than 4 doses of Korsuva are recommended per week, even if the number of dialysis treatments per week exceeds four.

If a dialysis treatment is not completed, your doctor will decide if it is better for you to receive Korsuva after the incomplete treatment or to wait until the next dialysis treatment. If you have missed a dialysis treatment, the usual dose of Korsuva will be given to you in your next dialysis treatment.

Itching is expected to decrease after 2-3 weeks of treatment with Korsuva.

Patients with reduced liver function:

No dosage adjustment is required for patients with a mild or moderate reduction in liver function.

Korsuva is not recommended for patients with severely reduced liver function, as its use has not been studied in these patients.

If you have accidentally taken a higher dosage this increases the occurrence of side effects as listed in section 4. You should speak to your doctor if you think this applies to you.

Do not take medicines in the dark! Check the label and dose each time you take a medicine. Wear glasses if you need them.
If you have further questions regarding use of the medicine, consult a doctor or pharmacist.

4. Side effects

As with any medicine, the use of Korsuva may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

The following side effects have been reported in patients who receive this medicine

Common side effects - effects that occur in 1-10 users out of 100

- drowsiness
- a sensation disorder in the skin such as tingling, prickling, burning or numbness, decreased sensation or sensitivity

Uncommon side effects – effects that occur in 1-10 users out of 1000

- dizziness
- headache
- changes in mental status (alertness and clarity of thought), including confusion
- nausea, vomiting
- diarrhea

If a side effect occurs, if one of the side effects worsens, or if you suffer from a side effect not mentioned in this leaflet, consult your doctor.

Reporting side effects
Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the homepage of the Ministry of Health (www.health.gov.il), which directs you to the online form for the report of side effects, or by entering the link: https://sideeffects.health.gov.il/

5. How should the medicine be stored?

- Prevent poisoning! This medicine and any other medicine should be kept in a closed place out of the reach and sight of children and/or infants to prevent poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.
- Do not use the medicine after the expiry date (EXP) that appears on the packaging. The expiry date refers to the last day of that month.

Storage conditions:

Store at a temperature below 25ºC.

6. Further Information:

- In addition to the active ingredient, this medicine also contains:
  Acetic acid (for pH adjustment), sodium acetate trihydrate (for pH adjustment), sodium chloride, water for injections

- What the medicine looks like and what the package contains:
  Korsuva is a clear, particle-free colorless solution (pH 4.5). The medicine is supplied in a glass vial with a rubber stopper, aluminium seal and blue plastic cap.

- The package contains 3 or 12 vials. Not all pack sizes may be marketed.
- License holder and address: CTS Ltd., 4 HaHarash St., Hod Hasharon, Israel
- Manufacturer name and address:

  Vifor Fresenius Medical Care Renal Pharma France
  100-101 Terrasse Boieldieu
  Tour Franklin La Défense 8
  92042 Paris La Défense Cedex
  France

- Registration number of the medicine in the National Drug Registry of the Ministry of Health: 173-72-37475-99

This leaflet was revised in 02/2025 according to Ministry of Health guidelines.