Package leaflet: Information for the patient

Kapruvia 50 micrograms/mL solution for injection
difelikefalin

▼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. See the end of section 4 for how to report side effects.

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 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 or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Kapruvia is and what it is used for

Kapruvia contains the active substance difelikefalin. It is used to **treat itching** in adults with chronic kidney disease who need dialysis to clean their blood.

Kapruvia works at targets in the body called kappa-opioid receptors which are involved in controlling the perception of itching. By stimulating these receptors on nerves and immune cells outside the brain, Kapruvia relieves the sensation of itch caused by chronic kidney disease. The active substance difelikefalin does not pass the blood-brain barrier (the natural protective barrier between blood vessels and the brain), which reduces the risk of side effects.

2. What you need to know before you use Kapruvia

Do not use Kapruvia
- if you are allergic to difelikefalin or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions
Talk to your doctor or nurse before you are given Kapruvia if you:
- have an increased potassium level in the blood
- have or have had heart weakness or a heart rhythm disorder
- have 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.

Children and adolescents
Kapruvia is not recommended for children under 18 years, as it has not been studied in these patients.

Other medicines and Kapruvia
Tell your doctor if you are using, have recently used or might use any other medicines.

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 for advice before you are given Kapruvia.

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

It is not known whether difelikefalin can pass into breast milk. If you are breast-feeding your doctor will advise you on whether to stop breast-feeding or using Kapruvia, considering the benefit of breast-feeding to the baby and Kapruvia to you, the mother.

Driving and using machines
Kapruvia 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 Kapruvia on your ability to react.

Kapruvia 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 Kapruvia

The doctor will work out the right dose of Kapruvia for you, 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.

Kapruvia will be given 3 times per week. This increases to 4 times per week in case of a fourth dialysis. No more than 4 doses are recommended, even if the number of dialysis treatments in a week is more than 4.

If a dialysis treatment is unfinished, your doctor will decide whether it is better for you to receive Kapruvia after the unfinished dialysis session or wait until your next dialysis treatment.
If a dialysis treatment is missed, the usual dose of Kapruvia will be given to you at the next dialysis treatment.

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

Patients with reduced liver function
No dose adjustment is required for patients with mild or moderate reduced liver function. Kapruvia is not recommended for patients with severely reduced liver function, as use has not been studied in these patients.

If you have been given more Kapruvia than you should

This increases the occurrence of side effects listed in section 4. Inform your doctor if you think this applies to you.

If you have any further questions on the use of this medicine, ask your doctor or nurse.

4. Possible side effects

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

The following side effects have been reported in patients receiving this medicine:
Common, may affect up to 1 in 10 people:
- drowsiness
- sensation disorder in the skin such as tingling, prickling, burning or numbness, decreased feeling or sensitivity

Uncommon, may affect up to 1 in 100 people:
- dizziness
- headache
- changes in mental status (alertness and clarity of thought), including confusion
- nausea, vomiting
- diarrhoea

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly in UK via:

Yellow Card Scheme
Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Kapruvia

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

This medicine does not require any special storage conditions.

6. Contents of the pack and other information

What Kapruvia contains
- The active substance is difelikefalin.
  Each vial contains 50 micrograms of difelikefalin (as acetate) in 1.0 mL solution.
- The other ingredients are acetic acid (for pH adjustment), sodium acetate trihydrate (for pH adjustment), sodium chloride, water for injections. See section 2 "Kapruvia contains sodium".

What Kapruvia looks like and contents of the pack
Kapruvia is a clear, colourless solution and free from particles (pH 4.5). It is supplied in a glass vial with rubber stopper, an aluminium seal and a blue flip-off plastic cap.

Pack sizes of 3 and 12 vials.

Not all pack sizes may be marketed.

Marketing Authorisation Holder
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For any information about this medicine, please contact the Marketing Authorisation Holder.

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