

Kepivance(R)

Palifermin (rbe)

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Kepivance.

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 having Kepivance against the benefits they expect it will have.

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

Keep this leaflet.

You may need to read it again.

What Kepivance is used for

Kepivance is used to reduce a condition called oral mucositis in patients with cancers of the blood receiving certain types of chemotherapy and/or radiotherapy. Oral mucositis is inflammation and ulceration of the lining of the mouth and throat.

How it works

Kepivance is a man-made form of a naturally-occurring substance called Keratinocyte Growth Factor, sometimes shortened to KGF. Keratinocyte Growth Factor stimulates the growth of epithelial cells, which are the uppermost layer

of cells that line your mouth, digestive tract and skin.

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

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

Before you are given Kepivance

When you must not be given Kepivance

Do not have Kepivance if you have an allergy to:

- * Kepivance or any of the ingredients listed at the end of this leaflet
- * medicines or other products that are produced by DNA technology using the bacteria E-coli.

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
- * skin rash, itching or hives.

Do not give Kepivance to a child under 18 years.

The safety and effectiveness of Kepivance in children under 18 years have not been established.

Do not have Kepivance after the expiry date printed on the pack.

Do not have Kepivance if the packaging is torn or shows signs of tampering.

Do not have Kepivance if the solution is cloudy or discoloured, or if it contains clumps or flakes.

If you are not sure whether you should have Kepivance, talk to your doctor or pharmacist.

Before you are given it

Tell your doctor if you have allergies to:

- * any other medicines
- * any other substances, such as foods, preservatives or dyes.

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

Your doctor will discuss the possible risks and benefits of having Kepivance during pregnancy.

Tell your doctor if you are breast-feeding.

Your doctor will discuss the possible risks and benefits of having Kepivance during breast-feeding. It is not known if the drug is excreted in human milk

Tell your doctor if you have had a previous skin cancer.

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

Taking other medicines

Kepivance may be given to you through a tube into your vein. If heparin (a drug used to stop blood clotting) is used in this tube, saline (salty water) should be used to rinse the tube before and after Kepivance is given to you.

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

How Kepivance is given

Kepivance is given as an injection into a vein, called an intravenous injection, by a doctor or nurse.

How much is given

The usual dose is 60 micrograms of Kepivance per kilogram of bodyweight per day.

Your doctor or nurse will determine exactly how much to inject.

When it is given

Kepivance is given each day for

- * three days in a row before and
- * three days in a row after chemotherapy and/or radiotherapy.

A total of six doses are given.

If you miss a dose

If you miss a dose, talk to your doctor, nurse or pharmacist.

After having Kepivance

Things you must NOT do

Do not have chemotherapy for 24 hours after having Kepivance.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well after having Kepivance, even if you do not think the problems are connected with the medicine or are not listed in this leaflet.

Like other medicines, Kepivance may have unwanted side effects. Some side effects may be serious and need medical attention. Other side effects are minor and are likely to be temporary. You may also experience side effects caused by other medicines you are having at the same time as Kepivance.

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

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

Kepivance may increase the blood levels of some digestive enzymes. These increases do not require treatment and return to normal after stopping treatment with Kepivance.

If any of the following happen, stop having Kepivance and seek urgent medical attention:

- * rash over a large area of the body
- * shortness of breath
- * wheezing
- * faintness, rapid pulse or sweating.

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

- * an increase in the thickness of the lining of your mouth or tongue
- * a change in the colour of your mouth or tongue
- * an unusual taste in the mouth
- * flushing or redness of the skin
- * itchiness, hives or rash over the body
- * generalised swelling
- * generalised pain
- * pain in the joints.

Other side effects not listed above may occur in some patients. Tell your doctor or pharmacist if you

notice anything that is making you feel unwell.

Storing Kepivance

Kepivance is usually stored in the hospital pharmacy. However, if you need to store Kepivance:

- * **Keep it where children cannot reach it.**
- * **Keep Kepivance in the original pack, protected from light, in the refrigerator, between 2 degrees C and 8 degrees C, until it is time for it to be given. Do not freeze Kepivance.**
- * **After Kepivance powder has been dissolved, use the solution as soon as possible (within 1 hour).**

If the dissolved Kepivance solution will not be used within 1 hour, it can be stored for up to 24 hours in the refrigerator, between 2 degrees C and 8 degrees C. Do not freeze dissolved Kepivance solution.

- * **Do not place Kepivance powder or dissolved Kepivance solution in a freezer or the freezer compartment of a refrigerator.**
- * **Note the expiry date on the pack. Do not use after this expiry date.**

Product description

What it looks like

Kepivance is supplied as a white powder in small glass vials.

It is prepared for use by dissolving the powder in 1.2 mL of sterile Water for Injections.

Ingredients

The active ingredient in Kepivance is palifermin.

Other ingredients in Kepivance are

- * mannitol
- * sucrose
- * L-histidine
- * polysorbate 20

Kepivance does not contain lactose, gluten, tartrazine or any other azo dyes.

Supplier

Kepivance is supplied in Australia by:

Amgen Australia Pty Ltd

ABN 31 051 057 428

Level 7, 123 Epping Road

NORTH RYDE NSW 2113

Australian Registration Number:

AUST R 107304.

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