

KEPIVANCE[®]

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 nurse.

This leaflet was last updated on the date at the end of this leaflet.

Speak to your doctor or nurse to obtain the most up to date information on this medicine.

You can also download the most up to date leaflet from www.menarini.com.au.

All medicines have risks and benefits. Your doctor has weighed the risks of you having KEPIVANCE against the benefits they expect it will have for you.

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

Keep this leaflet with the medicine. 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.

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.

Your doctor may have prescribed it for another reason.

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

Before you are given KEPIVANCE

When you must not be given it

Do not have KEPIVANCE if you have an allergy to:

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

Some of the 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
- rash, itching or hives on the skin

Do not give this medicine to a child under the age of 18 years.

Safety and effectiveness in children younger than 18 years have not been established.

Do not give this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

Do not give KEPIVANCE if the solution is cloudy or discoloured, or if it contains clumps or flakes.

If you are not sure whether you should have this medicine, talk to your doctor.

Before you are given it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any of the following medical conditions:

- skin cancer

Tell your doctor if you are pregnant or plan to become pregnant or are breast-feeding. Your doctor can discuss with you the risks and benefits involved.

If you have not told your doctor about any of the above, tell him/her before you are given 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 nurse 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

Talk to your doctor or nurse if you miss a dose.

While you are having KEPIVANCE

Things you must do

If you are about to be started on any new medicine, remind your doctor and nurse that you are having KEPIVANCE.

Tell any other doctors, dentists, and pharmacists who treat you that you are having this medicine.

Things you must not do

Do not mix the contents of one vial of KEPIVANCE solution with the contents of another vial or transfer into another vial of KEPIVANCE.

Do not add any other medication to solutions containing KEPIVANCE.

Do not have chemotherapy for 24 hours after having KEPIVANCE.

Side effects

Tell your doctor or nurse as soon as possible if you do not feel well while you are having KEPIVANCE.

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.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

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

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.

Stop having KEPIVANCE and seek urgent medical attention if any of the following happen:

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

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

- swelling of the mouth, tongue or face
- 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
- tingling, pricking sensation in the mouth
- flushing or redness of the skin
- itchiness, hives or rash over the body
- generalised swelling
- generalised pain
- pain in the joints.
- Swelling (oedema) or redness (erythema) of the vagina
- Swelling (oedema) or redness (erythema) of the palms or soles
- Darkening of an area of the skin (hyperpigmentation)

Tell your doctor or nurse if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people.

Storing KEPIVANCE

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

Keep it where children cannot reach it.

Keep it in the original pack, protected from light, in the refrigerator, between 2°C and 8°C, until it is time for it to be given.

Do not freeze it.

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°C and 8°C.

Do not freeze dissolved KEPIVANCE solution.

Do not place KEPIVANCE powder or dissolved 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
- histidine
- polysorbate 20

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

Supplier

KEPIVANCE is supplied in
Australia by:

A Menarini Australia Pty Ltd
Level 8, 67 Albert Avenue
CHATSWOOD NSW 2067

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