

Package leaflet: Information for the patient

Pepaxti® 20 mg powder for concentrate for solution for infusion melphalan flufenamide

Read all of this leaflet carefully before you are given 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.
- 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

- What Pepaxti is and what it is used for
- What you need to know before you are given Pepaxti
- How Pepaxti is given
- Possible side effects
- How to store Pepaxti
- Contents of the pack and other information

1. What Pepaxti is and what it is used for

Pepaxti belongs to a group of cancer medicines called alkylating agents. It works by attaching to DNA (the genetic instruction needed for cells to survive and multiply) and damaging it, thereby helping to stop the cancer cells from growing.

Pepaxti is given with the steroid dexamethasone, to treat adults with the blood cancer multiple myeloma. It is used when the disease does not respond to at least three types of cancer medicines. If you have been treated with a blood stem cell transplant (a procedure where the cells that make your blood are cleared out and replaced), the time to when the multiple myeloma came back after transplantation should be at least 3 years.

2. What you need to know before you are given Pepaxti

Do not use Pepaxti

- if you are allergic to melphalan flufenamide or any of the other ingredients of this medicine (listed in section 6).
- if you are breast-feeding.

Warnings and precautions

Talk to your doctor or nurse before you are given Pepaxti.

Abnormal bleeding and bruising and low number of platelets (blood cells)

Pepaxti can lower the number of blood cells called platelets that help to clot your blood. Tell your doctor or nurse immediately if you start bleeding e.g. a nosebleed or get bruises on your skin.

Fever and low number of white blood cells

Pepaxti can lower the number of white blood cells that are important for fighting infections. Tell your doctor or nurse immediately if you have symptoms of infection such as fever, chills or cough.

Low number of red blood cells

Pepaxti can lower the number of red blood cells, which transport oxygen to the cells in your body. Your doctor will regularly take blood samples to monitor your blood cells. Tell your doctor or nurse immediately if you feel weak or tired, if you look pale or if you feel short of breath.

Infections

Infections such as lung infection (pneumonia) and upper respiratory tract infection (causing cold-like symptoms) are very common with Pepaxti. Tell your doctor or nurse immediately if you develop fever or other signs of infection. Your doctor might recommend preventive anti-biotics to lower the risk of developing infections.

Risk of diarrhoea, nausea or vomiting

You should tell your doctor if you get diarrhoea, nausea, or vomiting.

Risk of development of blood clots

The use of Pepaxti in combination with dexamethasone may increase the risk of developing blood clots. Tell your doctor or nurse if you have ever had a blood clot in a vein (thrombosis). Tell your doctor or nurse immediately if you develop a swelling of a leg or an arm, if you find it harder to breathe, or experience chest pain.

Risk of additional cancer

It is important to note that patients with multiple myeloma treated with Pepaxti may develop additional types of cancer, therefore your doctor should carefully evaluate the benefit and risk for you when you are prescribed this medicine.

Kidney disease

If you have lowered kidney function, the side effects of Pepaxti on your blood cells may be worse. There is too little information available on use of the medicine in patients with severely lowered kidney function to be able to recommend a safe and effective dose.

Vaccinations

Vaccines that contain live but weakened organisms, known as live attenuated vaccines (like measles, mumps, and rubella vaccines) should not be used while you are being treated with Pepaxti, as they may lead to an infection. Some other types of vaccines known as inactivated vaccines or mRNA based vaccines can, however, be used. Tell your healthcare provider you are being treated with Pepaxti before you get vaccinated.

Children and adolescents

Pepaxti is not intended for use in children or adolescents below 18 years of age.

Other medicines and Pepaxti

Tell your doctor if you are taking, have recently taken or might take any other medicines.

Pregnancy, breast-feeding and fertility

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 this medicine.

Pregnancy

This medicine is not recommended for use during pregnancy unless clearly necessary. Avoid becoming pregnant while being treated with this medicine as it may harm your unborn baby. Your doctor will discuss with you the potential risks of using Pepaxti during pregnancy.

If you are a woman who could become pregnant:

- Your doctor will ask you to take a pregnancy test before you start treatment with Pepaxti.
- You must use effective contraception during treatment and for 6 months after your last dose of Pepaxti. Talk to your doctor about effective contraception methods that may be right for you.

If you are a man who could father a child:

- You must use effective contraception during treatment and for 6 months after your last dose of Pepaxti.

Breast-feeding

You should not breast-feed during treatment with Pepaxti since it may be harmful for your baby.

Fertility

Pepaxti can affect ovaries or sperm, which may cause infertility (inability to have a baby). In women, menstruation can stop. In men, inability to father a child (sterility) due to lack of sperm can be permanent. Ask your doctor for advice on sperm preservation before treatment.

Driving and using machines

Pepaxti can cause nausea and dizziness, which may reduce your ability to drive or use machines.

3. How Pepaxti is given

Pepaxti is made up into a solution and given by your doctor or nurse as a drip into a vein (intravenous infusion) over 30 minutes. Your doctor will decide on the correct dose of Pepaxti. The recommended starting dose is 40 mg once every 4 weeks. If you have a body weight of 60 kg or less, the recommended starting dose is 30 mg once every 4 weeks. Treatment will carry on as long as you are benefitting from it and do not have unacceptable side effects. As part of your treatment, you will also take another medicine, dexamethasone, by mouth.

If you are given more Pepaxti than you should

This medicine will be given by your doctor or nurse. In the unlikely event that you are given too much (an overdose) your doctor will check you, including taking blood samples to monitor your blood cells.

If a dose of Pepaxti is missed

It is very important to go to all your appointments, to make sure your treatment works. If you miss an appointment, contact your doctor or hospital as soon as possible.

4. Possible side effects

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

Contact a doctor straight away if you notice any of the following serious side effects – you may need urgent medical treatment:

- Fever, chills, sore throat, cough, or any other signs of infection (due to lack of white blood cells called neutrophils, which fight infections).
- Rapid breathing, rapid pulse, fever and chills, passing very little to no urine, nausea and vomiting, confusion, unconsciousness (due to serious bacterial infection of the blood called sepsis or septic shock).
- Bleeding or bruising without a cause, including nosebleeds (due to low number of blood platelets [thrombocytopenia]).
- Shortness of breath (from serious chest infection, inflammation of the lungs, or blood clot in the lungs).
- Leg or arm pain and swelling, especially in your lower leg or calves (caused by blood clots).

Other side effects that can occur

Very common (may affect more than 1 in 10 people):

- Lower number of blood platelets (thrombocytopenia)
- Lower number of a type of white blood cells called neutrophils (neutropenia)
- Lower number of red blood cells which carry oxygen in the blood (anaemia), causing weakness and fatigue
- Infection of the lungs (pneumonia)
- Infection of the airways presenting with e.g. fever, cough, and cold-like symptoms
- Diarrhoea
- Nausea
- Fever
- Cough
- Shortness of breath
- Extreme tiredness (fatigue)
- Weakness

Common (may affect up to 1 in 10 people):

- Serious bacterial infection of the blood (sepsis)
- Fever together with reduced number of some white blood cells (neutropenia)
- Lower number of a type of white blood cells called lymphocytes (lymphopenia), which also help fight infections
- Overall lower number of white blood cells
- Decreased appetite
- Low potassium level (may cause muscle weakness and irregular heartbeat)
- High uric acid level in the blood (may cause gout and kidney problems)
- Headache
- Dizziness
- Shortness of breath when active
- Nosebleed
- Vomiting
- Deep vein thrombosis (blood clot in a vein)
- Bruises

Uncommon (may affect up to 1 in 100 people):

- Serious bacterial infection of the blood with dangerously low blood pressure (septic shock) which can be life threatening or even fatal
- Blood clot in the lungs
- A type of blood cancer called myelodysplastic syndrome (MDS)
- A type of blood cancer called acute myeloid leukaemia (AML)

Your doctor or nurse may give you additional medicines to treat your symptoms and/or prevent side effects.

Reporting of side effects

If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the 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 Pepaxti

Pepaxti will be stored at the hospital or clinic so these instructions are for the healthcare professionals.

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 vial label and carton after “EXP”. The expiry date refers to the last day of that month.

Store in a refrigerator (2 °C – 8 °C). Do not freeze.

Store in the original package in order to protect from light.

Do not throw away any medicines via wastewater or household waste. These measures will help protect the environment.

6. Contents of the pack and other information

What Pepaxti contains

- The active substance is melphalan flufenamide. One vial contains 20 mg of melphalan flufenamide (as hydrochloride).
- The other ingredient is sucrose (sugar).

What Pepaxti looks like and contents of the pack

Pepaxti is a white to off-white powder in a glass vial.

Each carton contains one vial.

Marketing Authorisation Holder

Oncopeptides AB (publ)
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111 37 Stockholm
Sweden

Manufacturer

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For any information about this medicine, please contact the Marketing Authorisation Holder:
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Other sources of information

Detailed information on this medicine is available on the Medicines and Healthcare products Regulatory Agency web site:
http://www.mhra.gov.uk.

The following information is intended for healthcare professionals only:

[Step-by-step instructions for use and handling, reconstitution and administration](#)

Pepaxti should be prepared by a healthcare professional using aseptic technique to ensure the sterility of the prepared solution.

[Additional solvents required for preparation](#)

5% glucose solution for injection/infusion (room temperature).
250 mL bag of cold (2 °C – 8 °C) sodium chloride 9 mg/mL (0.9%) solution for injection (refrigerate for at least 4 hours).

Volume description	Pepaxti dose			
	40 mg (2 vials)	30 mg (1.5 vials)	20 mg (1 vial)	15 mg (0.75 vial)
Volume of reconstituted Pepaxti solution needed for final product	80 mL	60 mL	40 mL	30 mL
Final total volume of infusion bag after dilution	250 mL	230 mL	210 mL	200 mL
Pepaxti concentration after dilution	0.16 mg/mL	0.13 mg/mL	0.10 mg/mL	0.08 mg/mL

[Preparation steps](#)

Read the complete instructions prior to starting preparation.

Steps 3 to 5 must be completed within 30 minutes.

<u>Reconstitution and dilution steps</u>			
<i>Step 1</i> Determine the number of vials needed for the dose as per Table 1 “Dilution volumes per Pepaxti dose”. Place vial(s) at room temperature for at least 30 minutes.			
<i>Step 2</i> Shake the vial(s) vigorously or vortex to disintegrate the lyophilised powder cake into a loose powder.			
Steps 3 to 5 must be completed within 30 minutes.			
<i>Step 3</i>			
For a Pepaxti dose of 40 mg	For a Pepaxti dose of 30 mg	For a Pepaxti dose of 20 mg	For a Pepaxti dose of 15 mg
Aseptically reconstitute each of the 2 vials with 40 mL of 5% glucose solution for infusion to obtain a final concentration of 0.5 mg/mL.	Aseptically reconstitute each of the 2 vials with 40 mL of 5% glucose solution for infusion to obtain a final concentration of 0.5 mg/mL.	Aseptically reconstitute 1 vial with 40 mL of 5% glucose solution for infusion to obtain a final concentration of 0.5 mg/mL.	Aseptically reconstitute 1 vial with 40 mL of 5% glucose solution for infusion to obtain a final concentration of 0.5 mg/mL.

Ensure the 5% glucose solution for infusion is at room temperature (20 °C – 25 °C). Shake the vial(s) vigorously until solution is clear. Let the vial(s) stand to allow air bubbles to dissipate to confirm a clear solution.

Step 4

Withdraw 80 mL from a refrigerated (2 °C – 8 °C) 250 mL bag sodium chloride 9 mg/mL (0.9%) solution for injection. Discard the withdrawn 80 mL.

Step 5

For a Pepaxti dose of 40 mg	For a Pepaxti dose of 30 mg	For a Pepaxti dose of 20 mg	For a Pepaxti dose of 15 mg
Withdraw 80 mL of reconstituted solution from the Pepaxti vials and transfer into an intravenous (IV) solution for injection containing sodium chloride 9 mg/mL (0.9%) to obtain a final concentration of 0.16 mg/mL.	Withdraw 60 mL of reconstituted solution from the Pepaxti vials and transfer into an intravenous (IV) solution for injection containing sodium chloride 9 mg/mL (0.9%) to obtain a final concentration of 0.13 mg/mL.	Withdraw 40 mL of reconstituted solution from the Pepaxti vial and transfer into an intravenous (IV) solution for injection containing sodium chloride 9 mg/mL (0.9%) to obtain a final concentration of 0.10 mg/mL.	Withdraw 30 mL of reconstituted solution from the Pepaxti vial and transfer into an intravenous (IV) solution for injection containing sodium chloride 9 mg/mL (0.9%) to obtain a final concentration of 0.08 mg/mL.

Discard any unused portion left in the vial(s). Gently invert the bag to mix the solution. Do not shake. Check that the solution is clear and colourless to pale yellow. Do not use if solution discolouration or particles are observed.

[Storage timelines](#)

Pepaxti degrades in solution, especially at room temperature, and the storage timelines for diluted solution should not be exceeded.

<i>For immediate administration</i>
Infusion of the diluted solution must begin within 60 minutes of start of reconstitution (step 3).
<i>For delayed administration</i>
If not used for immediate administration, the diluted solution should be placed in a refrigerator (2 °C – 8 °C) within 30 minutes after initial reconstitution (step 3) and store for up to 6 hours .

[Administration](#)

Parenteral medicinal products should be inspected visually for particulate matter and discolouration prior to administration. Do not use if visibly opaque particles, discolouration or foreign particles are observed.

<i>Administration steps</i>
<i>Step 6</i> Administer Pepaxti as a 30-minute intravenous infusion via peripheral venous route or a central venous access device, for example PICC or tunnelled central venous catheter. If the infusion bag has been stored in a refrigerator, allow to reach to room temperature (20 °C – 25 °C). Start infusion within 30 minutes of removing the diluted solution from the refrigerator.
<i>Step 7</i> Upon completion of Pepaxti infusion, flush the catheter with sodium chloride 9 mg/mL (0.9%) solution for injection.

[Disposal](#)

Pepaxti is a cytotoxic medicinal product for single use only. The procedure for the safe handling and disposal of nitrogen mustard analogues must be followed by healthcare professionals or medical personnel and should comply with the current recommendations for cytotoxic medicinal products. Any unused medicinal product or waste material should be disposed of in accordance with local requirements.