

Package Leaflet: Information for the patient

VEPESID™ SOFT CAPSULES 50 MG AND 100 MG (Etoposide)

Read all of this leaflet carefully before you start taking 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 pharmacist.
- 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 pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Vepesid is and what it is used for
2. What you need to know before you take Vepesid
3. How to take Vepesid
4. Possible side effects
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1. WHAT VEPESID IS AND WHAT IT IS USED FOR

The name of this medicine is Vepesid. Each capsule contains etoposide (either 50 mg or 100 mg) as the active ingredient.

Etoposide belongs to the group of medicines called anti-neoplastic agents which are used in the treatment of cancer.

Vepesid is used in the treatment of certain types of cancer, in particular small cell lung cancer and testicular cancer.

The exact reason why you have been prescribed Vepesid Capsules is best discussed with your doctor.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE VEPESID

DO NOT take Vepesid:

- If you are allergic to etoposide or any of the other ingredients of this medicine (listed in section 6).
- If you suffer from severe liver problems.
- If you have recently been given a live vaccine, including Yellow fever vaccine.

If any of the above affects you, or if you are unsure if they do, tell your doctor who will be able to advise you.

Warnings and precautions

Talk to your doctor or pharmacist before taking Vepesid

- if you have any **infections**
- if you have had **radiotherapy or chemotherapy** recently
- if you have low levels of a protein called **albumin** in your blood

Effective anti-cancer treatment can destroy cancer cells rapidly in large numbers. On very rare occasions this may cause harmful amounts of substances from these cancer cells to be released into the blood. If

this happens it can cause problems with the liver, kidney, heart or blood, which may result in death if not treated.

In order to prevent this, your doctor will need to do regular blood tests to monitor the level of these substances during treatment with this medicine.

This medicine can cause a reduction in the level of some blood cells, which could cause you to suffer from infections, or may mean that your blood doesn't clot as well as it should if you cut yourself. Blood tests will be taken at the start of your treatment, and before each dose you take, to make sure that this isn't happening.

If you have reduced liver or kidney function, your doctor may also want you to take regular blood tests to monitor these levels.

This product contains propyl parahydroxybenzoate which may cause allergic reactions (possibly delayed).

Children and Adolescents

Use of Etopophos in children under the age of 12 years old is not currently recommended

Other medicines and Vepesid

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This is especially important:

- If you are taking a medicine called ciclosporin (a drug used to reduce the activity of the immune system).
- If you are taking cisplatin (a medicine used to treat cancer)
- If you are taking phenytoin (a medicine used to treat epilepsy)
- If you are taking warfarin (a medicine used to prevent blood clots from forming)
- If you have recently been given any live vaccines
- If you are taking phenylbutazone, sodium salicylate, or aspirin
- If you are taking any anthracyclines (a group of medicines used to treat cancer)
- If you are taking any drugs with a similar mechanism of action as Vepesid

Vepesid with alcohol

Vepesid is not known to react with alcohol, however, you should speak to your doctor to find out if it is advisable for you to drink alcohol.

Pregnancy, breastfeeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Vepesid must not be used during pregnancy unless clearly indicated by your doctor.

You must not breastfeed while you are taking Vepesid.

Both male patients and female patients of child-bearing age should use an effective contraceptive method (e.g., the barrier method or condoms) during treatment and for at least 6 months after the end of treatment with Vepesid.

Male patients treated with Vepesid are advised not to father a child during treatment and for up to 6 months after treatment. In addition, men are advised to seek counselling on sperm preservation before starting treatment.

Both male and female patients who are considering having a child after having treatment with Vepesid should discuss this with their doctor or nurse.

Driving and using machines

Vepesid capsules should not affect your ability to drive or use machines. However, if you feel dizzy or light-headed you should not do so until you have discussed it with your doctor.

3. HOW TO TAKE VEPESID

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The dose you receive will be specific to you, which the doctor will calculate. The usual dose is 120-240mg/m² body surface area, daily for 5 days in a row. The dose may sometimes be split to be taken morning and evening.

The doctor may sometimes prescribe a different dose.

The capsules should be taken with a glass of water on an empty stomach.

This course of treatment may then be repeated, depending on the results of blood tests, but this will not be for at least 21 days after the first course of treatment.

If you take more Vepesid than you should

If you take too many tablets, go to your nearest hospital emergency department or tell your doctor immediately. Take the empty container and any remaining capsules with you.

If you forget to take Vepesid

If you miss or forget to take a dose of this medicine, DO NOT WORRY – just take the next dose when it is due. DO NOT take a double dose to make up for the forgotten dose.

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

4. POSSIBLE SIDE EFFECTS

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

Stop taking the medicine and tell your doctor immediately if you get any of the following symptoms: swelling of your tongue or throat, breathing difficulties, fast heartbeat, flushing of the skin or a rash. These may be signs of an allergic reaction.

Severe **liver, kidney or heart damage** from a condition called Tumour Lysis Syndrome, caused by harmful amounts of substances from the cancer cells getting into the blood stream, has been seen sometimes when Vepesid is taken along with other drugs used to treat cancer.

Possible side effects experienced with Vepesid are;

- blood disorders (this is why you will be having blood tests between courses of treatment)
- temporary hair loss
- nausea and vomiting
- abdominal pain
- loss of appetite
- changes in skin colour (pigmentation)
- constipation
- feeling weak (asthenia)
- generally feeling unwell (malaise)

- damage to the liver (hepatotoxicity)
- acute leukaemia
- irregular heart beat (arrhythmia), or a heart attack (myocardial infarction)
- dizziness
- diarrhoea
- high or low blood pressure
- sore lips, mouth or throat ulcers
- acid reflux
- skin problems such as itching or rash
- tingling or numbness in hands and feet
- flushing
- difficulty swallowing
- a change in the way things taste
- convulsions (seizure)
- fever
- sleepiness or tiredness
- breathing problems
- temporary blindness
- serious reactions of the skin and/or mucous membranes which may include painful blisters and fever, including extensive detachment of the skin (Stevens-Johnson syndrome and toxic epidermal necrolysis)
- a sunburn-like rash that may occur on skin that has previously been exposed to radiotherapy and can be severe (radiation recall dermatitis)

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 (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

United Kingdom

Yellow Card Scheme

Website: www.mhra.gov.uk/yellowcard

Ireland

Pharmacovigilance Section

Irish Medicines Board

Kevin O'Malley House

Earlsfort Centre

Earlsfort Terrace

IRL - Dublin 2

Tel: +353 1 6764971

Fax: +353 1 6767836

Website: www.imb.ie

e-mail: imbpharmacovigilance@imb.ie

5. HOW TO STORE VEPESID

Keep your medicines out of the sight and reach of children.

Do not store Vepesid capsules above 25°C

Vepesid capsules should not get too hot or damp; so do not leave your capsules near a radiator, on a window sill or in the bathroom.

Please check the expiry date of the product, shown on the blister strip and the outer packaging after EXP. The expiry date refers to the last day of that month. Do not use after the month stated.

Do not open any blister in which there is evidence of capsule leakage.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Vepesid contains

Each soft capsule contains etoposide (either 50 mg or 100 mg) as the active ingredient. In addition, Vepesid capsules contain the following ingredients: citric acid, glycerol, macrogol 400 and water; capsules containing gelatin, glycerol, iron oxide (E172), sodium hydroxybenzoic acid ethyl ester, sodium propyl parahydroxybenzoate (E217), titanium dioxide (E171) and water.

What Vepesid looks like and contents of the pack

Vepesid capsules are opaque pink, soft gelatin capsules.

The 50 mg capsules are packed in cartons of 20 capsules, and the 100 mg capsules are packed in cartons of 10 capsules.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

U.K.

Bristol-Myers Squibb Holdings Limited
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Ireland

Bristol-Myers Squibb Holdings Limited
t/a Bristol-Myers Pharmaceuticals
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Ireland.
Tel: 1 800 749 749

Manufacturer

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04013 Sermoneta
Latina, Italy

This leaflet was last revised in: February 2016