Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about VEPESID. 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 taking VEPESID against the benefits they expect it will have for you.

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

Keep this leaflet.

You may need to read it again.

What VEPESID is used for

VEPESID is used to treat lung cancer, leukaemia (blood cancer) and cancer of the lymph glands.

VEPESID contains ETOPOSIDE, an anti-cancer medicine. It interferes with the development of cells and causes cell death, particularly in cancer cells.

VEPESID may be used alone or in combination with other medicines to treat cancer. Your doctor will inform you if this is necessary.

Your doctor may have prescribed VEPESID for another reason. Ask your doctor if you have any questions about why VEPESID was prescribed for you.

Before you are given VEPESID

When you must not be given it

Do not take VEPESID if you have an allergy to VEPESID, or any of the ingredients listed at the end of this leaflet, unless you have discussed it with your doctor.

Symptoms of an allergic reaction may include:

- chills/fever
- fast heart beat
- difficulty in breathing, shortness of breath
- · dizziness or lightheadedness

Do not take VEPESID if you have, or have had any of the following medical conditions, unless you have discussed it with your doctor:

- · liver problems
- kidney problems
- your immune system is not working properly (you get a lot of infections requiring treatment with antibiotics)
- a blood disorder with a reduced number of white blood cells
- a blood disorder in which there is a decreased number of red blood cells
- a blood disorder with a low blood platelet count
- lowered immunity due to treatment with medicines such as corticosteroids, cyclosporin or other medicines used to treat cancer

Tell your doctor if you have an infection or high temperature.

Your doctor may decide to delay your treatment until the infection has gone.

Do not take VEPESID if you have had recent surgery.

Do not take VEPESID if you are receiving radiation therapy or any other medicine, which lowers your immune system.

Do not take VEPESID if you are pregnant or intend to become pregnant.

Like most medicines used to treat cancer, VEPESID is not recommended for use during pregnancy, unless you and your doctor have discussed the risks and benefits involved.

You should use some kind of birth control while you are having VEPESID and for at least 12 weeks after you stop using it.

VEPESID may cause birth defects if either the male or female is using it at the time of conception.

Do not breastfeed while having VEPESID, unless you have discussed it with your doctor.

It is not known whether VEPESID passes into breast milk. Therefore there is a possibility that the breast-fed baby may be affected.

If you have not told your doctor about any of the above, tell them before you start VEPESID.

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

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 have or have had any medical conditions, especially the following:

- · liver problems
- kidney problems
- a blood disorder with a reduced number of white blood cells
- a blood disorder in which there is a decreased number of red blood cells
- a blood disorder with a low blood platelet count
- lowered immunity due to treatment with medicines such as corticosteroids, cyclosporin or other medicines used to treat cancer
- lowered immunity due to treatment with medicines such as corticosteroids, cyclosporin or other medicines used to treat cancer (including radiation therapy)

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

Tell your doctor if you are breast-feeding or plan to breastfeed.

If you have not told your doctor about any of the above, tell them before you start taking VEPESID.

Taking other medicines

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

Some medicines and VEPESID may interfere with each other. These include:

- Some other medicines that are used to treat other forms of cancer
- Cyclosporin a medicine used to prevent rejection of transplanted organs

These medicines may be affected by VEPESID, or affect how well it works. You may need different amounts of your medicine, or you may need to have different medicines. Your doctor will advise you.

Your doctor may have more information on medicines to be careful with or avoid while taking VEPESID.

How VEPESID is given

How much is given

Your doctor will decide what dose you will receive. Your dose of VEPESID capsules are worked out based on your body weight and height and on the type of cancer you have. The dose worked out for you may be different to the dose for another patient.

VEPESID may be given alone or in combination with other anti-cancer drugs.

Several courses of VEPESID therapy may be needed depending on your response to treatment.

Additional treatment may not be repeated until your blood cell numbers return to acceptable levels and any uncontrolled effects have been controlled

Ask your doctor if you want to know more about the dose of VEPESID you receive.

How it is given

VEPESID capsules may be given to you at the hospital or surgery or you may take them yourself at home. You must only take VEPESID capsules with water preferably on an empty stomach.

If you forget to take VEPESID capsules

If you are taking VEPESID capsules at home and you forget to take a dose - if it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Otherwise, take it as soon as you remember, and then go back to taking your medicine as you would normally.

Do not take a double dose to make up for the dose that you missed.

This may increase the chance of you getting an unwanted side effect.

How long it is given

VEPESID is usually given each day for 5 days. This is followed by a treatment-free interval of 2-4 weeks. This is called one cycle of chemotherapy. Your doctor will decide how many of these cycles you will need. VEPESID may be given at the same time as other anticancer agents, or may be given alone.

Overdose

Immediately telephone your doctor or pharmacist or the Poisons Information Centre (telephone 13 11 26) or go to Accident or Emergency at your nearest hospital, if you think that you or someone else may have taken too many VEPESID capsules.

Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention

Symptoms of overdose may include collapse, kidney failure, liver failure, failure of the immune system, and continuing nausea and/or vomiting.

While you are using VEPESID

Things you must do

Be sure to keep all your doctor's appointments so your progress can be checked.

Your doctor may want to check your blood pressure and do some blood and other tests from time to time to check on your progress and detect any unwanted side effects.

Keep follow up appointments with your doctor It is important to have your follow-up infusions of VEPESID at the appropriate time to get the best effect from your treatments.

If you forget an appointment, contact your doctor immediately.

Tell any other doctors, dentists and pharmacists who are treating you that you are taking VEPESID.

If you are about to be started on any new medicine, tell your doctor, dentist or pharmacist that you are taking VEPESID.

If you plan to have surgery that needs a general anaesthetic, tell your doctor or dentist that you are taking VEPESID.

If you become pregnant while taking VEPESID, tell your doctor.

VEPESID can lower the number of white blood cells and platelets in your blood. This means that you have an increased chance of getting an infection or bleeding. The following precautions should be taken to reduce your risk if infection or bleeding:

- Avoid people who have infections. Check with you doctor immediately if you think you may be getting an infection, or if you get a fever, chills, cough, hoarse throat, lower back or side pain or find it painful or difficult to urinate.
- Be careful when using a toothbrush, toothpick or dental floss. Your doctor, dentist, nurse or pharmacist may recommend other ways to clean your teeth and gums. Check with your doctor before having any dental work.
- Be careful not to cut yourself when you are using sharp objects such as a razor or nail cutters.
- Avoid contact sports or other situations where you may bruise or get injured.

Things you must not do

Do not give VEPESID to anyone else, even if they have the same condition as you.

Do not take VEPESID to treat any other complaints unless your doctor tells you to.

Do not stop taking VEPESID, or lower the dose, without checking with your doctor.

Things to be careful of

Be careful driving or operating machinery until you know how VEPESID affects you.

As with other medicines used to treat cancer, VEPESID may cause dizziness, light-headedness or tiredness in some people. Make sure you know how you react to VEPESID before you drive a car, operate machinery, or do anything else that could be dangerous if you are dizzy or light-headed. If this occurs do not drive. If you drink alcohol, dizziness or light-headedness may be worse.

Side effects

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

Like other medicines that treat cancer, VEPESID may have unwanted side effects, some of which may be serious. You may need medical treatment if you get some of the side effects.

Ask your doctor to answer any questions you may have.

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

These are the more common side effects of VEPESID.

- nausea, vomiting, diarrhoea, constipation, stomach pain or discomfort
- · loss of appetite, aftertaste
- sore mouth, problems swallowing
- unusual hair loss or thinning
- dizzines
- feeling tired or down,
- · rash, itchy skin, discolouration of skin

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

These may be serious side effects. You may need medical attention.

- itching of the skin, joint aches, blisters that look like hives on the upper body, legs, arms, palms, hands, or feet and may involve the face or lips
- · sore mouth, eye pain, vision problems
- frequent infections such as fever, severe chills, sore throat and mouth ulcers
- bleeding or bruising more easily than normal, nose bleeds, rash of small reddish-purple spots on your skin), blood in your stool or urine
- tiredness, headaches, being short of breath when exercising, dizziness and looking pale
- numbness, tingling and pain in hands or feet
- pain in lungs, shortness of breath or change in breathing, cough, unusual tiredness
- heart problems (e.g. fast heartbeat)
- ceizures
- nausea, vomiting, diarrhoea, abdominal pain, loss of appetite with yellowing of the skin and eyes, bleeding, fatigue, weakness, confusion
- passing little or no urine

Tell your doctor immediately, or go to accident and emergency at your nearest hospital if you notice any of the following signs of a sudden life-threatening allergic reaction:

 chills, fever, fast heart beat, wheezing or coughing, difficulty breathing, dizziness, flushing, sweating and swelling of the face, tongue or other parts of the body.

Other side effects not listed above may occur in some patients. Tell your doctor or nurse if you notice anything that is making you feel unwell.

After using VEPESID

The benefits and side effects of VEPESID may take some time to occur. Therefore even after you have finished your VEPESID treatment you should tell your doctor immediately if you notice any of the side effects listed in the previous section.

Storage

VEPESDID capsules should be stored below 25°C

Do not store VEPESID capsules or any other medicine in the bathroom or near a sink.

Do not leave them in the car on a hot day or on window sills.

Heat or dampness can destroy some medicines.

Keep VEPESID capsules where children cannot reach them.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Product description

What it looks like

VEPESID CAPSULES are pink oblong capsules, in either 50mg or 100mg strengths. VEPESID 50mg capsules are supplied in blister packs of either 10 or 20 capsules. VEPESID 100mg capsules are supplied in blister packs of 10 capsules.

Ingredients

CAPSULES:

Active: The active ingredient in VEPESID capsules is etoposide.

Each capsule either contains 50mg of etoposide or 100mg of etoposide.

Inactive: Each capsule also contains citric acid, glycerol, macrogol 400 gelatin, parabens, titanium dioxide & iron oxide pigment.

Sponsored by

Bristol-Myers Squibb Australia Pty Ltd,

4 Nexus Court, Mulgrave, Victoria 3170. Australia

Australian Registration Numbers:

- VEPESID Capsules 100mg AUST R 10234
- VEPESID Capsules 50mg AUST R 10233

Date of Preparation: November 2012

Further Information

Your doctor is the best person to answer any further questions you may have about VEPESID. You should follow any instructions given by your doctor.

Please note that knowledge about the safety of all medicines may change over time. You should discuss any problems you experience with VEPESID at any time with your doctor.

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