Package leaflet: Information for the user

Etomedac 20 mg/ml, concentrate for solution for infusion
Etoposide

Read all of this leaflet carefully before you start using 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.
- If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Etomedac is and what it is used for

The name of this medicine is Etomedac. Each vial contains etoposide 100 mg or 500 mg as the active ingredient.

Etoposide belongs to the group of medicines called cytostatics which are used in the treatment of cancer.

Etomedac is used in the treatment of certain types of cancers in adults:
- testicular cancer
- small cell lung cancer
- cancer of the blood (acute myeloid leukaemia)
- tumour in the lymphatic system (Hodgkin's lymphoma, non-Hodgkin's lymphoma)
- reproductive system cancers (gestational trophoblastic neoplasia and ovarian cancer)

Etomedac is used in the treatment of certain types of cancers in children:
- cancer of the blood (acute myeloid leukaemia)
- tumour in the lymphatic system (Hodgkin's lymphoma, non-Hodgkin's lymphoma)

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

2. What you need to know before you use Etomedac

Do not use Etomedac
- if you are allergic to etoposide or any of the other ingredients of this medicine (listed in section 6).
- if you have recently been given a live vaccine, including yellow fever vaccine.
- if you are breast-feeding or planning to breast-feed.

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, pharmacist or nurse before receiving Etomedac
- if you have any infections.
- if you have recently received radiotherapy or chemotherapy.
- if you have low levels of a protein called albumin in your blood.
- if you have liver or kidney problems.

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 does not 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 is not happening.

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

Other medicines and Etomedac
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 medicinal product used to reduce the activity of the immune system).
- if you are being treated with cisplatin (a medicine used to treat cancer).
- if you are taking phenytoin or any other medicines 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 (pain killers).
- if you are taking any anthracyclines (a group of medicines used to treat cancer).
- if you are taking any medicinal products with a similar myelosuppressive action (inhibiting bone marow activity) as etoposide.

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 or pharmacist for advice before taking this medicine.
Both male and female patients who are considering having a child after having treatment with Etomedac should discuss this with their doctor or nurse.

Contraception in men and women
Both male patients and female patients of reproductive age should use an effective contraceptive method (e.g. the barrier method or condoms) during treatment with Etomedac and for at least 6 months after treatment.

Pregnancy

Etoposide is suspected to cause serious birth defects when used during pregnancy. Etomedac must not be used during pregnancy unless clearly indicated by your doctor.

Breast-feeding
You must not breast-feed while you are receiving etoposide. Do not restart breast-feeding until your doctor tells you it is safe to do so.

Fertility in men
Male patients treated with Etomedac 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 since etoposide can cause infertility.

Driving and using machines
No studies on the effects on the ability to drive and use machines have been performed.
The amount of alcohol in this medicine may impair your ability to drive or use machines after a course of treatment.
In general, if you feel tired, sick to your stomach, dizzy or light-headed you should not drive or use machines until you have discussed it with your doctor.

Etomedac contains alcohol and polysorbate 80
This medicinal product contains 33 vol % ethanol (alcohol), i.e. 262 mg per ml. With a dose of 120 mg/m², 2.7 g ethanol is applied to a patient with a body surface of 1.73 m², equivalent to 68 ml beer, 28 ml wine per dose. Harmful for those suffering from alcoholism.
To be taken into account in pregnant or breast-feeding women, children and high-risk groups such as patients with liver disease, or epilepsy.
The amount of alcohol in this medicinal product may have effects on the central nervous system (the part of the nervous system that includes the brain and spinal cord).
The amount of alcohol in this medicinal product may alter the effects of other medicines.

Etomedac contains polysorbate 80. In premature infants a life-threatening syndrome of liver and kidney failure, pulmonary deterioration, reduced formation of platelets and accumulation of fluid in the peritoneal cavity has been associated with an injectable vitamin E product containing polysorbate 80.

3. How you will be given Etomedac

Etoposide will be given to you by a doctor or nurse. It will be given as a slow infusion into a vein. This may take between 30 to 60 minutes.

The dose you receive will be specific to you, which the doctor will calculate. The usual dose, based on etoposide, is 50 to 100 mg/m² body surface area, daily for 5 days in a row or 100 to 120 mg/m² body surface area on days 1, 3 and 5. 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.

For children being treated for cancer of the blood or lymphatic system the dose used is 75 to 150 mg/m^2 body surface area daily for 2 to 5 days.

The doctor may sometimes prescribe a different dose particularly if you are receiving, or have received, other treatments for your cancer or if you have kidney problems.

If you are given more Etomedac than you should
As etoposide is given to you by a doctor or nurse, overdose is unlikely. However, if this does occur your doctor will treat any symptoms that follow.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

Contamination with Etomedac
If etoposide comes into contact with skin or mucosa, immediately wash the skin or mucosa thoroughly with soap and water.

4. Possible side effects

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

Tell your doctor or nurse 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 a severe 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 etoposide is taken along with other drugs used to treat cancer.

Possible side effects experienced with etoposide that are;

Very common (may affect more than 1 in 10 people)
- 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)
- increased liver enzymes
- jaundice (increased bilirubin)

Common (may affect up to1 in 10 people)
- acute leukaemia
- irregular heart beat (arrhythmia), or a heart attack (myocardial infarction)
- dizziness
- diarrhoea
- reactions at the site of infusion
- severe allergic reactions
- high blood pressure
- low blood pressure
- sore lips, mouth or throat ulcers
- skin problems such as itching or rash
- inflammation of a vein
- infection (including infections seen in patients with a weakened immune system, e.g. a lung infection called *pneumocystis jirovecii* pneumonia)

Uncommon (may affect up to 1 in 100 people)
- tingling or numbness in hands and feet
- bleeding

Rare (may affect up to 1 in 1,000 people)
- acid reflux
- flushing
- difficulty swallowing
- a change in the way things taste
- severe allergic reactions
- 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)

Not known (frequency cannot be estimated from the available data)
- tumour lysis syndrome (complications of substances released from treated cancer cells entering the blood)
- face and tongue swelling
- infertility
- difficulty breathing

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 via the national reporting system listed in Appendix V. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Etomedac

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 label and carton.

Do not refrigerate or freeze.

Once opened, the product is chemically and microbiologically stable for five days.
The diluted product (0.2 mg/ml) should be used immediately.

Do not use this medicine if you notice crystal formation in the diluted product.

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 Etomedac contains
- The active substance is etoposide.
  1 ml concentrate contains 20 mg etoposide.
- 1 vial of 5 ml concentrate for solution for infusion contains 100 mg etoposide.
- 1 vial of 25 ml concentrate for solution for infusion contains 500 mg etoposide.
- The other ingredients are citric acid (anhydrous) (E330), polysorbate 80, macrogol 300 and ethanol.

What Etomedac looks like and contents of the pack
Etomedac is a clear, yellowish liquid.
Etomedac is available in packs of 1 vial with 5 ml or 25 ml.

Marketing Authorisation Holder and Manufacturer
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This medicine is authorised in the Member States of the European Economic Area and in the United Kingdom (Northern Ireland) under the following names:

Germany	Etomedac 20 mg/ml Konzentrat zur Herstellung einer Infusionslösung
Netherlands	Etomedac 20 mg/ml, concentraat voor oplossing voor infusie
United Kingdom (Northern Ireland)	Etoposide 20 mg/ml concentrate for solution for infusion

This leaflet was last revised in January 2024.

The following information is intended for healthcare professionals only:

Handle according to guidelines for cytotoxics.
Cytotoxics should not be handled by pregnant personnel.

Only for intravenous use.
Unused solution should be discarded.
The concentrate for solution for infusion must be diluted.
Etomedac should only be diluted with sodium chloride 9 mg/ml (0.9 %) solution for injection or 5 % glucose solution. The concentration of etoposide in the reconstituted solution for infusion should not exceed 0.4 mg/ml due to the risk of precipitation.
This medicinal product must not be mixed with other medicinal products except the above mentioned solutions.
Only clear solutions practically free from particles should be used.

As with other potentially cytotoxic compounds caution should be exercised when handling etoposide (gloves, mask, overall). Contact with skin and mucosa should be avoided.

If etoposide comes into contact with skin or mucosa, immediately wash the skin or mucosa thoroughly with soap and water.

Syringes, containers, absorbent materials, solution and any other contaminated material should be placed in a designated impervious container and incinerated, in accordance with local procedures. Any unused medicinal product or waste material should be disposed of in accordance with local requirements.