

ETOPOSIDE SOFT CAPSULES

50 MG AND 100 MG

Package leaflet:

Information for the patient

Etoposide 50 mg and 100 mg Soft Capsules

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 Etoposide Capsules is and what it is used for
2. What you need to know before you take Etoposide Capsules
3. How to take Etoposide Capsules
4. Possible side effects
5. How to store Etoposide Capsules
6. Contents of the pack and other information

1. WHAT ETOPOSIDE CAPSULES IS AND WHAT IT IS USED FOR

The name of this medicine is Etoposide Capsules. Each capsule contains etoposide 50 mg or 100 mg as the active ingredient.

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

Etoposide Capsules 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)
- ovarian cancer

The exact reason why you have been prescribed ETOPOSIDE CAPSULES capsules is best discussed with your doctor.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE ETOPOSIDE CAPSULES

Do not take Etoposide Capsules:

- 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 or pharmacist before taking Etoposide Capsules 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.
- 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

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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.

Children and adolescents

The safety and effectiveness in paediatric patients has not been established

Other medicines and Etoposide Capsules

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 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
- 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 Etoposide Capsules

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.

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

You must not breastfeed while you are taking Etoposide Capsules.

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 Etoposide Capsules.

Male patients treated with Etoposide Capsules 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 Etoposide Capsules should discuss this with their doctor or nurse.

Driving and using machines

No studies on the effects on the ability to drive and use machines have been performed. However, if you feel tired, sick to your stomach, dizzy or light-headed you should not do so until you have discussed it with your doctor.

3. HOW TO TAKE ETOPOSIDE CAPSULES

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 100 to 200 mg/m² body surface area, daily for 5 days in a row or 200 mg/m² body surface area on days 1, 3 and 5.

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The daily dose may sometimes be split to be taken morning and evening. 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.

An alternative dosing of 50 mg/m² body surface area taken each day for 2 to 3 weeks is sometimes used. This course of treatment may then be repeated, depending on the results of blood tests, but this will not be for at least 7 days after the first course of treatment.

The doctor may sometimes prescribe a different dose particularly if you have kidney problems.

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

If you take more Etoposide Capsules than you should

If you take too many capsules, 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 Etoposide Capsules

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 Etoposide Capsules is taken along with other drugs used to treat cancer.

Other side effects experienced with Etoposide Capsules that are;

Very common side effects (affecting 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)

Common side effects (affecting between 1 in 10 and 1 in 100 people)

- acute leukaemia
- irregular heart beat (arrhythmia), or a heart attack (myocardial infarction)
- dizziness
- diarrhoea
- high blood pressure
- sore lips, mouth or throat ulcers
- skin problems such as itching or rash

Uncommon side effects (affecting between 1 in 100 and 1 in 1000 people)

- tingling or numbness in hands and feet

Rare side effects (affecting between 1 in 1,000 and 1 in 10,000 people)

- acid reflux
- flushing
- difficulty swallowing
- a change in the way things taste
- severe allergic reactions
- convulsions (seizure)
- fever

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- 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)
- infection
- face and tongue swelling
- infertility
- bleeding
- difficulty breathing
- increased liver enzymes
- increased bilirubin

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 (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

5. HOW TO STORE ETOPOSIDE CAPSULES

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

Do not use this medicine after the expiry date which is stated on the carton and blister after

EXP. The expiry date refers to the last day of that month.

Do not store above 25°C.

Store in the original package.

Etoposide 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.

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

As with all medicines used to treat cancer, care must be taken when handling Etoposide Capsules. You should avoid touching the capsules by wearing gloves and wash your hands with soap and water after handling the medicine.

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 FURTHER INFORMATION

What Etoposide Capsules contain

- The active substance is etoposide. Each capsule contains 50 mg or 100 mg etoposide.

The other ingredients are: citric acid, anhydrous (E330), glycerol (85 per cent) (E422), macrogol 400 (E1521) and water. The capsule shell contain gelatin (E441), glycerol (85 per cent) (E422), red iron oxide (E172), sodium ethyl parahydroxybenzoate (E215), sodium propyl parahydroxybenzoate (E217) and titanium dioxide (E171).

What Etoposide Capsules look like and contents of the pack

Opaque, pink capsules, softgels.

The 50 mg capsules are supplied in blister packs of 20, 50 Capsules, softgels.

The 100 mg capsules are supplied in blister packs of 10, 60 Capsules, softgels.

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Not all pack sizes may be marketed.

Manufactured by:

Taj Pharmaceuticals Limited

220, Mahagujarat Ind. Estate, Moraiya, Tal.
Sanand, Dist. Ahmedabad, Gujarat, INDIA

Marketing Authorization

Holder:

Regal sun co., Ltd.Myanmar