Package leaflet: Information for the user

Topotecan medac 1 mg/ml concentrate for solution for infusion
Topotecan

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.
- 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 Topotecan medac is and what it is used for

Topotecan medac helps to destroy tumours. A doctor or a nurse will give you the medicine as an infusion into a vein in hospital.

Topotecan medac is used to treat
- **ovarian cancer or small cell lung cancer** that has come back after chemotherapy.
- **advanced cervical cancer** if surgery or radiotherapy treatment is not possible. When treating cervical cancer, Topotecan medac is combined with another medicine called cisplatin.

Your doctor will decide with you whether Topotecan medac therapy is better than further treatment with your initial chemotherapy.

2. What you need to know before you are given Topotecan medac

You will not be given Topotecan medac
- if you are allergic to topotecan or any of the other ingredients of this medicine (listed in section 6).
- if you are breast-feeding.
- if your blood cell counts are too low. Your doctor will tell you whether this is the case, based on the results of your last blood test.

Tell your doctor if any of these applies to you.

Warnings and precautions
Talk to your doctor before you are given Topotecan medac
- if you have any kidney or liver problems. Your dose of Topotecan medac may need to be adjusted.
- if you are pregnant or plan to become pregnant. See section “Pregnancy, breast-feeding and fertility” below.
- if you plan to father a child. See section “Pregnancy, breast-feeding and fertility” below.

Tell your doctor if any of these applies to you.

Other medicines and Topotecan medac
Tell your doctor if you are taking, have recently taken, or might take any other medicines, including any herbal products or medicines obtained without a prescription.

Remember to tell your doctor if you start to take any other medicines while you are on Topotecan medac.

Pregnancy, breast-feeding and fertility
Topotecan medac is not recommended for pregnant women. It may harm the baby if conceived before, during or soon after treatment.
An effective method of contraception should be used. Ask your doctor for advice.
Women should take measures to avoid pregnancy during treatment and for at least 6 months after the end of the treatment.
Men should ensure that their partner will not become pregnant during treatment and for at least 3 months thereafter.
Genetic counselling is recommended for patients intending to have children after therapy.
Male patients, who may wish to father a child, should ask their doctor for family planning advice and about the possibility of sperm conservation prior starting treatment.
If your partner becomes pregnant during your treatment, tell your doctor immediately.

Do not breast-feed if you are being treated with Topotecan medac. Do not restart breast-feeding until the doctor tells you it is safe to do so.

Driving and using machines
Topotecan medac can make people feel tired. If you feel tired or weak, do not drive or use machines.

Topotecan medac contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per vial (1/2/4ml), that is to say essentially 'sodium-free'.

3. How Topotecan medac is given

The dose of Topotecan medac you are given will be worked out by your doctor, based on
- your body size (surface area measured in square metres).
- the results of blood tests carried out before treatment.
- the disease being treated.

The recommended dose is:
- **Ovarian and small cell lung cancer:** 1.5 mg per square metre of body surface area per day. You will have treatment once a day for 5 days. This pattern of treatment will normally be repeated every 3 weeks.
- **Cervical cancer:** 0.75 mg per square metre of body surface area per day. You will have treatment once a day for 3 days. This pattern of treatment will normally be repeated every 3 weeks.
  When treating cervical cancer, Topotecan medac is combined with another medicine, called cisplatin. Your doctor will determine the correct dose of cisplatin.

The treatment may vary, depending on the results of your regular blood tests.

How Topotecan medac is given
A doctor or nurse will administer Topotecan medac as an infusion into your arm lasting about 30 minutes.

4. Possible side effects

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

Serious side effects – tell your doctor
These **very common** side effects may affect **more than 1 in 10 people** treated with Topotecan medac:
- **Signs of infections:** Topotecan medac may reduce the number of white blood cells and lower your resistance to infection. This can even be life threatening. Signs include:

- fever
- serious deterioration of your general condition
- local symptoms such as sore throat or urinary problems (for example, a burning sensation when urinating, which may be a urinary infection)

• Occasionally severe stomach pain, fever and possibly diarrhoea (rarely with blood) can be signs of bowel inflammation (colitis).

This **rare** side effect may affect **up to 1 in 1,000 people** treated with Topotecan medac:

• **Lung inflammation** (interstitial lung disease): You are most at risk if you have existing lung disease, have had radiation treatment to your lungs, or have previously taken medicines that caused lung damage. Signs include:
  - difficulty in breathing
  - cough
  - fever

Tell your doctor immediately if you get any symptoms of these conditions, as hospitalisation may be necessary.

Very common side effects: may affect **more than 1 in 10 people**

• Feeling generally weak and tired (temporary anaemia). In some cases you may need a blood transfusion.
• Unusual bruising or bleeding, caused by a decrease in the number of clotting cells in the blood. This can lead to severe bleeding from relatively small injuries such as a small cut. Rarely, it can lead to more severe bleeding (haemorrhage). Talk to your doctor for advice on how to minimise the risk of bleeding.
• Weight loss and loss of appetite (anorexia); tiredness; weakness.
• Feeling sick (nausea), being sick (vomiting); diarrhoea; stomach pain; constipation.
• Inflammation and ulcers of the mouth, tongue, or gums.
• High body temperature (fever).
• Hair loss.

Common side effects: may affect **up to 1 in 10 people**

• Allergic or hypersensitivity reactions (including rash).
• Yellow skin.
• Feeling unwell.
• Itching sensation.

Rare side effects: may affect **up to 1 in 1,000 people**

• Severe allergic or anaphylactic reactions.
• Swelling caused by fluid build-up (angioedema).
• Mild pain and inflammation at the site of injection.
• Itchy rash (or hives).

Side effects with frequency not known: frequency cannot be estimated from the available data

• Severe stomach pain, nausea, vomiting of blood, black or bloody stools (possible symptoms of gastrointestinal perforation).
• Mouth sores, difficulty swallowing, abdominal pain, nausea, vomiting, diarrhoea, bloody stools (possible signs and symptoms of inflammation of the inner lining of the mouth, stomach and/or gut [mucosal inflammation]).

If you are being treated for cervical cancer, you may get side effects from the other medicine (cisplatin) that you will be given along with Topotecan medac. Those effects are described in the cisplatin patient leaflet.

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 Topotecan medac

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 carton.

Keep the vial in the outer carton in order to protect from light.

Store in a refrigerator (2 °C – 8 °C).

6. Contents of the pack and other information

What Topotecan medac contains
- The active substance is topotecan. Each vial contains topotecan hydrochloride equivalent to 1 mg, 2 mg or 4 mg of topotecan.
- The other ingredients are: water for injections, hydrochloric acid and sodium hydroxide.

What Topotecan medac looks like and contents of the pack
Topotecan medac is a concentrate for solution for infusion.
It is available in packs containing either 1 or 5 vials; each vial contains 1 mg, 2 mg or 4 mg of topotecan.
The concentrate needs to be diluted before infusion.
The concentrate in the vial provides 1 mg per ml of active substance.

Marketing Authorisation Holder and Manufacturer

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The following information is intended for healthcare professionals only:

Instructions on how to dilute, store, and dispose of Topotecan medac

Dilution
Further dilution of the appropriate volume of the concentrate with either 0.9 % w/v sodium chloride intravenous infusion or 5 % w/v glucose intravenous infusion is required to a final concentration of between 25 and 50 microgram/ml.

Shelf life after opening the container
Chemical and physical in-use stability has been demonstrated for 48 hours at 2 °C – 8 °C or at room temperature. From a microbiological point of view, unless the method of opening precludes the risk of microbiological contamination, the product should be used immediately. If not used immediately, in-use storage times and conditions are the responsibility of the user.

Shelf life after preparing the solution for infusion ready for use
Chemical and physical in-use stability has been demonstrated for 96 hours at 2 °C – 8 °C and for 48 hours at room temperature. From a microbiological point of view, the product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at 2 °C – 8 °C, unless dilution has taken place under controlled and validated aseptic conditions.

Handling and disposal
The normal procedures for proper handling and disposal of anticancer medicinal products should be adopted, namely:
- Pregnant staff should be excluded from working with this medicinal product.
- Personnel handling this medicinal product during dilution should wear protective clothing including mask, goggles and gloves.
- All items for administration or cleaning, including gloves, should be placed in high-risk, waste disposal bags for high-temperature incineration.
- Any unused product or waste material should be disposed of in accordance with local requirements.
- Accidental contact with the skin or eyes should be treated immediately with copious amounts of water.