Package leaflet: Information for the user

Topotecan Accord 1 mg/ml concentrate for solution for infusion
topotecan

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, pharmacist or nurse
- If you get any side effects, talk to your doctor, pharmacist, or nurse. This includes any possible side effects not listed in this leaflet See section 4.

What is in this leaflet

1. What Topotecan Accord is and what it is used for

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

Topotecan Accord 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 Accord is combined with another medicine called cisplatin.

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

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

You should not receive Topotecan Accord:
- 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 or pharmacist or nurse before you are given this medicine:
- if you have any kidney or liver problems. Your dose of Topotecan Accord 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 Accord
Tell your doctor or pharmacist 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 Accord

Pregnancy, breast-feeding and fertility
Topotecan Accord is not recommended for pregnant women. It may harm a baby conceived before, during or soon after treatment. You should use effective contraceptive measures while being treated with Topotecan Accord and for 6 months following completion of treatment. Ask your doctor for advice. Do not try to become pregnant until a doctor advises you it is safe to do so.

Men are recommended to use effective contraceptive measures and to not father a child while receiving Topetecan Accord and for 3 months following completion of treatment Male patients who wish to father a child, should ask their doctor for family planning advice or treatment. If your partner becomes pregnant during your treatment, tell your doctor immediately.

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

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

Topotecan Accord contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially "sodium free".
If your doctor uses a solution of common salt to dilute Topotecan Accord, the dose of sodium received would be larger.

3. How to use Topotecan Accord

The dose of Topotecan Accord 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 usual dose
- **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 Accord is combined with another medicine, called cisplatin. Your doctor will determine the correct dose of cisplatin.

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

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

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 Accord

- **Signs of infections:** Topotecan Accord 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).

These **rare** side effects may affect **up to 1 in 1,000 people** treated with Topotecan Accord

- Severe allergic or anaphylactic reactions causing swelling of the lips, face or neck leading to severe difficulty in breathing, skin rash or hives, anaphylactic shock (a severe reduction in blood pressure, paleness, agitation, weak pulse, decreased consciousness.
- **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 breathing
    - cough
    - fever.

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

Very common side effects

These may affect **more than 1 in 10 people treated with** Topotecan Accord

- Feeling generally weak and tired (temporary anaemia). In some cases, you may need a blood transfusion.
- Abnormally low white blood cell count (neutropenia) which may be accompanied with fever and signs of infections (febrile neutropenia)
- 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

These may affect **up to 1 in 10 people** treated with Topotecan Accord

- Allergic or hypersensitivity reactions (including rash)
- Yellow skin
- Itching sensation
- Feeling unwell (malaise)
- Deficiency of all three cellular components (red cells, white cells, and platelets) of the blood (pancytopenia).

Rare side effects

These may affect up to 1 in 1,000 people treated with Topotecan Accord

- *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).

Very rare: (may affect up to 1 in 10,000 people)
- Discharge of blood into tissues (extravasation).

Side effects with frequency not known
The frequency of some side effects is not known (events from spontaneous reports and the 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, diarrhea, 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 Accord. Those effects are described in the cisplatin patient leaflet.

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via
HPRA Pharmacovigilance
Website: www.hpra.ie
By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Topotecan Accord

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 vial and carton after EXP. The expiry date refers to the last day of that month.

Store below 25°C.

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

This medicine is for single use only. After opening, the product should be used immediately for dilution.

Chemical and physical in-use stability after dilution has been demonstrated for 30 days at 25°C under normal light conditions and at 2-8°C when protected from light.

From a microbiological point of view, the product after dilution 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 24 hours at 2 to 8°C, unless dilution has taken place in controlled and validated aseptic conditions.

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

6. Contents of the pack and other information

What Topotecan Accord contains

- The active substance is topotecan hydrochloride.

Each 1 ml vial of concentrate contains 1 mg topotecan (as hydrochloride)
Each 4 ml vial of concentrate contains 4 mg topotecan (as hydrochloride)
- The other ingredients are: tartaric acid (E334), water for injections and hydrochloric acid (E507) or sodium hydroxide (for pH adjustment).

What Topotecan Accord looks like and contents of the pack

This medicine is a concentrate for solution for infusion.
The concentrate is a clear yellow colour solution. It is filled in an amber colour glass vial sealed with flurotec rubber stoppers and aluminium flip-off seals.

Each vial of 1 ml contains 1 mg topotecan (as hydrochloride).
Each vial of 4 ml contains 4 mg topotecan (as hydrochloride).

This medicine is available in two pack sizes, containing either 1 vial or 5 vials.

Not all pack sizes may be marketed.

Marketing Authorisation Holder:

Accord Healthcare Ireland Limited,
Euro House,
Euro Business Park,
Little Island,
Cork T45 K857,
Ireland

Manufacturer:

Accord Healthcare Polska Sp.z o.o.,
ul. Lutomierska 50,95-200 Pabianice, Poland

Accord Healthcare Single Member S.A.
64th Km National Road Athens, Lamia, Schimatari, 32009, Greece

This medicinal product is authorized in the member states of European Economic Area and in the United Kingdom (Northen Ireland) under the following names:

Name of the member state	**Name of the medicine**
United Kingdom (Northern Ireland)	Topotecan Accord 1 mg/ml Concentrate for Solution for Infusion
Austria	Topotecan Accord 1 mg/ml Konzentrat zur Herstellung einer Infusionslösung
Belgium	Topotecan Accord Healthcare 1 mg/ml Solution à Diluer pour Perfusion / concentraat voor oplossing voor infusie / Konzentrat zur Herstellung einer Infusionslösung
Bulgaria	Topotecan Accord 1 mg/ml Concentrate for Solution for Infusion
Cyprus	Topotecan Accord Healthcare 1 mg Concentrate for Solution for Infusion
Czech Republic	Topotecan Accord 1 mg/ml Koncentrát pro Přípravu Infuzního Roztoku
Germany	Topotecan Accord 1 mg/ml Konzentrat zur Herstellung einer Infusionslösung
Denmark	Topotecan Accord
Estonia	Topotecan Accord 1 mg/ml
Greece	Τοποτεκάνη Accord 1 mg / ml Πυκνό Διάλυμα για έγχυση
Spain	Topotecán Accord 1 mg/ml concentrado para solución para perfusión
Finland	Topotecan Accord 1 mg/ml Infuusiokonsentraatti, Liuosta Varten/koncentrat till infusionsvätska, lösning

France	Topotecan Accord 1 mg/ml Solution à Diluer pour Perfusion
Hungary	Topotecan Accord 1 mg/ml Concentrate for Solution for Infusion
Ireland	Topotecan Accord 1 mg/ml Concentrate for Solution for Infusion
Italy	Topotecan Accord
Latvia	Topotecan Accord 1 mg/ml koncentrāts infūziju šķīduma pagatavošanai
Lithuania	Topotecan Accord 1mg/ml koncentratas infuziniam tirpalui
Poland	Topotecanum Accord
The Netherlands	Topotecan Accord 1 mg/ml Concentraat voor Oplossing voor Infusie
Norway	Topotecan Accord 1 mg/ml Konsentrat til infusjonsvæke
Portugal	Topotecan Accord
Romania	Topotecan Accord 1 mg / ml concentrat pentru soluţie perfuzabilă.
Slovak Republic	Topotecan Accord 1 mg/ml concentrate for solution for infusion
Slovenia	Topotekan Accord 1 mg/ml koncentrat za raztopino za infundiranje
Sweden	Topotecan Accord 1 mg/ml Koncentrat till Infusionsvätska, Lösning

This leaflet was last revised in July 2025.

The following information is intended for medical or healthcare professionals only

Instructions on how to prepare, store and dispose of Topotecan Accord

Instructions for dilution
The concentrate is clear yellow colour solution and contains 1 mg per ml of Topotecan. Further dilution of the appropriate volume of the concentrate with sodium chloride 9 mg/ml, (0.9 %) solution for injection or glucose 50 mg/ml (5%) solution for injection to reach a final Topotecan concentration of between 25 and 50 microgram/ml in the solution for infusion.

Storage of the diluted solution
Chemical and physical in-use stability has been demonstrated for 30 days at 25°C under normal light conditions and at 2-8°C when protected from light. 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 24 hours at 2 to 8°C, unless dilution has taken place in controlled and validated aseptic conditions.

Handling and disposal
The normal procedures for proper handling and disposal of anti-tumour medicinal products should be adopted:

- Staff should be trained to dilute the medicinal product.
- Pregnant staff should be excluded from working with this medicinal product.
- Staff 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.
- Accidental contact with the skin or eyes should be treated immediately with copious amounts of water.