PACKAGE LEAFLET: INFORMATION FOR THE USER

Topotecan 4 mg powder for concentrate for solution for infusion

topotecan

Read all of this leaflet carefully before you start using this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor.
- If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor.

In this leaflet:

1. What Topotecan is and what it is used for

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

Topotecan 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 is combined with another drug called cisplatin.

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

2. Before you are given Topotecan

You should not receive Topotecan:

- **if you are allergic** *(hypersensitive)* to topotecan or any of the other ingredients of Topotecan.
- **if you are breast feeding**
- **if your blood cell counts are too low.** Your doctor will tell you, based on the results of your last blood test.

→**Tell your doctor** if any of these applies to you.

Take special care with Topotecan

Your doctor needs to know before you are given this medicine:

- **if you have any kidney or liver problems.** Your dose of Topotecan may need to be adjusted.
- **if you are pregnant or plan to become pregnant**
- **if you plan to father a child**

Topotecan may harm a baby conceived before, during or soon after treatment. You should use an effective method of contraception.

Ask your doctor for advice.

→**Tell your doctor** if any of these applies to you.

Using other medicines

Please tell your doctor if you are taking or have recently taken 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're on Topotecan.

Using Topotecan with food and drink

There is no known interaction between Topotecan and alcohol. However, you should check with your doctor whether drinking alcohol is advisable for you.

Pregnancy and breast feeding

Topotecan is not recommended for pregnant women. It may harm the baby if conceived before, during or soon after treatment. You should use an effective method of contraception. Ask your doctor for advice. Do not try and become pregnant/father a child until a doctor advises you it is safe to do so.

Male patients who may wish to father a child, should ask their doctor for family planning advice or treatment. If pregnancy occurs during treatment, tell your doctor immediately.

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

Driving and using machines

Topotecan can make people feel tired.

If you feel tired or weak, do not drive and do not use machines.

3. How Topotecan is used

The dose of Topotecan 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

- **For ovarian and small cell lung cancer:** 1.5 mg per square metres of body surface area per day.
- For cervical cancer: 0.75 mg per square metres of body surface area per day.

When treating cervical cancer, Topotecan is combined with another medicine, called *cisplatin*. Your doctor will advise you about the correct dose of *cisplatin*.

How Topotecan is given

A doctor or nurse will give you a suitable dose of Topotecan as an infusion (a drip). It is usually dripped into your arm over about 30 minutes.

- **For ovarian and small cell lung cancer,** you will have treatment once a day for 5 days.
- **For cervical cancer,** you will have treatment once a day for 3 days.

This pattern of treatments will normally be repeated every three weeks, for all cancers.

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

Stopping treatment

Your doctor will decide when to stop the treatment.

4. POSSIBLE SIDE EFFECTS

Like all medicines, **Topotecan** 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 .

- **Signs of infections.** Topotecan 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 1000** treated with Topotecan.

- **Lung inflammation** *(interstitial lung disease):* You are most at risk if you have existing lung disease, 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

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

- 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 minimize the risk of bleeding.

The following information is intended for medical or healthcare professionals only:

Instructions on how to reconstitute, store and dispose of Topotecan

Reconstitution

Topotecan 4 mg powder for concentrate for solution for infusion should be reconstituted with 4 ml of water for injections to provide 1 mg per ml of Topotecan. **Further dilution is required.** The appropriate volume of the reconstituted solution should be diluted with **either** 0.9 % w/v sodium chloride intravenous infusion **or** 5 % w/v glucose intravenous infusion, to a final concentration of between 25 and 50 microgram per ml.

Storage of the prepared solution

Reconstituted solutions

The product should be used immediately after reconstitution as it contains no antibacterial preservative.

Diluted solutions

The physiochemical stability of the drug product after dilution in the recommended solutions for infusion (see section 6.6) has been demonstrated for 48 hours at 2 °C to 8 °C and 25 °C.

From a microbiological point of view, the product should be used immediately. If not used Immediately, in-use storage time and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at 2 °C to 8 °C, unless reconstitution/ dilution has taken place in controlled and validated aseptic condition.

Handling and disposal

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

- Staff should be trained to reconstitute the medicinal product.
- Pregnant staff should be excluded from working with this medicinal product.
- Staff handling this medicinal product during reconstitution 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.

- Weight loss and loss of appetite *(anorexia)*; tiredness; weakness; feeling unwell.
- 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

- Allergic or *hypersensitivity* reactions (including rash)
- Yellow skin
- Itching sensation
- Muscle pain

Rare side effects

These may affect **up to 1 in 1000 people** treated with Topotecan .

- 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*).

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. Those effects are described in the cisplatin patient information.

If you get side effects

→**Tell your doctor or pharmacist** if any of the side effects become **severe or troublesome,** or if you notice any side effects not listed in this leaflet.

5. How to store Topotecan

Keep out of the reach and sight of children.

Do not use Topotecan after the expiry date which is stated on the carton and vial. The expiry date refers to the last day of that month.

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

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Do not use Topotecan if certain visible signs of deterioration occur upon reconstitution/ dilution.

6. Further information

What Topotecan contains

The active substance is topotecan. Each vial contains topotecan hydrochloride equivalent to 4 mg of topotecan.

The other ingredients are: mannitol (E421), tartaric acid (E334), hydrochloric acid (E507) (for pH adjustment), sodium hydroxide (E524) (for pH adjustment).

What Topotecan looks like and contents of the pack

Topotecan comes as a light yellow to greenish lyophilized powder in a type I clear, colourless, tubular glass vials closed with a flurotec lyotec rubber stoppers and sealed with aluminium flip-off overseal.

Topotecan is available in packs containing 1 vial or 5 vials. Each vial may be shrink wrapped and may/ may not be packed in a plastic container.

Not all pack sizes may be marketed.

Each vial contains Topotecan hydrochloride equivalent to 4 mg Topotecan.

The powder needs to be reconstituted and diluted before infusion.

The powder in the vial provides 1 mg per ml of active substance when reconstituted as recommended.

Marketing Authorisation Holder and Manufacturer

Fresenius Kabi Oncology Plc.
Lion Court, Farnham Road, Bordon
Hampshire, GU35 0NF, United Kingdom

This medicinal product is authorised in the Member States of the EEA under the following names:

Austria	Topotecan Kabi 4 mg Pulver zur Herstellung einer Infusionslösungskonzentrats
Belgium	Topotecan Fresenius Kabi 4 mg poeder voor concentraat voor oplossing voor infusie
Bulgaria	Topotecan Kabi 4 mg Прах за концентрат за инфузионен разтвор
Cyprus	Topotecan Kabi 4 mg κόνις για πυκνό διάλυμα για παρασκευή διαλύματος προς έγχυση
Czech Republic	Topotecan Kabi 4 mg, prášek pro koncentrát pro přípravu infuzního roztoku
Germany	Topotecan Kabi 4 mg Pulver zur Herstellung einer Infusionslösungskonzentrats
Denmark	Topotecan Fresenius Kabi
Estonia	Topotecan Kabi 4 mg
Greece	Topotecan Kabi 4 mg κόνις για πυκνό διάλυμα για παρασκευή διαλύματος προς έγχυση
Spain	Topotecan Kabi 4 mg polvo para concentrado para solución para perfusión
Finland	Topotecan Fresenius Kabi 4 mg kuiva-aine välikonsentraatiksi infuusionestettä varten, liuos
France	Topotecan Kabi 4 mg poudre pour solution á diluer pour perfusion
Hungary	Topotecan Kabi 4 mg por oldatos infúzióhoz való koncentrátumhoz
Ireland	Topotecan 4 mg powder for concentrate for solution for infusion
Italy	Topotecan Kabi 4 mg polvere per concentrato per soluzione per infusione
Latvia	Topotecan Kabi 4 mg pulveris infuziju šķīduma koncentrāta pagatavošanai
Luthuania	Topotecan Kabi 4 mg milteliai koncentratui infuziniam tirpalui
Luxemburg	Topotecan Kabi 4 mg Pulver zur Herstellung einer Infusionslösungskonzentrats
The Netherlands	Topotecan Fresenius Kabi, 4 mg poeder voor concentraat voor oplossing voor infusie
Norway	Topotecan Fresenius Kabi 4 mg pulver til konsentrat til infusjonsvæske, opplØsning
Poland	Topotecan Kabi
Portugal	Topotecano Kabi
Romania	Topotecan Kabi 4 mg pulbere pentru concentrat pentru soluție perfuzabilă
Sweden	Topotecan Fresenius Kabi 4 mg pulver till koncentrat till infusionsvätska, lösning
Slovenia	Topotekan Kabi 4 mg prašek za koncentrat za raztopino za infundiranje
Slovak Republic	Topotecan Kabi 4 mg, prášok na infúzny koncentrát
United Kingdom	Topotecan 4 mg powder for concentrate for solution for infusion

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