Package leaflet: Information for the user

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

What is in this leaflet:

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

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
- 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. What you need to know before you use Topotecan

Do not use Topotecan:

- if you are allergic (hypersensitive) to topotecan or any of the other ingredients of this medicine (listed in section 6);
- if you are breast feeding.
- if your blood cells count is too low. Your doctor will tell you, based on the results of your last blood test.
- → Tell your doctor if you think any of these could apply to you.

Warnings and precautions

Talk to your doctor or nurse:

- if you have any kidney problems. Your dose of topotecan may need to be adjusted. The use of topotecan is not recommended in patients with severe renal impairment
- if you have liver problems. Your dose of topotecan may need to be adjusted. The use of topotecan is not recommended in patients with
- · 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.

Other medicines and Topotecan

Please tell your doctor if you are taking, have recently taken any other medicines.

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

Pregnancy, breast-feeding and fertility.

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 to use Topotecan

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.

- 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

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

Stopping treatment

4. Possible side effects

Your doctor will decide when to stop the treatment.

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:

- 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 decline 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 people 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
- → 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.
- Abnormally low white blood cell count (leucopenia, neutropenia) which may be accompanied with fever and signs of infections (febrile neutropenia).
- · Weight loss and loss of appetite (anorexia), tiredness, weakness (asthenia), feeling unwell.
- Feeling sick (nausea), being sick (vomiting), diarrhoea, stomach pain due to neutropenic colitis which may be fatal, constipation ulcers of the mouth tongue or gums.

The normal procedures for proper handling and disposal of anticancer medicinal products dilute the medicinal product trained is intended for healthcare Staff should be General precautions professionals only: should be adopted:

All items for administration Staff handling this medicinal excluded from working with product during dilution should protective clothing including mask, goggles and or cleaning, including gloves, staff should this medicinal product. Pregnant gloves.

Accidental contact with the waste disposal bags for highskin or eyes should be treated immediately with copious should be placed in high-risk temperature incineration.

The concentrate is clear yellow Instructions for dilution amounts of water.

Further dilution of the appropriate to yellow green in colour and contains 1 mg per ml of topotecan

solution for injection to reach a or glucose 50 mg/ml (5%) The diluted solution should be ml (0.9%) solution for injection either sodium chloride 9 mg/ between 25 and 50 microgram/ml final topotecan concentration in the solution for infusion.

clear, colourless to light yellow Chemical and physical in-use colour, free from visible particles Storage of the diluted solution

stability has been demonstrated

Black

Ver. 12

volume of the concentrate with

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for 10 days at 2-8°C and 25°C

- 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 (jaundice) caused by abnormal liver function (i.e. increase in bilirubin).

Topotecan RTU Pack Insert - Bordon - UK+IRL

- · Itching sensation
- · Reduction in the number of red and white blood cells as well as platelets (pancytopenia)
- Muscle pain.
- Severe infection (sepsis) which may be fatal.

Rare side effects

These may affect up to 1 in 1,000 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
- Lung disease affecting the tissue and space around the air sacs of the lungs (interstitial lung disease which may be fatal)
- 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.

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. By reporting side effects you can help provide more information on the safety of this

For UK - You can also report side effects directly via the Yellow Card Scheme

at: www.mhra.gov.uk/yellowcard

For Ireland - Reports may be made by following the links to the online reporting option accessible from the IMB homepage, or by completing the downloadable report form also accessible from the IMB website, which may be completed manually and submitted to the IMB via freepost, to the following address:

FREEPOST

Pharmacovigilance Section

Irish Medicines Board

Kevin O'Malley House

Earlsfort Centre

Earlsfort Terrace

Dublin 2 Tel: +353 1 6764971

Fax: +353 1 6762517

Website: www.imb.ie (http://www.imb.ie) e-mail: imbpharmacovigilance@imb.ie

5. How to store Topotecan

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

Store in a refrigerator (2°C - 8°C). Do not freeze.

Chemical and physical in-use stability has been demonstrated for 10 days at 2-8°C and 25°C.

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 not normally be longer than 24 hours at 2-8°C, unless dilution has taken has taken place in controlled and validated aseptic conditions.

Do not use this medicine if you notice any visible particles or if the solution is unclear.

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 Topotecan contains

• The active substance is topotecan hydrochloride.

ch ml of concentrate contains 1 mg topotecan (as hydrochloride)

One vial of 1 ml of concentrate contains 1 mg topotecan (as hydrochloride).

One vial of 4 ml of concentrate contains 4 mg topotecan (as hydrochloride).

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

Any unused product or waste material should be disposed requirements. • The other ingredients are: tartaric acid (E334), hydrochloric acid (E507), sodium hydroxide (E524) and water for injections.

What Topotecan looks like and contents of the pack

Topotecan is clear, yellow or yellow-green concentrate for solution for infusion for intravenous infusion.

Topotecan 1 mg/ml, 1 ml is supplied in 2 ml colorless, Type I glass vial, closed with a 13 mm flurotec rubber stopper and sealed with an flip-off aluminium seal.

Topotecan 1 mg/ml, 4 ml is supplied in 6 ml colorless, Type I clear glass vial, closed with a 20 mm Flurotec rubber stopper and sealed with an flip-off aluminium over seal.

Each vial contains 1 ml or 4 ml of the concentrate for solution for infusion. Topotecan is supplied in cartons containing 1 x 1 ml, 5 x 1 ml, 1 x 4 ml and 5 x 4 ml vials.

Not all pack sizes may be marketed.

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 1 mg/ml Konzentrat zur
	Herstellung einer Infusionslösung
Belgium	Topotecan Fresenius Kabi 1 mg/ml concentraat voor
	oplossing voor infusie
Cyprus	Topotecan Kabi 1 mg πυκνό διάλυμα για
	παρασκευή διαλύματος προς έγχυση
Czech Republic	Topotecan Kabi 1 mg/ml koncentrát pro infuzní
_	roztok
Germany	Topotecan Kabi 1 mg/ml Konzentrat zur
	Herstellung einer Infusionslösung
Denmark	Topotecan Fresenius Kabi
Estonia	Topotecan Kabi 1 mg/ml
Greece	Topotecan Kabi 1 mg πυκνό διάλυμα για
	παρασκευή διαλύματος προς έγχυση
Spain	Topotecán Kabi 1 mg/1 ml concentrado para
	solución para perfusión
Finland	Topotecan Fresenius Kabi 1 mg/ml
	infuusiokonsentraatti, liuosta varten
France	TOPOTECAN KABI 1mg/ml, solution à diluer
	pour perfusion
Hungary	Topotecan Kabi 1 mg/ml koncentrátum oldatos
	infúzióhoz
Ireland	Topotecan 1mg/ml Concentrate for Solution for
	Infusion
Italy	Topotecan Kabi
Latvia	Topotecan Kabi 1 mg/ml koncentrāts infūziju
	šķīduma pagatavošanai
Lithuania	Topotecan Kabi 1 mg/ml koncentratas infuziniam
	tirpalui
Luxemburg	Topotecan Kabi 1 mg/ml Konzentrat zur
	Herstellung einer Infusionslösung
Malta	Topotecan 1mg/ml Concentrate for Solution for
	Infusion
The Netherlands	Topotecan Fresenius Kabi 1 mg/ml concentraat voor
	oplossing voor infusie
Norway	Topotecan Fresenius Kabi
Poland	Topotecan Kabi
Portugal	Topotecano Kabi
Romania	Topotecan Kabi 1 mg/ml concentrat pentru soluție
	perfuzabilă
Sweden	Topotecan Fresenius Kabi 1 mg/ml koncentrat till
	infusionsvätska, lösning
Slovak Republic	Topotecan Kabi 1 mg/ml koncentrát pro prípravu
	infúzneho roztoku
United Kingdom	Topotecan 1mg/ml Concentrate for Solution for
	Infusion

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