

- 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).
- 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 medicine.

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 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.
- Each 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).

- **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 infūzijai
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

This leaflet was last revised in Aug 2013

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Disposal
Any unused product or waste material should be disposed of in accordance with local requirements.

Size: 200 x 380 mm

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