Package leaflet: Information for the user

Topotecan Hospira 4 mg/4 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.
• 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 Hospira is and what it is used for

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

Topotecan Hospira 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 Hospira is combined with another medicine called cisplatin.

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

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

You should not receive Topotecan Hospira:
• 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
Before you are given this medicine
your doctor needs to know:
- if you have any kidney or liver problems. Your dose of Topotecan Hospira may need to be adjusted.
- if you are pregnant or plan to become pregnant. See section "Pregnancy and breast-feeding" below.
- if you plan to father a child. See section "Pregnancy and breast-feeding" below.

Tell your doctor if any of these applies to you.

Other medicines and Topotecan Hospira
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 Hospira**.**

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

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. 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 or use machines.

3. How Topotecan Hospira 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
• **Ovarian and small cell lung cancer:** 1.5 milligrams per m^2 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 milligrams per m^2 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 Hospira 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 is given
A doctor or nurse will administer topotecan as an infusion into your arm lasting about 30 minutes.

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

4. Possible side effects

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

<u>Serious side effects: tell your doctor</u>

These **very common** side effects may affect **more than 1 in 10 people** treated with Topotecan Hospira:
• **Signs of infection:** 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*) can be signs of bowel inflammation (*colitis*).

This **rare** side effect may affect **up to 1 in 1,000 people** treated with Topotecan Hospira:
• **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 Hospira:
• 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
These **may affect up to 1 in 10 people** treated with Topotecan Hospira:

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

Rare side effects
These **may affect up to 1 in 1,000 people** treated with Topotecan Hospira:

• 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
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, 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 Hospira. 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 the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Topotecan Hospira

Keep this medicine out of the sight and reach of children.

Do not use Topotecan Hospira after the expiry date stated on the vial and carton after EXP.

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

Keep the vial 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. If not used immediately, Topotecan Hospira can be used for up to 24 hours when stored in the fridge (protected from light) or at room temperature (in normal daylight conditions).

If visible particles are observed, the medicine should not be administered.

Do not throw away any medicines via wastewater. 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 Hospira contains
The active substance in Topotecan Hospira is topotecan (as hydrochloride). 1 ml of concentrate for solution for infusion 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 (to adjust the pH of the solution).

What Topotecan Hospira looks like and the contents of the pack
Topotecan Hospira is a clear, yellow or yellow-green concentrate for solution for infusion supplied in clear glass vials, each containing 4 ml concentrate. Topotecan Hospira is available in two pack sizes, containing either 1 vial or 5 vials. Not all pack sizes may be marketed.

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Pfizer Limited,
Ramsgate Road,
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Manufacturer
Pfizer Service Company BVBA
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For any information about this medicine, please contact:
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Telephone 01304 616161.

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

Storage, Use, Handling & Disposal of Topotecan Hospira

Storage
Unopened vial: Store in a refrigerator (2°C-8°C). Do not freeze. Keep the vial in the outer carton in order to protect from light.

Use
Refer to the SmPC for full details.

Topotecan Hospira 4 mg/4 ml concentrate for solution for infusion requires dilution to a final concentration of 25-50 micrograms/ml, prior to administration to the patient. The approved diluents for the concentrate are sodium chloride 9 mg/ml (0.9%) solution for injection and glucose 50 mg/ml (5%) solution for injection. Use the aseptic technique during any further dilution of the solution for infusion.

Parenteral products should be visually inspected for particulate matter and discolouration prior to administration. Topotecan Hospira is a yellow/yellow green solution.

Prior to administration of the first course of topotecan, patients must have a baseline neutrophil count of $\geq 1.5 \times 10^9$/l, a platelet count of $\geq 100 \times 10^9$/l and a haemoglobin level of $\geq$ 9g/dl (after transfusion if necessary). Neutropenia and thrombocytopenia should be managed. For further details, refer to the SPC.

Dosage: Ovarian and Small Cell Lung Carcinoma
Initial dose: 1.5 mg/ m^2 body surface area/day, administered by intravenous infusion over 30 minutes for 5 consecutive days, with a 3 week interval between the start of each course.

Subsequent doses: Topotecan should not be re-administered unless the neutrophil count is $\geq 1 \times 10^9$/l, the platelet count is $\geq 100 \times 10^9$/l, and the haemoglobin level is $\geq$ 9 g/dl (after transfusion if necessary).

Dosage: Cervical Carcinoma
Initial dose: 0.75 mg/m^2/day administered as 30 minute intravenous infusion daily, on days 1, 2 and 3. Cisplatin is administered as an intravenous infusion on day 1 at a dose of 50 mg/m^2/day and following the topotecan dose. This treatment schedule is repeated every 21 days for 6 courses or until progressive disease.

Subsequent doses: Topotecan should not be re-administered unless the neutrophil count is more than or equal to 1.5 x 10^9/l, the platelet count is more than or equal to 100 x 10^9/l, and the haemoglobin level is more than or equal to 9g/dl (after transfusion if necessary).

Dosage: Renally impaired patients
Limited data indicate that the dose should be reduced in patients with moderate renal impairment. Please refer to the SPC for further details.

Dosage: Paediatric population
Limited data available. Use not recommended.

Chemical and physical in-use stability has been demonstrated for 24 hours at 25°C under normal light conditions and at 2°C -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 than 24 hours at 2°C to 8°C, unless reconstitution/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 adequately trained in the preparation, administration and disposal of cytotoxics
• Pregnant staff should be excluded from working with this medicinal product.
• Staff handling this medicinal product should wear adequate protective clothing including mask, goggles and gloves.
• All items used in the preparation, administration, and cleaning of the medicinal product, including gloves, should be placed in high-risk, waste disposal bags for high-temperature incineration. Liquid waste may be flushed with large amounts of water.
• Accidental contact with the skin or eyes should be treated immediately with copious amounts of water. If there is lasting irritation, a doctor should be consulted.
• Any unused product or waste material should be disposed of in accordance with local requirements.