

## **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
2. What you need to know before you are given Topotecan Hospira
3. How Topotecan Hospira is used
4. Possible side effects
5. How to store Topotecan Hospira
6. Contents of the pack and other information

#### **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 effective contraceptive measures while being treated with topotecan 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 topotecan 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. 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.

### **Topotecan Hospira 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 Hospira, the dose of sodium received would be larger.

## **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 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 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.

## **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 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).

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](http://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.

### **Marketing Authorisation Holder**

Pfizer Limited,  
Ramsgate Road,  
Sandwich,  
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CT13 9NJ,  
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**Manufacturer**

Pfizer Service Company BV  
Hoge Wei 10  
1930 Zaventem  
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For any information about this medicine, please contact:  
Medical Information, Pfizer Ltd, Walton Oaks, Dorking Road, Tadworth, Surrey, KT20 7NS.  
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  $\geq 9$  g/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<sup>2</sup> 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<sup>2</sup>/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<sup>2</sup>/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  $\geq 1.5 \times 10^9/l$ , the platelet count is  $\geq 100 \times 10^9/l$ , and the haemoglobin level is  $\geq 9$  g/dl (after transfusion if necessary).

**Dosage: 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.