

TOPOTECAN ACCORD

Topotecan (as hydrochloride) Concentrated Injection 1 mg/1 mL and 4 mg/4 mL

Consumer Medicine Information

What is in this leaflet

This leaflet answers some of the common questions about Topotecan Accord. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

The information in this leaflet was last updated on the date listed on the final page. More recent information on the medicine may be available.

You should ensure that you speak to your pharmacist or doctor to obtain the most up to date information on the medicine.

All medicines have risks and benefits. Your doctor will have weighed the risks of you taking Topotecan Accord against the benefits they expect it will have for you.

If you have any concerns about being given this medicine, ask your doctor or pharmacist.

Keep this leaflet until you have finished treatment with Topotecan Accord.

You may need to read it again.

What Topotecan Accord is used for

Topotecan Accord contains topotecan hydrochloride as the active ingredient.

Topotecan Accord is an anti-cancer medicine. It works by killing cancer cells and preventing cancer cells from reproducing. Topotecan Accord is used to treat patients with ovarian cancer, small cell lung cancer and cervical cancer.

Your doctor may have prescribed Topotecan Accord for another reason.

Follow all directions given to you by your doctor carefully.

They may differ from the information contained in this leaflet.

Topotecan Accord is not addictive.

Before you are given Topotecan Accord

You must not be given it if:

- you have had an allergic reaction to topotecan hydrochloride or any of the other ingredients contained in this medicine
- you are, or think you may be pregnant or if you intend to become pregnant
- you are breast feeding

If you have been breast feeding prior to receiving Topotecan Accord, do not restart until the doctor tells you it is safe to do so.

- you have very low blood count.
- the expiry date printed on the pack has passed
- the packaging is torn or shows signs of tampering.

Before you are given it

Before you receive Topotecan Accord, tell your doctor if you have any:

- kidney problems; the dosage of Topotecan Accord may need to be reduced
- liver problems
- other medical problems. In particular tell your doctor if you have any of the

following:

- bleeding or bruising; Topotecan Accord may cause a reduction in blood cells which may increase the risk of bleeding.
- fever or other symptoms of infection; Topotecan Accord may decrease your body's ability to fight infection.
- Recent exposure to chickenpox or shingles (Herpes zoster).

Treatment with Topotecan Accord may increase the severity of these infections.

Many medicines used to treat cancer may impair your ability to have children in the future.

Talk to your doctor if you are concerned about how Topotecan Accord might affect your ability to have children.

Taking other medicines

Tell your doctor if you are taking any other medicines or have taken other medicines until recently.

This includes those medicines that you buy without a prescription from a pharmacy, supermarket or health food shop.

In particular mention if you are receiving any other medicines to treat cancer.

Some medicines may affect the way other medicines work. Your doctor or pharmacist will be able to tell you what to do when receiving Topotecan Accord with other medicines.

Pregnancy

Female patients who might become pregnant should make sure they are not pregnant before starting treatment.

Topotecan Accord may harm your unborn baby.

Tell your doctor if you are pregnant or think you could be pregnant before you are given Topotecan Accord.

If you are a woman who could become pregnant, you must use effective birth control (contraception) during treatment with Topotecan Accord.

Ask your doctor for methods of effective birth control.

Breast-feeding

If you are breast-feeding, check with your doctor before you are given Topotecan Accord.

Do not restart breast-feeding until your doctor tells you that it is safe to do so.

Male patients

Male patients being treated with Topotecan Accord, with female partners who are or may become pregnant, should use condoms during sexual intercourse and for at least three months after stopping treatment with Topotecan Accord.

How Topotecan Accord is given

How much is given

Your doctor will decide the dosage of Topotecan Accord to be given to you. The dosage you receive is based on your height and weight.

How Topotecan Accord is given

Your doctor or nurse will inject the necessary dose of Topotecan Accord.

Topotecan Accord is given into the vein by an intravenous drip over a 30-minute period.

Topotecan Accord is given once daily for five days for the treatment of ovarian and small cell lung cancer and once every day for three days for cervical cancer. This is usually repeated every three weeks from the start of each course. This may vary depending on the results of your blood tests. Your doctor will decide how many courses of Topotecan Accord you will need.

If you have any concerns about Topotecan Accord, talk to your doctor or pharmacist.

If you are given too much (overdose)

In the event of a suspected overdose you will be monitored by your doctor and treated for any unwanted side effects that may occur.

There is no antidote for an overdose of Topotecan Accord.

While you are given Topotecan Accord

Things you must do

Follow your doctor's directions regarding treatment with Topotecan Accord.

Remember to keep your appointments with your doctor. If you miss an appointment contact your doctor for instructions.

It is very important that your doctor checks your progress at regular visits.

Remember to have your blood tests regularly, as instructed by your doctor.

Topotecan Accord may cause a reduction in blood cells which may make you prone to infection and bleeding.

Tell your doctor immediately if you experience a fever or any other symptoms of infection or any bleeding or bruising.

If you see another doctor or dentist for treatment, tell them that you are being treated with Topotecan Accord.

Do not have any vaccinations without your treating doctor's approval. In addition, avoid contact with anyone who has recently received the oral polio vaccine.

Topotecan Accord may lower your body's resistance to infection. Some vaccines may cause illness in people with decreased resistance to infection.

If you experience low blood counts, there are precautions you can take to reduce the risk of infection or bleeding:

- avoid people with infections
- take care when using a toothbrush, dental floss or toothpick. Your doctor, dentist or nurse may recommend other ways to clean your teeth and gums.

Check with your doctor before having any dental work done.

- take care not to cut yourself when using sharp objects such as a safety razor or nail cutters.
- avoid contact sports or other situations where bruising or injury could occur

Things to be careful of

Be careful driving or operating machinery after you have been given Topotecan Accord and you are feeling tired and weak.

Side Effects

Tell your doctor, nurse or pharmacist as soon as possible if you do not feel well while you are receiving Topotecan Accord.

Like most anti-cancer drugs, Topotecan Accord may cause some unwanted side effects. Some side effects will have symptoms that you will notice. Your doctor may check for others by doing certain tests. Some side effects may need medical treatment.

Topotecan Accord may cause other unwanted effects that may not occur until months or years after it is given.

These delayed effects may include a decreased ability to have children or certain types of cancer.

Discuss these possible effects with your treating doctor.

Like many anticancer medicines, Topotecan Accord may cause you to feel sick or be sick. You will be prescribed medicines to help prevent these side effects.

The most common side effects with Topotecan Accord are infections. Blood disorders are also common, where reduced levels of certain blood cells may cause anaemia, reduced resistance to infections and increased bruising or bleeding. Your doctor will monitor your blood tests for these side effects.

Conditions you need to look out for

Severe allergic reactions

These are very rare in people receiving Topotecan Accord. Signs include:

- raised and itchy rash (hives)
- swelling, sometimes of the face or mouth (angioedema), causing difficulty in breathing
- collapse.

Signs of infection

Topotecan Accord may reduce your white blood cell count, lowering your resistance to infection. This can be life threatening. Signs include:

- Fever
- diarrhoea and vomiting
- feeling extremely weak
- local symptoms such as sore throat or urinary problems (for example, a burning sensation when urinating, which may be caused by a urinary infection).

Bowel inflammation

Topotecan Accord can occasionally cause severe stomach pain, fever and diarrhoea (rarely with blood). These could be signs of bowel inflammation (colitis).

Lung inflammation (interstitial lung disease)

This rarely occurs in people taking Topotecan Accord. 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 of these symptoms. You may need to be treated in hospital.

Very common side effects (these may affect more than 1 in 10 people):

- feeling generally weak and tired (anaemia), which can occasionally require blood transfusion
- weight loss and loss of appetite (anorexia); tiredness; weakness; feeling unwell
- feeling sick (nausea), being sick (vomiting), stomach pain, diarrhoea, constipation
- local symptoms such as sore throat or urinary problems (for example a burning sensation when urinating, which may be caused by a urinary infection)
- inflammation and ulcers of the mouth, tongue or gums
- high body temperature (fever)
- hair loss.

Very common side effects that may show up in your blood tests:

- low numbers of cells needed for blood clotting. This can cause bruising, bleeding, and rarely, severe bleeding (haemorrhage).
- decrease in the number of white blood cells (neutropenia). This can cause an infection.

Common side effects (these may affect up to 1 in 10 people):

- allergic or hypersensitivity reactions
- yellow skin (jaundice)
- itching sensation.

Rare side effects (these may affect up to 1 in 1000 people):

- mild pain and inflammation at the site of injection
- lung inflammation (interstitial lung disease).

Frequency unknown (events from spontaneous reports)

- **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 stool that could be signs and symptoms of inflammation of the inner lining of the mouth, stomach and / or gut (mucosal inflammation).

Your doctor, nurse or pharmacist may be able to tell you about ways to prevent or reduce some of these side effects.

Tell your doctor or nurse if any of these or any other side effects no listed occur during or between treatments with Topotecan Accord.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

Storage

Topotecan Accord will be stored in the pharmacy or on the ward. It is kept in a cool dry place where the temperature stays below 25°C.

Product Description

What it looks like

Topotecan Accord containing injections are clear yellow solutions. It is available in vials in packs of 1 and 5.

Not all presentations and pack sizes may be marketed.

Ingredients

Active ingredient:
topotecan (as hydrochloride)

Inactive ingredients:
tartaric acid
sodium hydroxide
hydrochloric acid
water for injections

Name and Address of the Sponsor

Accord Healthcare Pty Ltd
Level 24, 570 Bourke Street
Melbourne, VIC, 3000
Australia

Australian Registration Numbers

1 mg/1 mL: AUST R 310762

4 mg/4 mL: AUST R 310761

Date of Preparation

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