

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I given Hycamtin?

Hycamtin contains the active ingredient topotecan (as hydrochloride). Hycamtin is used to treat ovarian cancer, small cell lung cancer and cervical cancer.

For more information, see Section [1. Why am I given Hycamtin?](#) in the full CMI.

2. What should I know before I am given Hycamtin?

Do not use if you have ever had an allergic reaction to Hycamtin or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I am given Hycamtin?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Hycamtin and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How is Hycamtin given?

- Your doctor will decide the dosage of Hycamtin to be given to you. The dosage you receive is based on your height and weight.
- Your doctor or nurse will inject the necessary dose of Hycamtin. Hycamtin is given into the vein by an intravenous drip over a 30 minute period.
- Hycamtin 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 Hycamtin you will need.

More instructions can be found in Section [4. How do is Hycamtin given?](#) in the full CMI.

5. What should I know while being given Hycamtin?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using Hycamtin.• Remember to have your blood tests regularly, as instructed by your doctor.• Tell your doctor immediately if you experience a fever or any other symptoms of infection or any bleeding or bruising.
Things you should not do	<ul style="list-style-type: none">• 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.
Driving or using machines	<ul style="list-style-type: none">• Be careful before you drive or use any machines or tools until you know how Hycamtin affects you.
Looking after your medicine	<ul style="list-style-type: none">• Hycamtin is usually stored at the hospital or at the pharmacy.• Store in a cool, dry place where temperatures stay below 30°C.

For more information, see Section [5. What should I know while being given Hycamtin?](#) in the full CMI.

6. Are there any side effects?

Common side effects: feeling generally weak and tired (anaemia), weight loss, loss of appetite, feeling sick (nausea), being sick (vomiting), stomach pain, diarrhoea, constipation, high body temperature (fever)

Serious side effects: sore throat, urinary problems (burning sensation when urinating), severe stomach pain, raised and itchy rash (hives), swelling of face or mouth, difficulty breathing, cough

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

HYCAMTIN®

Active ingredient(s): *topotecan (as hydrochloride)*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Hycamtin. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Hycamtin.**

Where to find information in this leaflet:

- [1. Why am I using Hycamtin?](#)
- [2. What should I know before I use Hycamtin?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use Hycamtin?](#)
- [5. What should I know while using Hycamtin?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using Hycamtin?

Hycamtin contains the active ingredient **topotecan hydrochloride**. Hycamtin is an anti-cancer medicine that works by killing cancer cells and preventing cancer cells from reproducing.

Hycamtin is used to treat patients with either of the following cancers:

- ovarian cancer
- small cell lung cancer
- cervical cancer.

Your doctor may have prescribed Hycamtin for another reason.

2. What should I know before I use Hycamtin?

Warnings

Do not use Hycamtin if:

- you are allergic to topotecan (as hydrochloride), or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.
- you have a very low blood count.

Check with your doctor if you:

- have any other medical conditions
 - kidney problems; the dosage of Hycamtin may need to be reduced
 - liver problems

- bleeding or bruising; Hycamtin may cause a reduction in blood cells which may increase the risk of bleeding
 - fever or other symptoms of infection; Hycamtin may decrease your body's ability to fight infection
 - recurrent exposure to chickenpox or shingles (Herpes zoster). Treatment with Hycamtin may increase the severity of these infections.
- take any medicines for any other condition
 - 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 Hycamtin might affect your ability to have children

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Do not take if you are pregnant, think you may be pregnant, or if you intend to become pregnant.

Female patients who might become pregnant should make sure they are not pregnant before starting treatment. Hycamtin may harm your unborn baby.

If you are a woman who could become pregnant, you must use effective birth control (contraception) during treatment with Hycamtin. Ask your doctor for methods of effective birth control.

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

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

Male patients

- Male patients being treated with Hycamtin, 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 Hycamtin.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

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

Some medicines may interfere with Hycamtin and affect how it works. Your doctor or pharmacist will be able to tell you what to do when receiving Hycamtin with other medicines.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Hycamtin.

4. How Hycamtin is given?

How much is given

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

How Hycamtin is given

- Your doctor or nurse will inject the necessary dose of Hycamtin.
- Hycamtin is given into the vein by an intravenous drip over a 30 minute period.
- Hycamtin 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 Hycamtin you will need.

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

If too much Hycamtin is given

In the event of 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 Hycamtin.

If you think that you have been given too much Hycamtin, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling **13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using Hycamtin?

Things you should do

- **Follow your doctor's directions regarding treatment with Hycamtin.**
- **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.** Hycamtin may cause a

reduction in blood cells which may make you prone to infection and bleeding.

- **If you see another doctor or dentist for treatment, tell them you are being treated with Hycamtin.**
- **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.
 - 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.
- **Check with your doctor before having any dental work done.**

Call your doctor straight away if you:

- experience a fever or any other symptoms of infection or any bleeding or bruising

Remind any doctor, dentist or pharmacist you visit that you are using Hycamtin.

Things you should not do

- **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.**
Hycamtin may lower your body's resistance to infection. Some vaccines may cause illness in people with decreased resistance to infection.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Hycamtin affects you.

Looking after your medicine

- Hycamtin is an anti-cancer medicine which requires special care in handling and preparation. It should be given to your pharmacist, doctor or nurse as soon as possible.
- Hycamtin is usually stored at the hospital or at the pharmacy.

Store it in a cool dry place below 30°C away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date or the packaging is torn or shows signs of tampering.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Like most anti-cancer drugs, Hycamtin 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.

Hycamtin 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, Hycamtin may cause you to feel sick or be sick. You will be prescribed medicines to help prevent these side effects.

Less serious side effects

Less serious side effects	What to do
<p>General</p> <ul style="list-style-type: none"> feeling generally weak and tired (anaemia), which can occasionally require blood transfusion tiredness; weakness; feeling unwell mild pain and inflammation at the site of injection itching sensation <p>Gastrointestinal or Gut related</p> <ul style="list-style-type: none"> feeling sick (nausea), being sick (vomiting), stomach pain, diarrhoea, constipation weight loss and loss of appetite (anorexia) <p>Others</p> <ul style="list-style-type: none"> inflammation and ulcers of the mouth, tongue or gums high body temperature (fever) hair loss 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p> <p>They are generally mild and do not cause patients to stop taking Hycamtin.</p>

Serious side effects

Serious side effects	What to do
<p>Allergy related</p> <ul style="list-style-type: none"> allergic or hypersensitivity reaction raised and itchy rash (hives) swelling, sometimes of the face or mouth (angioedema), causing 	<p>Call your doctor straight away, or go straight to the Emergency Department at</p>

<p>difficulty in breathing</p> <ul style="list-style-type: none"> collapse <p>These are very rare in people receiving Hycamtin.</p> <p>Signs of infection</p> <ul style="list-style-type: none"> local symptoms such as sore throat or urinary problems (for example, a burning sensation when urinating, which may be caused by a urinary infection) fever diarrhoea and vomiting feeling extremely weak <p>Hycamtin may reduce your white blood cell count (neutropenia), lowering your resistance to infection.</p> <p>Liver related</p> <ul style="list-style-type: none"> yellow skin (jaundice) <p>Signs of gastrointestinal perforation (bowel inflammation)</p> <ul style="list-style-type: none"> severe stomach pain, nausea, vomiting of blood, black or bloody stools fever diarrhoea (rarely with blood) <p>Signs of mucosal inflammation</p> <ul style="list-style-type: none"> Mouth sores, difficulty swallowing, abdominal pain, nausea, vomiting, diarrhoea, bloody stool <p>Lungs related</p> <ul style="list-style-type: none"> lung inflammation (interstitial lung disease) difficulty breathing cough fever <p>This rarely occurs in people taking Hycamtin. 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.</p> <p>Blood related</p> <ul style="list-style-type: none"> low numbers of cells needed for blood clotting. This can cause bruising, bleeding, and rarely, severe bleeding (haemorrhage). 	<p>your nearest hospital if you notice any of these serious side effects.</p>
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Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

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

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What Hycamtin contains

Active ingredient (main ingredient)	topotecan (as hydrochloride)
Other ingredients (inactive ingredients)	<ul style="list-style-type: none">• tartaric acid (E334)• mannitol• hydrochloric acid (E507)• sodium hydroxide (E524)
Potential allergens	<ul style="list-style-type: none">• mannitol

Do not take this medicine if you are allergic to any of these ingredients.

What Hycamtin looks like

Hycamtin 4mg powder for infusion – clear glass vials with grey butyl rubber stoppers and aluminium seals with plastic flip-off caps. The vials contain topotecan as a yellow powder (Aust R 58598).

Who distributes Hycamtin

Sandoz Pty Ltd
ABN 60 075 449 553
54 Waterloo Road
Macquarie Park, NSW 2113
Tel: 1800 726 369

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