

HYCAMTIN®

topotecan (as hydrochloride) powder for injection vial

Consumer Medicine Information

What is in this leaflet

Please read this leaflet carefully before you start taking Hycamtin capsules.

This leaflet answers some of the common questions about Hycamtin (topotecan). 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. You can also download the most up to date leaflet from www.novartis.com.au.

Those updates may contain important information about the medicine and its use of which you should be aware.

All medicines have risks and benefits. Your doctor has weighed the possible risks of Hycamtin against the expected benefits.

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

Keep this leaflet until you have finished treatment with Hycamtin.

You may need to read it again.

What Hycamtin is used for

Hycamtin is an anti-cancer medicine that contains topotecan hydrochloride as the active ingredient.

Hycamtin 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.

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

Hycamtin is not addictive.

Before receiving Hycamtin

You must not receive Hycamtin if:

- you have had an allergic reaction to topotecan hydrochloride or any of the other ingredients contained in this medicine
- **you are pregnant, think you may be pregnant, or if you intend to become pregnant; see Pregnancy**
- **you are breast feeding; see Breast-feeding**
- you have very low blood count.
- the expiry date printed on the pack has passed
- the packaging is torn or shows signs of tampering.

Tell your doctor if

Before you receive Hycamtin, tell your doctor if you have any:

- kidney problems; the dosage of Hycamtin 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; 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.
 - recent exposure to chickenpox or shingles (Herpes zoster).

Treatment with Hycamtin 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 Hycamtin 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 Hycamtin with other medicines.

Pregnancy

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

Hycamtin may harm your unborn baby.

Tell your doctor if you are pregnant, or think you could be pregnant before you are given Hycamtin.

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.

Breast-feeding

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.

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.

Overdose

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.

While you are receiving Hycamtin

Things you must 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.

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 Hycamtin.

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.

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.

Side Effects

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

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.

The most common side effects with Hycamtin 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 Hycamtin. Signs include:

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

SIGNS OF INFECTION

Hycamtin 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

Hycamtin 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 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. 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.

Possible side effects

As with all medicines, patients treated with Hycamtin may experience side effects, although not everybody gets them.

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

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.

Remember you should tell your doctor, nurse or pharmacist as soon as possible if any of these, or any other side effects not listed occur during or between treatments with Hycamtin.

Storage

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.

If you need to store Hycamtin:

- always keep the pack in a cool dry place where the temperature stays below 30°C
- do not:
 - leave it in the car on a hot day
 - store medicine in the bathroom or near a sink. Heat and dampness can destroy some medicines.

Keep all medicines out of the reach of children, such as in a locked cupboard.

If your doctor tells you to stop using Hycamtin, return any leftover vials to your pharmacist.

www.sandoz.com.au

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Hycamtin Australian Registration Number:

AUST R 58598 Hycamtin topotecan (as hydrochloride) 4 mg powder for injection vial.

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Product description

What it looks like

Hycamtin powder for infusion is supplied in clear glass vials with grey butyl rubber stoppers and aluminium seals with plastic flip-off caps. The vials contain topotecan as a yellow powder.

Other ingredients:

Hycamtin also contains the inactive ingredients:

- tartaric acid (E334)
- mannitol (E421)
- hydrochloric acid (E507), and
- sodium hydroxide (E524).

Sponsor

Hycamtin is supplied in Australia by:

Sandoz Pty Ltd

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Australia

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