

Hycamtin®

 **SANDOZ**

SZ22301LT01A

Package leaflet: Information for the user

Hycamtin® 0.25 mg hard capsules

Hycamtin® 1 mg hard capsules

topotecan

Read all of this leaflet carefully before you start taking 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 or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms seem to be the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Hycamtin is and what it is used for
2. What you need to know before you take Hycamtin
3. How to take Hycamtin
4. Possible side effects
5. How to store Hycamtin
6. Contents of the pack and other information

1. What Hycamtin is and what it is used for

Hycamtin helps to destroy tumours.

Hycamtin is used to treat small cell lung cancer that has come back after chemotherapy.

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

2. What you need to know before you take Hycamtin

Do not take Hycamtin

- 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 Hycamtin 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 Hycamtin

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.

There may be a higher than usual chance of you getting side effects if you are also being treated with cyclosporin A. You will be monitored closely if you are taking both these medicines.

Remember to tell your doctor if you start to take any other medicines while you are on Hycamtin.

Pregnancy and breast-feeding

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

Driving and using machines

Hycamtin can make people feel tired. If you feel tired or weak, do not drive or use machines.

Hycamtin contains ethanol

This medicine contains small amounts of ethanol (alcohol).

3. How to take Hycamtin

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

The capsule(s) must be swallowed whole, and must not be chewed, crushed or divided.

The dose (and number of capsules) of Hycamtin 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 prescribed number of capsules should be swallowed whole, once a day for 5 days.

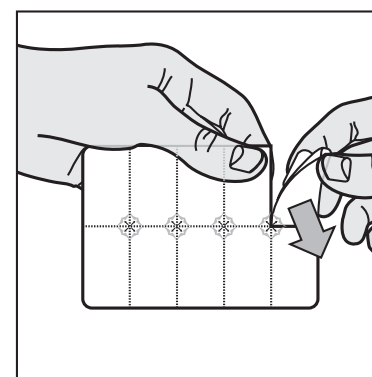
Hycamtin capsules must not be opened or crushed. If the capsules are punctured or leaking, you should

immediately wash your hands thoroughly with soap and water. If you get the capsule contents in your eyes, wash them immediately with gently flowing water for at least 15 minutes. Consult your doctor after eye contact or if you experience a skin reaction.

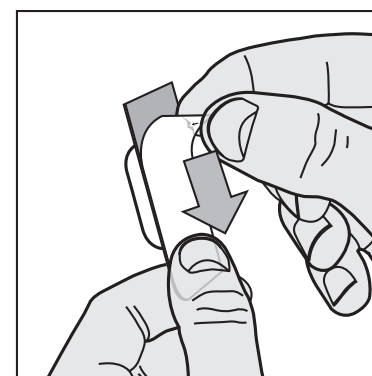
Taking out a capsule

These capsules come in special packaging to prevent children removing them.

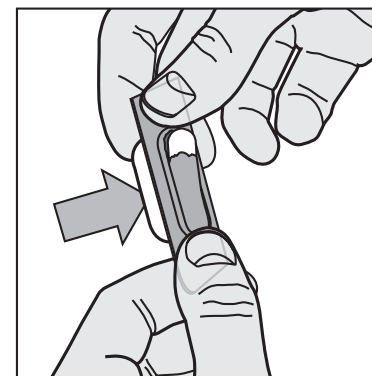
1. **Separate one capsule:** tear along the perforated lines to separate one capsule “pocket” from the strip.



2. **Peel back the outer layer:** starting at the coloured corner, lift and peel over the pocket.



3. **Push out the capsule:** gently push one end of the capsule through the foil layer.



If you take more Hycamtin than you should

Contact a doctor or pharmacist immediately for advice if you have taken too many capsules or if a child has accidentally taken the medicine.

If you forget to take Hycamtin

Do not take a double dose to make up for a forgotten dose. Just take the next dose at the scheduled time.

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 Hycamtin:

- Signs of infections: Hycamtin 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).
- Diarrhoea. This can be serious. If you have more than 3 episodes of diarrhoea per day you should contact your doctor immediately.
- 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 Hycamtin).

- Lung inflammation (interstitial lung disease):

You are most at risk if you have existing lung disease, had radiation treatment to your lungs, or have previously taken medicines that caused lung damage. Signs include:

- difficulty in 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 Hycamtin:

- 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).
- Hair loss.

Common side effects

These may affect **up to 1 in 10 people** treated with Hycamtin:

- Allergic or hypersensitivity reactions (including rash).
- Inflammation and ulcers of the mouth, tongue or gums.
- High body temperature (fever).
- Stomach pain, constipation, indigestion.
- Feeling unwell.
- Itching sensation.

Uncommon side effects

These may affect **up to 1 in 100 people** treated with Hycamtin:

- Yellow skin.

Rare side effects

These may affect **up to 1 in 1,000 people** treated with Hycamtin:

- Severe allergic or anaphylactic reactions.
- Swelling caused by fluid build up (angioedema).
- 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]).

Reporting of side effects

If you get any side effects, talk to your **doctor or pharmacist**. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see details below). By reporting side-effects you can help provide more information on the safety of this medicine.

United Kingdom	Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store
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5. How to store Hycamtin

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

Do not use this medicine after the expiry date which is stated on the carton.

Store in a refrigerator (2°C - 8°C).

Do not freeze.

Keep the blister in the outer carton in order to protect from light.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Contents of the pack and other information

What Hycamtin contains

- The active substance is topotecan. Each capsule contains 0.25 mg or 1 mg of topotecan (as hydrochloride).
- The other ingredients are: hydrogenated vegetable oil, glyceryl monostearate, gelatin, titanium dioxide (E171), and for 1 mg capsules only, red iron oxide (E172). The capsules are printed with black ink that contains black iron oxide (E172), shellac, anhydrous ethanol, propylene glycol, isopropyl alcohol, butanol, concentrated ammonia solution and potassium hydroxide.

What Hycamtin looks like and contents of the pack

Hycamtin 0.25 mg capsules are white to yellowish white and imprinted with “Hycamtin” and “0.25 mg”.

Hycamtin 1 mg capsules are pink and imprinted with “Hycamtin” and “1 mg”.

Hycamtin 0.25 mg and 1 mg capsules are available in packs containing 10 capsules.

Marketing Authorisation Holder

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