

Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986

The medicine is dispensed according to a physician's prescription only

Hycamtin® 0.25 mg Hycamtin® 1 mg

Hard gelatin capsules

The active ingredient and its quantity:

Each Hycamtin 0.25 mg capsule contains 0.25 mg Topotecan (as Hydrochloride).

Each Hycamtin 1 mg capsule contains 1 mg Topotecan (as Hydrochloride).

List of the additional ingredients detailed in section 6.

Read the entire leaflet carefully before using the medicine. This leaflet contains concise information about the medicine. If you have any other questions, refer to the physician or the pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar.

1. What is the medicine intended for?

Hycamtin is used to treat:

patients with relapsed small cell lung cancer (SCLC) for whom retreatment with the first-line regimen is not considered appropriate.

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

Therapeutic group

Antineoplastic agent

2. Before using the medicine

Do not use the medicine:

- **If you are sensitive (allergic)** to topotecan or to any of the additional ingredients contained in the medicine (listed in Section 6).
- Do not use the medicine if you are **breast-feeding**.
- **If your blood cell counts are too low.** Your physician will tell you whether this is the case, based on the results of your last blood test.

Tell your physician if any of these applies to you.

Special warnings regarding the use of the medicine

Before the treatment with Hycamtin, tell the physician if:

- **You have any kidney or liver problems.** Your dose of Hycamtin may need to be adjusted.
- **You are pregnant or are planning to become pregnant** (see "Pregnancy and breast-feeding" section).
- **You plan to father a child** (see "Pregnancy and breast-feeding" section).

Tell your physician if any of these applies to you.

Drug interactions

If you are taking or have recently taken other medicines including non-prescription medicines and food supplements, tell the physician or the pharmacist.

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

Remember to tell your physician if you start to take any other medicine while you're taking Hycamtin.

Use of the medicine and food

Hycamtin capsules may be taken with or without food.

Pregnancy and breast-feeding

Hycamtin is not recommended for pregnant women. It may harm the baby if conceived before, during or soon after treatment. You should use an effective method of contraception. Ask your physician for advice. For women: Do not try to become pregnant until a physician advises you that it is safe to do so.

Male patients who wish to father a child should ask their physician for family planning advice or treatment. If your partner becomes pregnant during your treatment, tell your physician immediately.

Do not breast-feed if you are being treated with Hycamtin. Do not restart breast-feeding until the physician 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.

Important information about some of the ingredients of the medicine

Hycamtin contains a small amount of ethanol (alcohol).

3. How should you use the medicine?

Always use Hycamtin according to the physician's instructions. You should check with the physician or the pharmacist if you are unsure.

The dose (and number of capsules) of Hycamtin you are given will be worked out by your physician, based on:

- **Your body size** (surface area measured in square metres).
- **The results of blood tests** carried out before treatment.

The dosage and treatment regimen will be determined by the physician only.

Do not exceed the recommended dose.

Method of administration

The prescribed number of capsules should be swallowed whole.

Do not chew, crush or halve them.

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's content in your eyes, wash them immediately with gently flowing water for at least 15 minutes. Consult your physician/healthcare provider after eye contact or if you experience a skin reaction.

If you accidentally have taken a higher dosage

Refer to a physician or pharmacist immediately for advice if you have taken too many capsules.

If you took an overdose, or if a child has accidentally swallowed the medicine, refer immediately to a physician or to a hospital emergency room and bring the package of the medicine with you.

If you forgot to take the medicine

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

Persist with the treatment as recommended by the physician.

Do not take medicines in the dark! Check the label and the dose each time you take a medicine. Wear glasses if you need them.

If you have any other questions regarding the use of the medicine, consult the physician or the pharmacist.

4. Side effects

As with any medicine, use of Hycamtin may cause side effects in some of the users. Do not be alarmed by reading the list of side effects. You may not experience any of them.

Serious side effects: tell your physician

These very common side effects may occur in **more than 1 in 10 people** being 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 physician immediately.
- Occasionally, severe stomach pain, fever and possibly diarrhoea (rarely with blood) can be signs of bowel inflammation (*colitis*)

This rare side effect may occur in **1-10 in 10,000 people** being 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 physician immediately if you get any symptoms of these conditions, as hospitalisation may be necessary.

Additional side effects

Very common side effects

These may occur in **more than one in ten people** being 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 physician for advice on how to minimize the risk of bleeding.
- Weight loss and loss of appetite (*anorexia*); tiredness; weakness.
- Nausea (feeling sick), vomiting (being sick).
- Hair loss.

Common side effects

These may occur in **1-10 in 100 people** being 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
- Yellow skin

Rare side effects

These may occur in **1-10 in 10,000 people** being treated with Hycamtin:

- Severe allergic or *anaphylactic* reactions
- Swelling caused by fluid build-up (*angioedema*)
- Itchy rash (or *hives*)
- Collapse.

Side effects whose frequency is not known

The frequency of some side effects is not known (events from spontaneous reports whose frequency cannot be estimated from the available data):

- Severe stomach pain, nausea, vomiting blood, black or bloody stools (a possible sign of gastrointestinal perforation)
- Mouth sores, difficulty swallowing, abdominal pain, nausea, vomiting, diarrhoea, bloody stools (possible signs and symptoms of infection of the inner lining of the mouth, stomach and/or gut [mucosal inflammation])

If a side effect has appeared, if any of the side effects get worse or when you suffer from a side effect that has not been mentioned in the leaflet, you should consult the physician.

Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link: <https://sideeffects.health.gov.il>

5. How to store the medicine?

Avoid poisoning! This medicine and any other medicine should be kept in a closed place out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting without an explicit instruction from the physician.

Do not use the medicine after the expiry date (exp. date) appearing on the carton. The expiry date refers to the last day of that month.

Store in a refrigerator at temperature of 2°C-8°C.

Do not freeze.

Store in the original package to protect from light.

Do not discard capsules in waste water or waste bin. Consult the pharmacist regarding how to dispose of medicines that are no longer needed. This being, to protect the environment.

6. Additional information

In addition to the active ingredient the medicine also contains -

- Hydrogenated vegetable oil, gelatin, glyceryl monostearate, titanium dioxide (E171), black iron oxide (E172), shellac, ethanol anhydrous, propylene glycol, isopropyl alcohol, butanol, ammonia solution concentrated, potassium hydroxide.

For 1 mg capsules only, red iron oxide (E172).

What does the medicine look like and what is the content of the package -

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 packages that contain 10 capsules.

Registration Holder and Importer and its address: Novartis Israel Ltd., P.O.B 7126, Tel Aviv.

Revised in December 2020

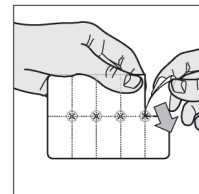
Registration number of the medicine in the National Drug Registry of the Ministry of Health: Hycamtin 0.25 mg: 141 37 31862

Hycamtin 1 mg: 141 38 31863

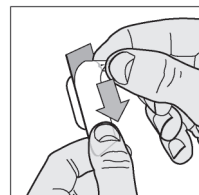
Taking out a capsule

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

1. **Separate one capsule:** tear along the cutting lines to separate one "pocket" from the strip that contains a capsule.



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.

