

Patient Information Leaflet

Read all of this leaflet carefully before you start taking HYCAMTIN.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.

HYCAMTIN has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.

SCHEDULING STATUS: S4

PROPRIETARY NAME AND DOSAGE FORM:

HYCAMTIN® 0,25 mg Hard Capsules

HYCAMTIN® 1 mg Hard Capsules

WHAT HYCAMTIN CONTAINS:

HYCAMTIN 0,25 mg: Each hard capsule contains topotecan hydrochloride equivalent to 0,25 mg topotecan free base.

HYCAMTIN 1 mg: Each hard capsule contains topotecan hydrochloride equivalent to 1 mg topotecan free base.

List of excipients: Hydrogenated vegetable oil, glyceryl monostearate, gelatin, titanium dioxide. Black printing ink comprising black iron oxide (E172), shellac, anhydrous ethanol, propylene glycol, isopropyl alcohol, butanol, concentrated ammonia solution and potassium hydroxide.

1 mg capsules also contain red iron oxide.

WHAT HYCAMTIN IS USED FOR:

HYCAMTIN helps destroy tumours and is used to treat small cell lung tumours. It acts on an enzyme (topoisomerase-I) to prevent growth of tumour cells.

BEFORE YOU TAKE HYCAMTIN:

Do not take HYCAMTIN:

- If you are allergic to topotecan or any of the other ingredients in HYCAMTIN.
- If you are pregnant, or think you are pregnant.

- If you are breastfeeding. You should not restart breastfeeding, until your doctor tells you it is safe to do so.
- If your bone marrow is severely affected by HYCAMTIN, your doctor will tell you to stop HYCAMTIN.

Take special care with HYCAMTIN capsules:

Tell your doctor before you start taking HYCAMTIN if you have any kidney or liver problems, as the dose may need to be adjusted.

Driving and using machines:

HYCAMTIN may make you feel tired. Do not drive or operate any tools or machines if you feel tired or weak.

Taking other medicines:

Please inform your doctor if you are taking or have recently taken any other medicines, even those which you bought without a prescription.

There is no known interaction between HYCAMTIN and alcohol. However, you should check with your doctor whether drinking alcohol is advisable for you.

HOW TO TAKE HYCAMTIN:

The dose of HYCAMTIN which you will have to take is based on your body size and the results of blood tests done before treatment.

The dose should be taken every day for 5 days. This treatment will normally be repeated every three weeks.

HYCAMTIN may be taken with or without food.

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

Once you have started taking HYCAMTIN:

Do not stop taking HYCAMTIN until your doctor advises you to do so.

If you forget to take HYCAMTIN at any time, do not double the dose to make up for a forgotten dose.

Just wait and take the next scheduled dose.

If you have any problems/questions regarding the use of HYCAMTIN, please consult with your doctor.

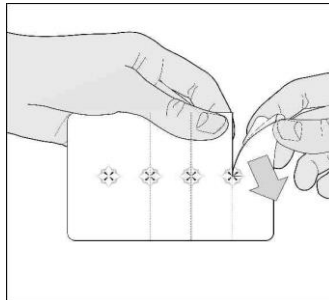
Instructions for Handling:

HYCAMTIN capsules should not be opened or crushed. If the capsules are punctured or leaking, you should immediately wash your hands thoroughly with soap and water or if you get it in your eyes wash them immediately with gently flowing water for at least 15 minutes. Consult your doctor/healthcare provider after eye contact or if you experience a skin reaction.

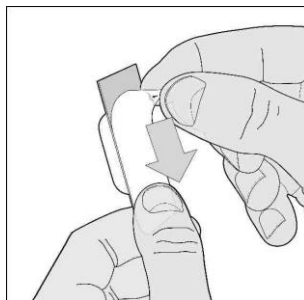
Taking out a capsule:

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

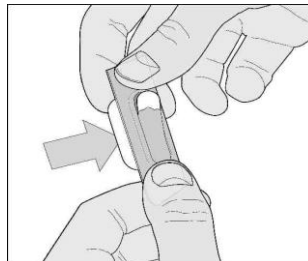
1. **Separate one capsule:** tear along the cutting lines to separate one "pocket" from the strip.



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.



POSSIBLE SIDE EFFECTS:

HYCAMTIN can cause side effects.

The most common side effects with HYCAMTIN are:

- Diarrhoea. This can be serious. If you have more than 3 episodes of diarrhoea per day you should contact your doctor immediately.
- A temporary reduction in the amount of new blood cells produced by your body, particularly of a type of white blood cell which is important for your body to prevent and fight-off an infection. In approximately 1 in 20 patients a serious infection is caught during treatment which can be fatal. If at any time during treatment you feel unwell or develop a temperature you should contact your doctor immediately. In addition you may become temporarily anaemic and tired or it may take longer for a minor injury to stop bleeding. Once again, should you have any concerns contact your doctor immediately. The reduction in the amount of blood cells usually lasts for a few days, starting from approximately day 8 of each treatment cycle and lasting for about a week. In most cases the level of blood cells return to normal in time for the next cycle of treatment.

Other possible side effects are:

- nausea (feeling sick), vomiting, stomach pain, constipation, inflammation of the mouth, tongue or gums
- anorexia (weight loss and loss of appetite)
- hair loss
- fatigue (tiredness), weakness, feeling unwell
- hyperbilirubinaemia (high levels of bilirubin in the blood)
- rash, itching.

Several of these effects may occur during your treatment. If you notice any of these or any other effects not mentioned in this leaflet between courses or after treatment has finished, tell your doctor.

STORING AND DISPOSING OF HYCAMTIN:

Store in a refrigerator (2 °C to 8 °C). Do not freeze.

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

Keep out of the reach and sight of children.

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

If your doctor tells you to stop taking the capsules, please return any left over to your pharmacist. Only keep them if instructed to do so by your doctor.

PRESENTATION:

HYCAMTIN capsules are supplied in a white, opaque, PVC/PCTFE/aluminium, child resistant ('peel-push' layer) blister strip of 10 capsules.

IDENTIFICATION:

HYCAMTIN 0,25 mg: Opaque white to yellowish white hard gelatin capsules, imprinted with HYCAMTIN
0.25 mg

HYCAMTIN 1 mg: Opaque pink hard gelatin capsules, imprinted with HYCAMTIN 1 mg

REGISTRATION NUMBER:

HYCAMTIN 0,25 mg: 42/26/0739

HYCAMTIN 1 mg: 42/26/0740

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE REGISTRATION CERTIFICATE:

Sandoz SA (Pty) Ltd ¹

72 Steel Road

Spartan

Kempton Park

1619

DATE OF PUBLICATION OF THIS PACKAGE INSERT:

9 May 2012

¹ Company Reg. No.: 1990/001979/07