

IRINOTECAN ALPHAPHARM

contains the active ingredient irinotecan hydrochloride

CONSUMER MEDICINE INFORMATION

What is in this leaflet

Please read this leaflet carefully before being treated with IRINOTECAN ALPHAPHARM.

This leaflet answers some common questions about IRINOTECAN ALPHAPHARM.

It does not contain all of the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have benefits and risks. Your doctor has weighed the risks of you taking IRINOTECAN ALPHAPHARM against the benefits they expect it will have for you.

Ask your doctor or pharmacist, if you have any concerns about being treated with this medicine.

Keep this leaflet.

You may need to read it again.

What IRINOTECAN ALPHAPHARM is used for

IRINOTECAN ALPHAPHARM contains the active ingredient, irinotecan hydrochloride.

It is used to treat bowel cancer which has spread to other parts of the body. Cancer, which has spread, cannot be treated by surgery alone and one of the options in this situation is treatment with an anticancer medicine, known as chemotherapy.

IRINOTECAN ALPHAPHARM may be used once spread of cancer

beyond the bowel is first diagnosed. At this time IRINOTECAN ALPHAPHARM will be given in combination with other anticancer medicines. Alternatively, IRINOTECAN ALPHAPHARM is used alone when the cancer has not responded or has returned after initial treatment.

Your doctor may have prescribed IRINOTECAN ALPHAPHARM for another reason.

Ask your doctor if you have any questions about why IRINOTECAN ALPHAPHARM has been prescribed for you.

Use in children

It is not known if IRINOTECAN ALPHAPHARM is safe and effective in the treatment of children.

Before being treated with IRINOTECAN ALPHAPHARM

Some information is provided below. However, always talk to your doctor if you have concerns or questions about your treatment.

When IRINOTECAN must not be given

IRINOTECAN must not be given if you:

- are allergic to irinotecan hydrochloride, or any of the other ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin

Do not take this medicine if you are pregnant.

It may affect your developing baby if you take it during pregnancy.

Pregnancy should be avoided if you or your partner is receiving IRINOTECAN ALPHAPHARM.

Females: Tell your doctor or pharmacist if you are pregnant or intend to become pregnant.

Avoid becoming pregnant by using effective contraception during treatment and up to 6 months after therapy.

Males: Tell your doctor or pharmacist if your partner intends to become pregnant while you are being given IRINOTECAN ALPHAPHARM, or shortly after you have stopped treatment with irinotecan.

It is recommended that you use effective contraception while you are using IRINOTECAN ALPHAPHARM and for at least 3 months after you stop treatment.

Do not breast-feed if you are taking this medicine.

The active ingredient in IRINOTECAN ALPHAPHARM passes into breast milk and there is a possibility that your baby may be affected.

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

If it has expired or is damaged, return it to your pharmacist for disposal.

Before treatment with IRINOTECAN ALPHAPHARM

You should only be treated with IRINOTECAN ALPHAPHARM by a doctor who is experienced in treating patients with cancer. Treatment will normally take place in a hospital because of the need for hospital facilities and skilled personnel.

You will probably feel nauseous and have diarrhoea, vomiting, stomach cramping and possibly infections during or after treatment with IRINOTECAN ALPHAPHARM.

It is likely that your doctor will give you one or more medicines before administering IRINOTECAN ALPHAPHARM, which will help stop you vomiting or feeling sick after the treatment. You will probably also have a blood test before each treatment.

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

You should tell your doctor if:

- you are 65 years of age or older
- you have or have had liver disease; kidney disease or heart disease
- you have previously been treated with radiation therapy
- you have diabetes
- you have asthma
- you have constipation or difficulty urinating
- you have had diarrhoea or have taken anti-diarrhoea medication with the last 24 hours
- you have hereditary fructose intolerance
- you have Crigler-Najjar syndrome or Gilbert's syndrome

- you are going to be vaccinated (have an injection to prevent a certain disease)

Tell your doctor if you are pregnant or plan to become pregnant or are breast-feeding.

Your doctor can discuss with you the risks and benefits involved.

If you have not told your doctor about any of the above, tell him/her before you are given IRINOTECAN ALPHAPHARM.

Taking other medicines

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

Some medicines and IRINOTECAN ALPHAPHARM may interfere with each other. In particular, tell your doctor if you are taking:

- laxatives (e.g. for constipation)
- diuretics (medicines which make you pass urine more frequently e.g. for heart disease)
- any medicine for nausea or diarrhoea
- dexamethasone (may be used to treat e.g. skin diseases, asthma or other allergic disorders)
- anti-convulsants used to treat seizures
- St. Johns Wort, a herbal medicine used to treat depression
- Ketoconazole, used to treat fungal infections.
- Atazanavir, used to treat HIV-1 infection
- Prochlorperazine, used to treat nausea, vomiting and dizziness
- Suxamethonium or other medicines used as an anaesthetic
- Other medicines used to treat cancer.

These medicines may be affected by IRINOTECAN ALPHAPHARM or may affect how well it works. You may need different amounts of your

medicines, or you may need to take different medicines.

If you are not sure whether you are taking any of these medicines, check with your doctor or pharmacist.

Your doctor or pharmacist can tell you what to do if you are taking any of these medicines.

Treatment with IRINOTECAN ALPHAPHARM

How IRINOTECAN ALPHAPHARM is given

IRINOTECAN ALPHAPHARM will be given to you by your doctor. It is diluted and given by slow infusion into a vein over a period of 90 minutes.

It is recommended that IRINOTECAN ALPHAPHARM be given in different treatment courses depending on whether IRINOTECAN ALPHAPHARM is given alone or in combination with other anticancer medicines.

When IRINOTECAN ALPHAPHARM is given in combination, treatment courses are of 6 weeks' duration given either weekly or fortnightly. Rest periods of 1 or 2 weeks are incorporated into the 6-week courses.

When IRINOTECAN ALPHAPHARM is given alone, treatment courses include IRINOTECAN ALPHAPHARM being given weekly for 4 weeks followed by a 2-week rest period and IRINOTECAN ALPHAPHARM being given once every 3 weeks.

Depending on your response, treatment courses may be repeated more than once.

It is recommended that treatment with IRINOTECAN ALPHAPHARM should be interrupted if you get severe diarrhoea or other intolerable side effects.

Dose

The recommended dose for IRINOTECAN ALPHAPHARM varies between 125mg/m² and 350mg/m² (based on body surface area), depending on the dosing schedule.

Your doctor will decide the dose of IRINOTECAN ALPHAPHARM to be given.

Ask your doctor if you want more information on the dose of IRINOTECAN ALPHAPHARM and the other medicines that you will be receiving and how they are given.

After your first treatment course, the dose of IRINOTECAN ALPHAPHARM may be increased by your doctor if you have not had too many side effects.

Your doctor will lower the dose or stop treatment if you have serious side effects, particularly diarrhoea or changes appearing in your blood tests.

In case of overdose

Overdose is unlikely as treatment will be given in hospital under the supervision of a doctor. The possible effects of overdose are the same as those listed below under Side Effects.

Tell your doctor immediately if you do not feel well while being given IRINOTECAN ALPHAPHARM.

You may need urgent medical attention.

While being treated with IRINOTECAN ALPHAPHARM

Things you must do

Keep all appointments with your doctor and always discuss with your doctor any problems during or after treatment with IRINOTECAN ALPHAPHARM.

Tell your doctor as soon as possible if diarrhoea occurs.

Diarrhoea is a common side effect of IRINOTECAN ALPHAPHARM. If untreated, severe diarrhoea can be life-threatening.

Your doctor will prescribe loperamide (an antidiarrhoeal) for you to take in case you get diarrhoea after treatment. You should start taking loperamide, when you first have poorly formed or loose stools or bowel movements more frequent than you would normally expect.

You must tell your doctor if you cannot get diarrhoea under control within 24 hours after taking loperamide.

You should not take loperamide for more than 48 hours.

Also tell you doctor if you develop a fever in addition to the diarrhoea.

In these cases, your doctor may give you antibiotics. If the diarrhoea or fever persists you may become dehydrated and need to go to Accident and Emergency at your nearest hospital for treatment.

You may need to take antibiotics if there are changes in your blood tests indicating a lack of white blood cells. Symptoms of this may include frequent infections such as fever, severe chills, and sore throat or mouth ulcers. If this persists, you may need to go to Accident and Emergency at your nearest hospital for treatment.

If you have severe stomach cramps you may need to be treated with antibiotics.

You must use a reliable method of contraception (birth control) while being treated with IRINOTECAN ALPHAPHARM.

However, if you become pregnant while being treated with this medicine, tell your doctor immediately.

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are being given IRINOTECAN ALPHAPHARM.

Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.

It may affect other medicines used during surgery.

Keep all of your doctor's appointments so that:

- **your progress can be checked**
- **you have your follow up doses of IRINOTECAN ALPHAPHARM.**

Your doctor may want to check your blood pressure and do some blood and other tests from time to time to make sure the medicine is working and to prevent unwanted side effects.

It is also important to have your follow-up doses of IRINOTECAN ALPHAPHARM at the appropriate times to get the best effects from your treatments.

Things you must not do

Because of the risk of diarrhoea, do not take laxatives during treatment courses with IRINOTECAN ALPHAPHARM.

Talk to your doctor if you need more information about this.

Do not start taking any other medicines, prescription or not, without first telling your doctor or pharmacist.

Things to be careful of

This medicine can lower the number of white blood cells and platelets in your blood. This means that you have an increased chance of getting an infection or bleeding. The following precautions should be taken to reduce your risk of infection or bleeding.

Avoid people who have infections.

Check with your doctor immediately if you think you may be getting an infection, or if you get a fever, chills, cough, hoarse throat, lower back or side pain or find it painful or difficult to urinate.

Be careful when using a toothbrush, toothpick or dental floss.

Your doctor, dentist, nurse or pharmacist may recommend other ways to clean your teeth and gums. Check with your doctor before having any dental work.

Be careful not to cut yourself when you are using sharp objects such as a razor or nail cutters.

Avoid contact sports or other situations where you may bruise or get injured.

Take precautions to protect other people while you are receiving chemotherapy and for one week after the treatment period.

Your body breaks down irinotecan (the active ingredient of IRINOTECAN ALPHAPHARM) and uses it to fight cancer. The breakdown products may be excreted in body fluids and waste, including blood, urine, faeces, vomit and semen.

Take the following precautions:

- flushing the toilet twice to dispose of any body fluids and waste
- wearing gloves to clean any spill of body fluid or waste. Use paper towels or old rags, a strong solution of non-bleaching detergent and large amounts of water to mop up the spill. Discard the towels or rags into a separate waste bag and dispose of fluids in the toilet
- washing linen or clothing that is heavily contaminated by body fluids or waste separately from other items. Use a strong solution of non-bleaching detergent and large amounts of water
- placing soiled disposable nappies and other pads in a plastic bag, seal and dispose into the garbage
- using a barrier method such as a condom, for sexual intercourse

Make sure you know what to do if you experience nausea, vomiting or diarrhoea.

You may feel nauseous, and have vomiting, diarrhoea, and/or stomach cramping, during or after treatment with irinotecan. This can lead to dehydration. It is likely that your doctor will give you one or more medicines to help manage these side effects.

Be careful driving or operating machinery until you know how IRINOTECAN ALPHAPHARM affects you.

This medicine may cause dizziness or visual disturbances which may occur within 24 hours following the administration of irinotecan in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

Be careful when drinking alcohol while you are being given this medicine.

If you drink alcohol, dizziness light-headedness and diarrhoea may be worse.

Side effects

Like all other medicines, IRINOTECAN ALPHAPHARM may cause unwanted side effects. Side effects are very common with anti-cancer medicines such as IRINOTECAN ALPHAPHARM and they may be severe. Deaths have occurred which, in some cases, may have been related to treatment.

Tell your doctor immediately if you get any of the following side effects:

- diarrhoea
- start to vomit
- develop a fever or any type of infection
- fainting, light-headedness or dizziness
- bloody or black stools
- cannot eat or drink due to nausea or vomiting.

The above side effects may be serious. You may need urgent medical attention.

Very common side effects (occurring in over 50% of patients) are:

- diarrhoea or stomach cramps; may occur early (during or shortly after a treatment) or late (usually more than 24 hours after treatment)
- nausea, vomiting, loss of appetite
- anaemia which may make you weak and light-headed or may cause you to faint
- increased risk of infections including severe infections
- weakness
- hair loss

Common side effects (occurring in 10-50% of patients) are:

- constipation, flatulence (passing wind), sore mouth, heartburn
- fever (increased body temperature), chills, headache, back pain or other types of pain, infection, fluid retention which results in swelling
- weight loss, dehydration
- runny nose or eyes, increased saliva, sweating or flushing
- skin rash
- coughing, difficulty breathing
- difficulty sleeping or dizziness.

Less common side effects (occurring in less than 10% of patients) are:

- increased risk of bleeding
- severe fever associated with a reduction in white blood cell numbers
- bleeding from the bowel
- jaundice (yellowing of skin and eyes)
- severe breathing difficulties
- generally feeling unwell
- abnormal manner of walking
- fungal infections (e.g. thrush)
- kidney problems

- problem speaking

In addition to the above side effects the following have also been reported:

- allergic reactions; some of the symptoms of an allergic reaction may include: rash, itching or hives on the skin. In more severe cases symptoms may also include shortness of breath, wheezing or difficulty breathing, swelling of the face, lips, tongue or other parts of the body
- pins and needles
- abdominal bloating and/or pain
- chest pains
- hiccups.

Other side effects not listed above may happen in some people. Some of these side effects can only be found when your doctor does tests to check your progress.

Rare side effects of IRINOTECAN ALPHAPHARM have also been reported. These include effects on the heart and blood vessels such as:

- slowed heart beat
- fainting
- blackouts
- blood clots
- swelling and redness along a vein, which is extremely tender when touched
- chest pains
- heart attack
- stroke

Your doctor has information on monitoring for such side effects and their treatment. A very small number of patients have died suddenly while on irinotecan hydrochloride.

Tell your doctor as soon as possible if you experience any side effects, including any effects not listed above.

After treatment with IRINOTECAN ALPHAPHARM

Storage

IRINOTECAN ALPHAPHARM will normally be stored in a hospital.

It should be stored below 25°C and should be protected from light (kept in the packaging before use).

IRINOTECAN ALPHAPHARM must never be frozen.

Product description

What it looks like

IRINOTECAN ALPHAPHARM is a sterile, pale yellow, clear fluid for injection supplied as 2, 5 or 50 millilitres (mL) in amber glass vials. Each vial is for single use only and is packaged singly in a foil/plastic blister contained within an outer carton to protect against inadvertent breakage and leakage. It is recommended that the unopened blister should remain in the carton until time of use.

Ingredients

The active ingredient in IRINOTECAN ALPHAPHARM is irinotecan hydrochloride. There are 20 milligrams of irinotecan hydrochloride in 1 mL of IRINOTECAN ALPHAPHARM.

Other ingredients are sorbitol, lactic acid, sodium hydroxide and water injections.

Supplier

IRINOTECAN ALPHAPHARM is supplied in Australia by:

Alphapharm Pty Ltd

Level 1, 30 The Bond

30 - 34 Hickson Road

Millers Point NSW 2000

www.mylan.com.au

Australian registration number:

IRINOTECAN ALPHAPHARM

500mg/25mL: AUST R 163840

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