

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.
- are or may become pregnant
- are breastfeeding or intend to breast-feed.

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.

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 or asthma
- you have constipation or difficulty urinating
- 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)

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 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 (eg. for constipation)
- diuretics (medicines which make you pass urine more frequently eg. for heart disease)
- any medicine for nausea or diarrhoea
- dexamethasone (may be used to treat eg. 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.

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 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.

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 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 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 pregnancy occurs, consult your doctor.

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.

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 Limited

(ABN 93 002 359 739)

Level 1, 30 The Bond

30 - 34 Hickson Road

Millers Point NSW 2000

Phone: (02) 9298 3999

www.mylan.com.au

Medical Information

Phone: 1800 028 365

Australian registration numbers:

IRINOTECAN ALPHAPHARM

40mg/2mL: AUST R 148579

IRINOTECAN ALPHAPHARM

100mg/5mL: AUST R 148578

IRINOTECAN ALPHAPHARM

500mg/25mL: AUST R 163840

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