

DBL™ Irinotecan Injection Concentrate

Irinotecan hydrochloride trihydrate

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about DBL Irinotecan Injection Concentrate. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

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

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet.

You may need to read it again.

What DBL Irinotecan is used for

This medicine is used to treat cancer of the colon or rectum that has:

- spread to other parts of the body, or
- recurred or progressed following initial therapy.

This medicine belongs to a group of medicines called antineoplastic or cytotoxic medicines.

It works by killing cancer cells and stopping cancer cells from growing and multiplying. It may be used alone or in combination with other medicines to treat cancer.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

This medicine is not addictive.

It is available only with a doctor's prescription.

This medicine is not expected to affect your ability to drive a car or operate machinery.

There is not enough information to recommend the use of this medicine for children.

Before you are given DBL Irinotecan

When you must not be given it

You must not be given DBL Irinotecan Injection Concentrate if you have an allergy to:

- any medicine containing irinotecan hydrochloride trihydrate
- any of the 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.

You must not be given 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.

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 DBL Irinotecan Injection Concentrate, or shortly after you have stopped treatment with irinotecan.

It is recommended that you use effective contraception while you are using DBL Irinotecan Injection Concentrate and for at least 3 months after you stop treatment.

Do not breast-feed if you are being treated with this medicine.

Irinotecan passes into breast milk and there is a possibility that your baby may be affected.

If you are not sure whether you should be given this medicine, talk to your doctor.

Do not use this medicine after the expiry date printed on the pack.

If you use this medicine after the expiry date has passed, it may not work as well.

Do not use this medicine 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 you are given it

Tell your doctor if you have an infection or high temperature.

Your doctor may decide to delay your treatment until the infection has gone. A mild illness, such as a cold, is not usually a reason to delay treatment.

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

Tell your doctor if you have or have had any of the following medical conditions:

- problems with your heart or blood vessels
- liver problems, including liver disease or raised liver enzymes
- constipation/obstruction of the bowel
- you have kidney disease or have difficulty urinating
- Crigler-Najjar syndrome or Gilbert's syndrome
- hereditary fructose intolerance
- asthma
- diabetes.

Tell your doctor if you have previously received pelvic/abdominal radiotherapy.

Tell your doctor if you have had diarrhoea or taken anti-diarrhoea medication, within the last 24 hours.

Tell your doctor if 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.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from

your pharmacy, supermarket or health food shop.

Some medicines and irinotecan may interfere with each other. These include:

- other medicines used to treat cancer, radiation therapy, or any other treatment which lowers your immune system
- dexamethasone (also called a glucocorticoid), which may be used to prevent nausea or vomiting, or to treat skin diseases, asthma, or other allergic disorders
- any medicine used to treat nausea or vomiting
- laxatives, medicines used to treat constipation
- diuretics, also called water or fluid tablets
- anticonvulsants, used to treat seizures
- St John's Wort, a herbal medicine used to treat depression
- ketoconazole, used to treat fungal infections
- atazanavir, used to treat HIV infection
- prochlorperazine, used to treat nausea, vomiting and dizziness
- suxamethonium and other medicines used to relax muscles.

These medicines may be affected by irinotecan or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

How DBL Irinotecan is given

How much is given

Your doctor will decide what dose you will receive. This depends on several factors including your height and weight, and whether or not other chemotherapy medicines are also being given.

Irinotecan may be given alone or in combination with other medicines to treat cancer.

Several treatment courses of irinotecan may be needed, depending on your response to treatment.

Additional treatment may not be repeated until your blood cell numbers return to acceptable levels and any uncontrolled effects have been controlled.

Ask your doctor if you want to know more about the dose of irinotecan you will be receiving.

How it is given

DBL Irinotecan Injection Concentrate is given as a slow injection into a vein. It must only be given by a nurse or doctor.

If you receive too much (overdose)

As Irinotecan Injection Concentrate is given to you under the supervision of your doctor, it is very unlikely that you will receive an overdose. However if you experience severe side effects tell your doctor immediately or call the Poison Information Centre (in Australia call 131

126), or go to Accident and Emergency at your nearest hospital.

You may need urgent medical attention.

Symptoms of an overdose may include the side effects listed below in the 'Side Effects' section, but are usually of a more severe nature.

Ask your doctor or pharmacist if you have any concerns.

While you are being given DBL Irinotecan

Things you must do

Tell your doctor as soon as possible if diarrhoea occurs.

Diarrhoea is a common side effect of irinotecan. Your doctor will prescribe a medicine (loperamide) 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 frequently than you would normally expect.

If untreated, severe diarrhoea can be life-threatening

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

You must use a reliable method of contraception (birth control) while being treated with irinotecan. However, if you become pregnant while you are 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.

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.

Your doctor may want to check your blood pressure and do some blood and other tests from time to time to check on your progress and to detect any unwanted side effects. It is also important to have your follow-up doses of irinotecan at the appropriate times to get the best effects from your treatments.

Things you must not do

Do not take any laxatives without checking with your doctor.

Diarrhoea is a common side effect of irinotecan. Taking laxatives, even if you are constipated, may cause or worsen diarrhoea.

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 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 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

Tell your doctor or pharmacist as soon as possible if you do not feel well or if you

experience severe side effects while you are being treated with irinotecan.

Like other medicines used to treat cancer, irinotecan may have unwanted side effects, some of which may be serious. You may need medical attention if you get some of the side effects.

If you are over 65 years of age you may have an increased chance of getting side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- nausea
- loss of appetite
- weight loss
- hair loss
- constipation (remember do not take laxatives)
- heartburn, indigestion, hiccups
- bloating, excessive wind
- sore mouth, mouth ulcers
- difficulty sleeping
- headache.

The above list includes side effects which are usually mild and short-lived.

Tell your doctor or nurse as soon as possible if you notice diarrhoea.

If untreated, severe diarrhoea can be life threatening. Your doctor will probably prescribe loperamide (a medicine used to treat diarrhoea) 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 more frequent bowel movements than you would normally expect.

Tell your doctor or nurse as soon as possible if you notice any of the following:

- vomiting
- abdominal cramping/pain
- runny nose or eyes, increased salivation, sweating or flushing
- shortness of breath when exercising, dizziness, looking pale and walking abnormally
- unusual tiredness or weakness
- swelling and redness along a vein
- fluid retention that results in swelling.
- fungal infections (e.g. thrush)

The above list includes serious side effects that may require medical attention.

Tell your doctor or nurse immediately, or go to Accident and Emergency at your nearest hospital, if you notice any of the following:

- inability to control diarrhoea within 24 hours after taking loperamide
- any signs of infection such as fever, chills, sore throat or cough, low back or side pain, painful or difficult urination
- symptoms of dehydration, such as faintness, light-headedness or dizziness, increased thirst, wrinkling of the skin
- inability to drink due to nausea or vomiting
- signs of an allergic reaction, such as shortness of breath, wheezing or

- difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching, hives on the skin
- unusual bleeding or bruising (such as bloody or black stools, blood in urine)
 - yellowing of the skin and/or eyes (these may be symptoms of a type of liver disease called jaundice)
 - chest pain.
 - heart and blood vessels related side effects such as slowed heartbeat, fainting, blackout, blood clot, heart attack or stroke.

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people.

Some of these side effects can only be found when your doctor does tests from time to time to check your progress.

The benefits and side effects of irinotecan may take some time to occur. Therefore even after you have finished treatment with irinotecan, you should tell your doctor if you notice anything that is making you feel unwell.

After using DBL Irinotecan

Storage

DBL Irinotecan Injection Concentrate will be stored in the pharmacy or on the ward. The injection is kept in a cool dry place, protected from light where the temperature stays below 30°C. Do not freeze.

Product description

What it looks like

DBL Irinotecan Injection Concentrate is a pale yellow, clear fluid for injection in an amber glass vial. It is available in single pack sizes of 40mg/2mL, 100mg/5mL and 500mg/25mL.

Ingredients

DBL Irinotecan Injection Concentrate contains 20mg/mL of irinotecan hydrochloride trihydrate as the active ingredient. It also contains:

- sorbitol
- lactic acid
- water for injections.

It might also contain sodium hydroxide and dilute hydrochloric acid

This medicine does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

Sponsor

Pfizer Australia Pty Ltd
Sydney NSW 2000
Toll Free Number: 1800 675 229
www.pfizer.com.au
AUST R numbers:

DBL Irinotecan Injection Concentrate:

40mg/2mL AUST R 97881

100mg/5mL AUST R 98118

500mg/25mL AUST R 131536

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