

CAMPTOSAR[®]

Irinotecan hydrochloride

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about CAMPTOSAR.

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 treating you with CAMPTOSAR against the expected benefits it will have for you.

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

Keep this leaflet.

You may need to read it again.

What CAMPTOSAR is used for

CAMPTOSAR 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. One of the options in this situation is treatment with an anticancer medicine, known as chemotherapy.

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

Ask your doctor if you have any questions about why

CAMPTOSAR has been prescribed for you.

Your doctor may have prescribed it for another purpose.

Use in children

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

Before being treated with CAMPTOSAR

When CAMPTOSAR must not be given

CAMPTOSAR must not be given if you:

- are allergic to irinotecan hydrochloride or any of the ingredients listed at the end of this leaflet
- are or may become pregnant
- are breastfeeding or intend to breastfeed.

Before treatment with CAMPTOSAR

You should be treated with CAMPTOSAR 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.

It is likely that your doctor will give you one or more medicines before administering CAMPTOSAR, to 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
- you have asthma
- you have constipation
- you have 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 your doctor before you are given CAMPTOSAR.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including:

- all prescription medicines
- all medicines, vitamins, herbal supplements or natural therapies you buy without a prescription from a pharmacy, supermarket, naturopath or health food shop.

Some medicines and CAMPTOSAR 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 skin diseases, asthma or other allergic disorders)
- 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-1 infection
- prochlorperazine, used to treat nausea, vomiting and dizziness
- suxamethonium or other medicines used as an anaesthetic
- other medicines used to treat cancer.

Ask your doctor or other health care professional if you are not sure about this list of medicines.

You may need to take different amounts of your medicines or you may need to use different medicines. Your doctor will advise you.

How CAMPTOSAR is given

CAMPTOSAR 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 CAMPTOSAR be given in different treatment courses depending on whether CAMPTOSAR is given alone or in combination with other anticancer medicines.

Combination Treatment Courses

When CAMPTOSAR 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.

Single Treatment Courses

CAMPTOSAR may be given either weekly for 4 weeks followed by a 2 week rest period or it may be given once every 3 weeks.

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

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

Dose

Your doctor will decide the most appropriate dose of CAMPTOSAR to be given.

Ask your doctor if you want more information about the dose of CAMPTOSAR and the other medicines you will be receiving and how they are given while you are being treated with CAMPTOSAR.

After your first treatment course, the dose of CAMPTOSAR 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 CAMPTOSAR.

While being treated with CAMPTOSAR

Things you must do

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

Tell your doctor as soon as possible if diarrhoea occurs.

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

Your doctor will prescribe loperamide (a medicine 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 have more frequent bowel movements 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 your 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, 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 CAMPTOSAR. 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 CAMPTOSAR.

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

CAMPTOSAR, like all other medicines, may cause unwanted side effects. Side effects are very common with anti-cancer medicines such as CAMPTOSAR 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
- problems 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
- bloating or pain in upper stomach
- 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 CAMPTOSAR 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 CAMPTOSAR.

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

After treatment with CAMPTOSAR

Storage

CAMPTOSAR will normally be stored in a hospital. It should be stored below 30°C and should be protected from light (kept in the packaging before use). CAMPTOSAR must never be frozen.

Product description

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What it looks like

CAMPTOSAR is a sterile, clear, light yellow, solution in a vial. Each vial is for single use only and is contained in an outer carton.

Ingredients

The active ingredient in CAMPTOSAR is irinotecan hydrochloride. There is 20 mg of irinotecan hydrochloride in each 1 mL of CAMPTOSAR injection.

CAMPTOSAR also contains:

- sorbitol
- lactic acid
- Water for Injections.

It might also contain sodium hydroxide or hydrochloric acid.

Supplier

CAMPTOSAR is supplied in Australia by:

Pfizer Australia Pty Ltd

ABN 50 008 422 348

38-42 Wharf Road

West Ryde NSW 2114

Toll Free Number 1800 675 229.

CAMPTOSAR is supplied in New Zealand by:

Pfizer New Zealand Ltd

PO Box 3998

Auckland

Toll Free Number: 0800 736 363.

Australian Registration Numbers

40 mg/2 mL: AUST R 58807
(not currently supplied)

100 mg/5 mL: AUST R 58806
(not currently supplied)

300 mg/15 mL: AUST R 146909.

Date of preparation

This leaflet was revised in September 2014.