

# CAMPTOSAR(R) INJECTION

*Irinotecan hydrochloride*

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## Consumer Medicine Information

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### What is in this leaflet

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**Please read this leaflet carefully before being treated with CAMPTOSAR.**

This leaflet answers some common questions about CAMPTOSAR. It does not contain all the available information and 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.**

**Consider keeping this leaflet even after your treatment with CAMPTOSAR is finished.**

You may need to read it again.

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### What CAMPTOSAR is used for

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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 and one of the options in this situation is treatment with an anticancer medicine (known as chemotherapy). CAMPTOSAR contains the active ingredient, irinotecan hydrochloride.

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.

Your doctor, however, may prescribe CAMPTOSAR for another purpose.

**Ask your doctor if you have any questions about why CAMPTOSAR has been prescribed for you.**

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### Before being treated with CAMPTOSAR

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

#### **When CAMPTOSAR must not be given**

CAMPTOSAR 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 CAMPTOSAR**

You should only 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.

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

It is likely that your doctor will give you one or more medicines before administering CAMPTOSAR, 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.

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

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 medicines used to treat depression
- \* ketoconazole, an oral antifungal medicine.

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

### **Children**

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

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## **Treatment with CAMPTOSAR**

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### **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.

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.

When CAMPTOSAR is given alone, treatment courses include CAMPTOSAR being given weekly

for 4 weeks followed by a 2 week rest period and CAMPTOSAR being 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**

The recommended dose for CAMPTOSAR varies between 125 mg/m<sup>2</sup> and 350 mg/m<sup>2</sup> (based on body surface area), depending on the dosing schedule.

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

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 by your 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.**

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## **While being treated with CAMPTOSAR**

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### **Things you must do**

**Keep all appointments with your doctor and always discuss with**

**your doctor any problems during or after treatment with CAMPTOSAR.**

Diarrhoea is a common side effect of CAMPTOSAR.

**Tell your doctor as soon as possible if diarrhoea occurs.**

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

**You should not take loperamide for more than 48 hours.**

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, 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 CAMPTOSAR.**

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 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.**

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## Side effects

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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 diarrhoea, start to vomit, develop a fever or any type of infection, if you experience symptoms such as fainting, light-headedness or dizziness, have bloody or black stools or cannot eat or drink due to nausea or vomiting.**

Side effects of CAMPTOSAR are:

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

- \* 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):**

- \* 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):**

- \* 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.

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.

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.**

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## After treatment with CAMPTOSAR

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### **Storage**

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

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## Product Description

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### **What CAMPTOSAR looks like**

CAMPTOSAR is a sterile, pale yellow, clear fluid for injection supplied as 2 or 5 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.

### **Identification**

CAMPTOSAR can be identified by an Australian Register Number which is found on the carton:

2 mL AUST R 58807

5 mL AUST R 58806

## ***Ingredients***

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

Other ingredients are sorbitol, lactic acid, sodium hydroxide and 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  
Australia

**Toll Free number: 1800 675 229**

This leaflet was revised 28 November 2006.

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