

APPROVED PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: **S4**

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM:

CAMPTO[®] 40 mg/2 ml Solution for Infusion

CAMPTO[®] 100 mg/5 ml Solution for Infusion

CAMPTO[®] CSV 300 mg/15 ml Solution for Infusion

Read all of this leaflet carefully before you are administered CAMPTO:

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or pharmacist.
- CAMPTO has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

WHAT CAMPTO CONTAINS:

The active substance is irinotecan hydrochloride trihydrate 40 mg in CAMPTO 40 mg/2 ml, irinotecan hydrochloride trihydrate 100 mg in CAMPTO 100 mg/5 ml and irinotecan hydrochloride trihydrate 300 mg in CAMPTO 300 mg/15 ml.

The other ingredients in CAMPTO 40 mg/2 ml, CAMPTO 100 mg/5 ml and CAMPTO 300 mg/15 ml are D-sorbitol, lactic acid, sodium hydroxide and water for injection.

WHAT CAMPTO IS USED FOR:

CAMPTO is used to treat colorectal cancer.

BEFORE YOU ARE ADMINISTERED CAMPTO:

You should not be administered CAMPTO:

- If you are hypersensitive (allergic) to irinotecan hydrochloride trihydrate or any of the other ingredients of CAMPTO.
- If you are pregnant or breastfeeding.
- If you have severe bone marrow failure.
- If your WHO performance status > 2 (i.e. if your general health status does not allow you to carry out general activities of daily living).
- If you have a disease involving frequent inflammation of the intestine (chronic inflammatory bowel disease) or blockage of the intestine (ileus).
- If your bilirubin (breakdown product of red blood cells) level is high.
- If you are a child.
- If you are taking azole antifungal medication (used to treat fungal infections) or St John's Wort (a herbal supplement).

Tell your doctor or healthcare professional before being given CAMPTO if:

- you have impaired liver function you are at greater risk of developing severe decrease in white blood cells or fever.
- you experience nausea and vomiting. If you experience vomiting together with delayed diarrhoea, you should be hospitalised for treatment.
- you experience early diarrhoea together with a group of symptoms such as sweating, abdominal cramping, watery eyes and salivation. If this occurs, inform your doctor as a specific medication is required in order for these symptoms to disappear.
- you are an elderly patient, the dose may have to be adjusted accordingly.

Contraceptive measures must be taken during and for at least 3 months after stopping therapy.

Avoid vaccination with live vaccines.

CAMPTO should only be administered under the supervision of a qualified medical doctor in units specialised in the administration of chemotherapy. It is recommended that CAMPTO be administered only in healthcare institutions with adequately equipped facilities, including an intensive care unit.

Some people will need special care from their doctors when they are on CAMPTO. It is especially important that your doctor explains the need for sufficiently prolonged antidiarrhoeal treatment and abundant fluid intake if you require it.

You may develop diarrhoea soon after treatment or delayed diarrhoea, which if not properly treated can be life-threatening. As soon as the first liquid stool occurs please consult your doctor or healthcare professional immediately for appropriate treatment. You may need an antibiotic or hospitalisation.

Your blood cell count should be monitored weekly as infection may occur due to a decrease in white blood cells. Fever together with a decrease in white blood cells should be urgently treated in hospital. The CAMPTO dose should be delayed or reduced accordingly.

Pregnancy and Breastfeeding:

If you are pregnant or breastfeeding your baby while being administered CAMPTO, please consult your doctor, pharmacist or healthcare professional for advice before you receive this medicine.

You should not use CAMPTO if you are pregnant or breastfeeding your baby.

Driving and using machinery:

There is potential for dizziness or visual disturbances, and it is advised not to drive or operate machinery if these symptoms occur.

Important Information about some of the ingredients of CAMPTO:

Since CAMPTO contains sorbitol, it is unsuitable for use in hereditary fructose intolerance.

Taking other medicines with CAMPTO:

If you are taking other medicines on a regular basis, including complementary, traditional or herbal medicines (e.g. St. John's Wort), the use of CAMPTO with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or healthcare professional for advice.

CAMPTO may interact with the following medicines:

- Medicines used to cause muscle paralysis/anaesthesia during surgery (neuromuscular blocking agents). The effect of these medicines may be prolonged when administered together with CAMPTO.
- Other medicines used for cancer therapy (antineoplastic agents). When administered together with CAMPTO, these agents may worsen diarrhoea and blood disorders that may be experienced.
- A cortisone medicine known as dexamethasone used to treat inflammation and also cancer. When administered together with CAMPTO, dexamethasone may enhance the chances of experiencing a decrease in a type of white blood cells (a blood disorder known as lymphocytopenia).
- Laxatives, as these can worsen the incidence or severity of diarrhoea.
- Medicines that increase urination (diuretics) as this, together with the vomiting

and diarrhoea that may be experienced with CAMPTO, can result in dehydration.

- Medicines used to treat epilepsy (i.e. anticonvulsants e.g. carbamazepine, phenobarbital or phenytoin) decrease the effect of CAMPTO.
- Medicines used to treat fungal infection, known as azole antifungals (e.g. ketoconazole), as these may increase the effect of CAMPTO.
- A HIV medicine known as atazanavir may increase the effects of CAMPTO.
- A cancer medicine known bevacizumab may increase the effects of CAMPTO.
- St. John's Wort (a herbal medication used to treat depression). When administered together with CAMPTO, the effect of CAMPTO is reduced.

HOW TO RECEIVE CAMPTO:

CAMPTO is an injection. You will not be expected to give yourself CAMPTO. It will be given to you by a person who is qualified to do so.

If you receive more CAMPTO than you should:

Since a healthcare professional will administer CAMPTO, he/she will control the dosage. However in the event of overdosage, your doctor will manage the overdosage.

If you miss a dose of CAMPTO:

Do not receive a double dose to make up for forgotten individual doses.

POSSIBLE SIDE EFFECTS:

CAMPTO can have side effects. Not all side effects reported for CAMPTO are included in this leaflet. Should your general health worsen or if you experience any

untoward effects while taking CAMPTO please consult your doctor, pharmacist or other health care professional for advice.

The following conditions have been reported with the use of CAMPTO:

- severe allergic reactions
- perforation in the intestine
- kidney impairment or failure

These are very serious side effects. You may need urgent medical attention or hospitalisation. Tell your doctor or healthcare professional immediately.

Diarrhoea

CAMPTO may cause you to have diarrhoea. There are two types of diarrhoea, which can be distinguished by when they start. “Early” diarrhoea starts less than 24 hours after the infusion and “delayed” diarrhoea starts more than 24 hours after the infusion. If you have ANY DIARRHOEA it is IMPORTANT that you tell your doctor or healthcare professional immediately.

Patients with an increased risk of diarrhoea are those who had a previous abdominal/pelvic radiotherapy and initial raised white blood cells.

Early diarrhoea (Frequent)

- if your diarrhoea starts less than 24 hours after the infusion (“early diarrhoea”) you should contact your doctor IMMEDIATELY.

This “early diarrhoea” may be accompanied by a group of other symptoms listed below. This is known as acute cholinergic syndrome occurring during or within the first 24 hours after the infusion of CAMPTO. The symptoms may be:

Frequent:

- abdominal pain/cramping

Less frequent:

- chills
- lacrimation (watery eyes)
- rhinitis (irritation and inflammation inside the nose which may result in stuffy nose, runny nose and/or post-nasal drip)
- dizziness
- hypotension (low blood pressure)
- malaise (lack of well being)
- increased salivation (mouth watering)
- myosis (constriction to the pupil of the eyes)

Frequency unknown:

- sweating
- visual disturbances
- conjunctivitis (inflammation of the eye)
- vasodilation (widening of blood vessels)

Delayed diarrhoea (*Frequent*)

- if your diarrhoea starts more than 24 hours after the infusion (“delayed diarrhoea”) you should IMMEDIATELY contact your doctor.

You must tell your doctor if:

- you have nausea and vomiting as well as diarrhoea
- you have any fever as well as the diarrhoea
- you still have diarrhoea 48 hours after starting the diarrhoea treatment

Do not take any treatment for diarrhoea other than that given to you by your doctor.

Decrease in white blood cells (Frequent)

CAMPTO may cause a decrease in the number of some of your white blood cells, which play an important role in fighting infections. This is called neutropenia.

If you have any fever this may be an indication of infection associated with this neutropenia.

Nausea and vomiting (Frequent)

If you have any fever, and particularly if you also have diarrhoea and/or nausea and/or vomiting contact your doctor IMMEDIATELY.

Other side effects

If you experience any of the following conditions please report it to a doctor IMMEDIATELY:

Frequent:

- difficulty in breathing
- dehydration
- change in kidney function tests
- excessive bilirubin (breakdown product of red blood cells) in the blood
- low blood volume resulting in dizziness or fainting
- inflammation and ulceration of the membranes lining the digestive tract
- infection
- anaemia which is decreased number of red blood cells which may lead to a feeling of weakness, fatigue or poor concentration

- leucopenia which is too few white blood cells which results in greater risk of infection
- thrombocytopenia which is too few platelets in the blood which may result in bleeding into the skin, bruising or prolonged bleeding after injury
- blockage of blood vessels that can result in severe chest pain, stroke, inflammation of a vein with formation of a clot, heart attack, heart arrest, sudden death

Other side effects which may occur when you are treated with CAMPTO are:

Frequent:

- loss of hair
- lack of appetite
- constipation
- inflammation of the mouth
- decreased weight
- pain
- lack of energy

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

STORAGE AND DISPOSAL OF CAMPTO:

Store all medicines out of reach of children.

Single-dose vials of CAMPTO solution for infusion should be stored at or below 25 °C and protected from light.

The product must be kept in the carton until required for use.

CAMPTO 40 mg/2 ml and Campto 100 mg/5 ml: After dilution in either 0,9 % sodium chloride or 5 % dextrose, the diluted solution is stable for 24 hours at a temperature at or below 25 °C or 4 days under refrigeration (between 2 and 8 °C). Discard any unused portion thereafter.

CAMPTO CSV 300 mg/15 ml: After dilution in either 0,9 % sodium chloride or 5 % dextrose, the diluted solution is stable for 24 hours under refrigeration (between 2 and 8 °C). Discard any unused portion.

Do not freeze.

Do not use CAMPTO after the expiry date which is printed on the label.

Return all unused medicines to your pharmacist.

Do not dispose of unused medicines in drains or sewerage systems (e.g. toilets).

PRESENTATION OF CAMPTO:

CAMPTO 40 mg/2 ml: Carton containing one single-dose glass or polypropylene plastic, amber coloured vial, closed with a halobutyl/chlorobutyl rubber stopper and sealed with an aluminium cap with a plastic flip-off top.

CAMPTO 100 mg/5 ml: Carton containing one single-dose glass or polypropylene plastic, amber coloured vial closed with a halobutyl/chlorobutyl rubber stopper and sealed with an aluminium cap with a plastic flip-off top.

CAMPTO CSV 300 mg/15 ml: Carton containing one single-dose polypropylene plastic, amber coloured vial, closed with a halobutyl rubber stopper and sealed with an aluminium cap with a plastic flip-off top.

IDENTIFICATION OF CAMPTO:

A clear, slightly yellow solution.

REGISTRATION NUMBERS:

CAMPTO 40 mg/2 ml: 31/26/0182

CAMPTO 100 mg/5 ml: 31/26/0183

CAMPTO CSV 300 mg/15 ml: 43/26/1067

**NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF
REGISTRATION:**

Pfizer Laboratories (Pty) Ltd

85 Bute Lane

Sandton 2196

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