

## PATIENT INFORMATION LEAFLET

### SCHEDULING STATUS

S4

### PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

**COLOCAM 40** (Concentrate for solution for infusion)

**COLOCAM 100** (Concentrate for solution for infusion)

**COLOCAM 300** (Concentrate for solution for infusion)

**COLOCAM 500** (Concentrate for solution for infusion)

**Read all of this leaflet carefully before you are given COLOCAM 40, 100, 300 and 500 Concentrate for solution for infusion.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor, nurse or your hospital pharmacist.

### 1. WHAT COLOCAM CONTAINS

Each 1 ml contains 20 mg irinotecan hydrochloride.

COLOCAM 40 contains 40 mg irinotecan hydrochloride per vial.

COLOCAM 100 contains 100 mg irinotecan hydrochloride per vial.

COLOCAM 300 contains 300 mg irinotecan hydrochloride per vial.

COLOCAM 500 contains 500 mg irinotecan hydrochloride per vial.

Inactive ingredients: Sorbitol, lactic acid, water for injection.

### 2. WHAT COLOCAM IS USED FOR

COLOCAM belongs to a group of medicines called cytostatics (anti-cancer medicines).

COLOCAM may be used alone or in combination with a number of other medicines used to treat cancer. These combinations may be used to treat cancers of the colon and rectum.

### 3. BEFORE YOU ARE GIVEN COLOCAM

#### **You should not be administered COLOCAM:**

- If you are hypersensitive (allergic) to irinotecan hydrochloride trihydrate (the active ingredient) or any of the other ingredients of COLOCAM.
- If you have any other bowel disease or a history of bowel obstruction.
- If you are pregnant or breast feeding or if you think you might be pregnant.
- If your bilirubin upper limit count is high, tell your doctor.
- If you suffer from severe bone marrow failure.
- If you are in a poor general health.
- If you are taking the natural remedy St. John's Wort.

#### **Special care should be taken with COLOCAM**

You will be treated by a specialist team experienced in using these kinds of treatments and managing their side effects, which are usually temporary. However, it is essential that you read the section "Possible side effects" and follow the instructions carefully if you get any of the symptoms described.

As with all anti-cancer medicines the use of COLOCAM is associated with a number of side effects which may be serious. These side effects require special management to minimise the risk of complications.

If you suffer from an inherited condition called fructose intolerance, tell your doctor or hospital pharmacist before you are given COLOCAM. COLOCAM contains sorbitol, which is unsuitable for people who cannot tolerate fructose.

COLOCAM may cause you to have diarrhoea. There are two types of diarrhoea, which can be distinguished by when they start. "Early onset" 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 follow these instructions carefully.

***If your diarrhoea starts less than 24 hours*** after the infusion ("early diarrhoea") you should contact your doctor or nurse immediately and they will give you a suitable treatment.

**Do not use any anti-diarrhoeal treatment that your doctor has given you for “delayed diarrhoea”.**

This “early diarrhoea” may be accompanied by other symptoms such as

- sweating
- abdominal cramps
- watering eyes
- visual disturbance
- dizziness
- low blood pressure
- feeling unwell
- excessive mouth watering

Tell your doctor or nurse about all your symptoms.

***If your diarrhoea starts more than 24 hours* after the infusion (“delayed diarrhoea”) you should IMMEDIATELY take any anti-diarrhoeal treatment that the doctor has given you EXACTLY as he has told you. If you are unsure of what this is, ask your doctor or nurse.**

Drink large amounts of rehydration fluids, **IMMEDIATELY** (i.e. water, soda water, fizzy drinks, soup or oral rehydration therapy).

**You must tell your doctor**

- if you have nausea and vomiting as well as diarrhoea
- if you have any fever as well as the diarrhoea
- if 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 or nurse and the fluids described above.**

**Receiving COLOCAM with food and drink:**

Unless your doctor tells you otherwise, continue your normal diet.

**Pregnancy and breastfeeding:**

COLOCAM should not be used if you are pregnant or breastfeeding your baby.

Women of childbearing age receiving COLOCAM should be advised to avoid becoming pregnant and to inform the treating doctor immediately should this occur.

Contraceptive measures must be taken during and for at least three months after cessation of therapy.

**Driving and using machinery:**

COLOCAM may make you feel dizzy or cause visual disturbances. If this happens to you do not drive or operate machinery.

**Using other medicines with COLOCAM:**

Always tell your healthcare professional if you are taking any other medicine.

If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of COLOCAM with these medicines may cause undesirable interactions. Tell your doctor or pharmacist if you are taking any other medicines, including any you have bought at your pharmacy, supermarket or health food shop. Please consult your doctor, pharmacist or other healthcare professional for advice if you are using any of the following medication:

- other bone marrow depressants medication
- diuretics (tablets that increases water loss from the body)
- immunosuppressants (azathioprine, chlorambucil, corticosteroids etc.)
- laxatives

Loperamide should not be taken in advance for the treatment of the diarrhoea side effect.

**4. HOW COLOCAM WILL BE ADMINISTERED**

Do not share medicines prescribed for you with any other person.

COLOCAM will be given as an infusion into your veins over a period of 30 to 90 minutes.

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

The amount of COLOCAM you are given will depend on your age, size and general medical condition. It will also depend on any other treatment you may have received for your cancer. Your doctor will calculate your body surface area in square meters (m<sup>2</sup>).

Your doctor will tell you how long your treatment with COLOCAM will last. If you have the impression that COLOCAM is too strong or too weak, tell your doctor or pharmacist.

**If you receive more COLOCAM than you should:**

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

**5. POSSIBLE SIDE EFFECTS**

COLOCAM can have side effects. Not all side effects reported for COLOCAM are included in this leaflet. Should your general health worsen or if you experience any untoward effects while receiving COLOCAM, please consult your doctor, pharmacist or other health care professional for advice.

If any of the following happens, stop treatment with COLOCAM and tell your doctor immediately or go to the casualty department at your nearest hospital:

- allergic skin reactions
- inflammation at the injection site
- inflammation of the lining of the mouth
- swelling of feet and hands, headache, increased sweating, flushing

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to COLOCAM. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- upper respiratory tract infection, running nose
- if you have high blood pressure
- if you have or might have interstitial pneumonia (a dry cough, shortness of breath, which may occur after effort or become worse over time, difficult or laboured breathing, fatigue, clubbing, or enlargement of the fingertips at the base of the nails. Clubbing may be present due to a lack of oxygen in the blood.)

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

- decrease or loss in appetite, weight loss
- hair loss
- anorexia, abdominal enlargement, bloated feeling or gas, indigestion
- muscular contraction or cramps

COLOCAM 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.

Your doctor will probably arrange for you to have regular blood tests to monitor these white blood cells.

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

If you have any **fever**, and particularly if you also have **diarrhoea**, contact your doctor or nurse **IMMEDIATELY** so that they can give you any treatment necessary.

If you have breathing difficulties, nausea and/or vomiting contact your doctor or nurse **IMMEDIATELY**.

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

## 6. STORING AND DISPOSING OF COLOCAM

- Store at or below 25 °C and protect from light.
- Store the vials in the original cartons until required for use.
- After dilution with either 0,9 % sodium chloride or 5 % dextrose solution, the diluted solution is stable for 24 hours under refrigeration (2 - 8 °C) and for 6 hours when stored at room temperature (25 °C).
- Solution should be inspected visually for particulate matter and discoloration prior to administration.
- Procedures for proper handling and disposal of anti-cancer medicines should always be considered.
- Discard any unused portion thereafter.
- Do not freeze as crystallisation may occur.
- KEEP ALL MEDICINES OUT OF REACH OF AND SIGHT OF CHILDREN.
- Do not use this medicine after the expiry date printed on the carton.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

## **7. PRESENTATION OF COLOCAM**

COLOCAM 40: Amber Type I glass vial (2R) with grey halobutyl teflon coated rubber stopper and aluminium cap with red polypropylene flip-off seal.

COLOCAM 100: Amber Type I glass vial (6R) with grey halobutyl teflon coated rubber stopper and aluminium cap with yellow polypropylene flip-off seal.

COLOCAM 300: Amber Type I glass vial (20R) with grey halobutyl teflon coated rubber stopper and red aluminium cap with orange polypropylene flip-off seal.

COLOCAM 500: Amber Type I glass vial (30R) with grey halobutyl teflon coated rubber stopper and red aluminium cap with red polypropylene flip-off seal.

## **8. IDENTIFICATION OF COLOCAM**

Clear, yellow solution.

**9. REGISTRATION NUMBER**

Colocam 40: 46/26/0271

Colocam 100: 46/26/0272

Colocam 300: 46/26/0273

Colocam 500: 46/26/0274

**10. NAME AND ADDRESS OF REGISTRATION HOLDER**

EQUITY Pharmaceuticals (Pty) Ltd.

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**11. DATE OF PUBLICATION**

30 September 2016