

1.3.2 PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

PROPRIETARY NAME AND DOSAGE FORM

MITOMYCIN-C 2 mg

Powder for Injection

MITOMYCIN-C 10 mg

Powder for Injection

Read the entire leaflet carefully before you are given MITOMYCIN-C.

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

The active substance per vial of MITOMYCIN-C 2 mg is 2 mg of crystalline mitomycin-C.

The other ingredient is sodium chloride.

Sugar free

The active substance per vial of MITOMYCIN-C 10 mg is 10 mg of crystalline mitomycin-C.

The other ingredient is sodium chloride.

Sugar free

WHAT MITOMYCIN-C IS USED FOR

Anti-cancer medicine.

BEFORE YOU ARE GIVEN MITOMYCIN-C

MITOMYCIN-C should not be administered:

- If you have an active infection.
- If you are pregnant or breastfeeding.
- If you are hypersensitive to MITOMYCIN-C.
- If you have a liver or kidney disorder.

Special care should be taken with MITOMYCIN-C.

- Special care should be taken when administering MITOMYCIN-C to elderly patients, to children or patients of child bearing potential, bleeding tendency, bone marrow depression and patients with infectious disease.
- Care should be taken if MITOMYCIN-C is administered for long term use, patients should be monitored by frequent laboratory testing.

Pregnancy and breastfeeding

Do not use MITOMYCIN-C if you pregnant or breastfeeding.

Always tell your healthcare provider if you are taking any other medicine. If you are pregnant or breastfeeding your baby, please consult your healthcare provider for advice before receiving MITOMYCIN-C.

Taking other medicines with MITOMYCIN-C

Always tell your healthcare provider if you are taking any other medicine on a regular basis (this includes complementary or traditional medicines), the use of MITOMYCIN-C with these medicines may cause undesirable interactions.

Tell your doctor if you are taking any of the following medicines:

- captopril for high blood pressure
- carbamazepine for controlling epileptic seizures
- cephalosporin antibiotics for infection
- metronidazole for infections caused by bacteria and certain parasites
- phenothiazines to treat serious mental and emotional disorders, severe nausea and vomiting and certain types of porphyria
- sulphamethoxazole and trimethoprim for infections (upper and lower chest, kidney and bladder infections)
- sulphonamides for treatment of infections caused by bacteria, as diuretic and for inflammatory bowel disease
- thioxanthenes for the treatment of nervous, mental, and emotional conditions
- doxorubicin for treatment of cancer
- vaccines and radiation therapy

HOW TO RECEIVE MITOMYCIN-C

MITOMYCIN-C will be administered by your doctor or other healthcare provider.

Dosage:

Your doctor will decide what the correct dose is and for how long you will be receiving

MITOMYCIN-C.

Method of administration:

You will receive MITOMYCIN-C by injection: intravenously (directly into the vein or artery); intra-arterial (into an artery) or intravesical (into the bladder).

If you receive more MITOMYCIN-C than you should

As MITOMYCIN-C is administered under controlled conditions, and the effects are closely monitored, the likelihood of overdosage is extremely rare.

In the event of overdosage, your doctor will treat it.

Since a healthcare provider will administer this medicine, he/she will control the dosage.

However, in the event of an overdosage your doctor will manage the overdosage.

POSSIBLE SIDE EFFECTS

MITOMYCIN-C can have side effects.

Not all side effects reported for MITOMYCIN-C are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking MITOMYCIN-C, please consult your healthcare provider for advice.

- Changes in blood test counts (amount of leukocytes and platelets).
- Liver and renal disorders.
- Hypertension (High blood pressure).
- Anorexia (Eating disorder that results into weight loss), nausea and vomiting.
- Fever, malaise (general feeling of sickness) and alopecia (loss of hair).
- Local and tissue necrosis (death of cells and living tissue).

- Rash.
- Bladder infections.
- Pneumonia (fever, coughing, shortness of breath).

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

STORING AND DISPOSING OF MITOMYCIN-C

MITOMYCIN-C will be stored in pharmacy or in the hospital wards.

Store at or below 25 °C.

Protect from light.

The product reconstituted with water, saline or 5 % glucose solution is stable at room temperature for 6 hours.

Keep in original packaging until required for use.

Do not store in a bathroom.

Do not use after the expiry date stated on the label.

Unused portions of the injection should be discarded.

Return all unused medicine to your pharmacist.

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

STORE ALL MEDICINES OUT OF REACH OF CHILDREN

PRESENTATION OF MITOMYCIN-C

MITOMYCIN-C 2 mg: colourless Type III glass vial with an aluminium seal, butyl rubber stopper and a polypropylene cap containing a blue-purple powder. 1 vial is packed in an outer cardboard carton together with a leaflet.

MITOMYCIN-C 10 mg: Type I colourless 30 ml glass vial and closed with a butyl rubber

push in stopper and crimped with an aluminium cap with a polypropylene lid containing a blue-purple powder. 1 vial is packed in an outer cardboard carton together with a leaflet.

Not all packs are necessarily marketed.

IDENTIFICATION OF MITOMYCIN-C

Blue-purple powder.

REGISTRATION NUMBER

MITOMYCIN-C 2 mg: H2764 (Act 101/1965)

MITOMYCIN-C 10 mg: R/26/48

NAME, BUSINESS ADDRESS AND TELEPHONE NUMBER OF THE HOLDER OF THE CERTIFICATES OF REGISTRATION

PHARMACARE LIMITED

Healthcare Park

Woodlands Drive

Woodmead 2191

Hotline: 0800 122 912 (South Africa)

DATE OF PUBLICATION

Date of registration:

MITOMYCIN-C 2 mg: Old medicine

MITOMYCIN-C 10 mg: 04 April 1986

Date of the most recent amendment to the professional information as approved by the

Authority: 25 November 2011

