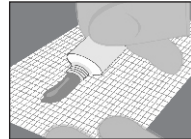


60mm

APPLYING CADOMER:

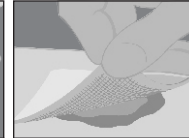
Clean the wound and the surrounding area with either a gentle stream of sterile water or saline. Do not dry the wound surface.



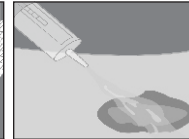
Invert cap to puncture seal in tube spread CADOMER in 1/8 - 1/4 In. Thickness to dry sterile gauze, sufficient to cover all parts of the wound. Larger amounts are unnecessary though not problematic.



With gloved hands, position the prepared gauze onto the wound.

CHANGING CADOMER:

CADOMER should be changed three times a week or when all the CADOMER has changed in color from brown to yellow/grey.



Remove CADOMER with a gentle stream of sterile water or saline, using a sterile wet swab if necessary.



Gently blot any excess fluid, leaving the wound surface slightly moist, before re-applying CADOMER.

For the use of Registered Medical Practitioner or Hospital or a Laboratory only

Cadexomer Iodine Ointment
CADOMER®

COMPOSITION

Each gram contains:

Cadexomer iodine500mg

(Equivalent to 0.9% w/w Iodine)

Excipients q.s.

DESCRIPTION

Cadomer is yellow-brown colored ointment containing cadexomer iodine (50% w/w) equivalent to 0.9% w/w available iodine.

PHARMACODYNAMICS

When in contact with wound exudates, **Cadomer** ointment absorbs fluid, removes exudates, pus and debris from the wound surface. One gram of cadexomer iodine ointment can absorb a minimum of 2.5 ml of fluid. Iodine is physically immobilized within the matrix of the dry cadexomer iodine and is slowly released in an active form during uptake of wound fluid. This mechanism of release provides antibacterial activity both at the wound surface and within the formed gel. There is no evidence of the development of bacterial resistance to iodine. The formed layer can easily be removed without damaging the fragile new epithelium underneath. **Cadomer** ointment reduces the bacterial count, facilitates de-sloughing, absorbs exudates and maintains a moist environment to promote healing of skin ulcers.

PHARMACOKINETICS

Iodine absorbed systemically from **Cadomer** ointment is rapidly and almost exclusively excreted in urine. Cadexomer is biodegradable by amylases, normally present in wound fluid.

INDICATIONS

Cadomer is indicated for the treatment of exuding wounds such as leg ulcers, pressure ulcers and diabetic ulcers, infected traumatic and surgical wounds.

DOSAGE AND DIRECTIONS FOR USE

- Clean the wound with sterile water or saline. Do not dry the wound surface.
- Apply **Cadomer** ointment to dry sterile gauze, ensuring an adequate amount to cover the entire wound to a depth of 3 mm.
- Place secondary dressing over the wound with a gloved finger, smoothen over the dressing and spread the ointment underneath

160mm

120mm

Back

Front

60mm

- to the shape of the ulcer and to a minimum depth of 3 mm.
- A single application of **Cadomer** should not exceed 50 g. The total amount of **Cadomer** used in one week should not exceed 150 g.
 - The duration of treatment should not exceed 3 months in any single course of treatment.

REMOVAL OF DRESSING

- Remove secondary dressing
- Loss of dark-brown coloration confirms need to change dressing (usually 2-3 times a week or daily if wound is discharging heavily).
- If necessary, soak dressing for a few minutes with sterile water or saline, then remove.
- Remove **Cadomer** with a gentle stream of sterile water or saline, using a sterile wet swab if necessary
- Gently blot excess fluid, leaving wound surface slightly moist, before reapplying **Cadomer**.
- The number of applications should be reduced as the exudate diminishes

CONTRAINDICATIONS

- Patients with known or suspected iodine sensitivity
- Hashimoto's thyroiditis
- Patients with history of Graves' disease or Non-toxic nodular goitre
- Children under 12 years of age
- Pregnant or lactating women

SPECIAL WARNINGS AND PRECAUTIONS FOR USE

Iodine may be absorbed systematically, when large wounds are treated. Patients with severely impaired renal function or a past history of any thyroid disorder are more susceptible to alterations in thyroid metabolism with chronic **Cadomer** ointment therapy. In endemic goitre there have been isolated reports of hyperthyroidism associated with exogenous iodine. It has been observed occasionally that an adherent crust can form when **Cadomer** ointment is not changed at required frequency. **Cadomer** is not effective in treating dry wounds

USE IN SPECIAL POPULATION

Pregnancy

Iodine can cross placental barrier. Clinical experience of use in pregnant women is limited. Therefore, **Cadomers** should not be used in pregnant women.

Lactation

Iodine is secreted into breast milk. Clinical experience of use in lactating women is limited.

Therefore, **Cadomers** should not be used in lactating women.

INTERACTIONS WITH OTHER DRUGS

There is a potential risk of interaction with lithium, resulting in an increased possibility of hypothyroidism. **Cadomer** ointment should not be used concomitantly with tauridine (since there is a risk of metabolic acidosis) or with mercurial antiseptics, e.g. mercurochrome and thiomersal. Since iodine may be absorbed systemically, the result of tests of thyroid function can be influenced.

ADVERSE REACTIONS

Patients treated with **Cadexomer** iodine ointment may experience a transient smarting or pain within the first hour after application. Minor reddening or swelling around the wound may occur without necessarily being an allergic reaction. Contact allergy and local edema have been reported.

OVERDOSAGE

There have been no reported overdoses. In case of excessive topical use of **Cadomer** the treatment should be stopped, the area is washed and symptomatic treatment is initiated.

LIST OF INACTIVE INGREDIENTS:

Polyethylene Glycol 400, Polyethylene Glycol 4000, Poloxamer P 124.

PRESENTATION

Tubes of 5g / 10g / 20g.

STORAGE

Store below 30°C. Do not expose to sunlight. Keep out of reach of children.

SHELF LIFE

Two years.

Note: Do not use if the package is damaged.

FOR EXTERNAL USE ONLY

Under the License from Virchow Biotech Private Limited, Hyderabad. Manufactured in India by:

Virchow Biotech Private Limited

Sy no 172 part, Gagillapur,
Dundigal Gandimaisamma Mandal,
Medchal – Malkajgiri District, Telangana state- 500043



Marketed by & ® Regd. Trade Mark of:

J. B. CHEMICALS AND PHARMACEUTICALS LTD.

Neelam Centre, B Wing, Hind Cycle Road,
Worli, Mumbai 400 030, India.

C-44-2000-5-4

128746


160mm

120mm

Inside

Inside

Generic Name Font and Size : RBN03.1 Black Italic 17.214 pt.
Brand Name Font and Size : RBN03.1 Black Italic 15.214 pt.

SAP Code: 128746	Country : Domestic (India)	Mfg. Location : Virchow Biotech Private Limited	Product Name : Cadomer Cream
Packaging Material : Leaflet	Existing / Reference Art : 128251	Version No.: 1	Date : 11/03/2020
Dimension : (L) 160 x (B) 120mm (Tolerance ± 1 mm)		Size After Folding : (L) 120 x (B) 20 mm ± 1 mm	Core Dia : NA
Reel Dia : NA	Varnish / Lamination : NA	Folding Pattern : Vertical 1 fold + Horizontal 3 folds	Print Repeat Length :
Packaging Material Specification : White Maplitho Paper		Pantone : <div><div></div>Black</div>	
Grammage: 56 ± 5% gm/m²			
Thickness : NA			
Other Test : NA			
Reasons for change : As per suggestion of Legal department, "Trade Mark" replaced with "Regd. Trade mark"			<div><div><div>Unique</div><div></div></div><div><div>J. B. CHEMICALS & PHARMACEUTICALS LTD.</div></div></div>
File Path : X:\Artworks\Kiran\AS PER DCGI GUIDELINE\Cadomer V5\Open File128746 Cadomer Leaflet 20 g.cdr			

Artist : Shyam Kawle	Initiated by	Checked by	Approved by	Approved by
Sign & Date				
Designation	Executive - PDD	Sr. Manager - PDD	Regulatory Affairs	V. P. (Supply Chain)