

Ozar® (Beta-Sitosterol 0.25%) w/w Ointment safety card

- Dosage and administration:

1. Burns

- First degree burns (Superficial burns)

OZAR® should be applied as immediately as possible. A thin layer (about 1mm thickness) should cover the burnt area. It is better to keep the wound exposed, but if there is a need, a light dressing can be used. Reapplication should be done 3 to 4 times daily if exposed or twice daily if closed.

- Second degree burns

First Phase – liquefying period a thin layer of OZAR® should cover the burnt area and renewed 3 to 4 times daily. Before reapplication, the liquefied necrotic tissue and the residues of the old OZAR® should be wiped off gently. It is better to keep the wound exposed, but if there is a need, a light dressing can be used and a relatively thicker layer (about 3mm thickness) should be applied and renewed twice daily. Second Phase – repair period OZAR® should be applied as before, but less frequently (2 - 3 times daily). Third Phase – rehabilitation period OZAR® should be applied as before, but only once daily.

- Third degree burns

OZAR® should be applied as mentioned before to liquefy the necrotic tissue. A thin layer should cover the burnt site and renewed 3 to 4 times daily.

2. Donor Site

A thin layer of OZAR® should cover the donor site and renewed 3 to 4 times daily if exposed or twice daily if closed.

3. Leg Ulcers

Sterile gauze should be impregnated with OZAR® and should fill the cavity of the ulcer, and renewed twice daily.

4. Surgical and Obstetrical Wounds

OZAR® should cover the wound in a relatively thick layer (about 3mm) under a sterile dressing and renewed twice daily.

5. Cracked Nipples

A thin layer of OZAR® should be applied to the nipple under a light pad, and renewed 3 - 4 times daily. OZAR® is safe for the infant that nursing can proceed without any hazards.

- Precautions:

It should not be used in individuals who have experienced hypersensitivity reactions.

OZAR® ointment may change its physical appearance during storage especially during hot seasons, but it does not lose its efficacy.

- Contraindications:

It should not be used in individuals who have experienced hypersensitivity to any of its components.

- Pregnancy and lactation:

Not enough is known about the use of OZAR® ointment during pregnancy and breast-feeding. Stay on the safe side and avoid use

(This card focuses on major safety information for medicinal products in order to minimize possible side effects that arise from improper use of medicinal products).

Pharmacovigilance Department

CONTACT DETAILS OF THE QPPV:

Phone: (962)/ (6) 5233349/113

email: e.alkhatatbeh@sana-pharma.com.

You can Also Report problems of Sana pharmaceutical products online via following link:

<http://www.sana-pharma.com/?q=node/3646>