Pantone 801 C

13.5 cm

20 cm

SEPIDYL™ Topical Gel

(7.1% w/w Chlorhexidine gluconate eq. to chlorhexidine 4% w/w)

COMPOSITION

Sepidyl Topical Gel, U.S.P.
Each gm of Gel contains: Chlorhexidine gluconate... 7.1% w/w eq. to Chlorhexidine ... 4% w/w.

THERAPEUTIC INDICATIONS

SEPIDYL is indicated for prophylaxis of omphalitis (infection of the umbilical cord) in newborn infants.

POSOLOGY AND METHOD OF ADMINISTRATION

Posology

The recommended dose is 3 gram (equivalent to 1/2 teaspoon) applied once daily for seven days. Healthcare providers should take account of local umbilical cord care guidelines regarding single dose application. The first application must occur within 24 hours of birth.
For infants born at less than 32 weeks gestation (or weighing less than 1500 grams at birth), the recommended dose is a single 3 gram applied once only in the first 24 hours after birth.

Method of administration

Apply SEPIDYL as soon as possible within 24 hours after birth. Clean the umbilical cord stump and the skin around the base of the stump with a dry cloth prior to applying SEPIDYL. Apply adequate content of the tube to ensure complete coverage of the umbilical cord, from the cut surface to the base and including the immediate surrounding abdominal skin. Wash hands before and after use.

Important Note

SEPIDYL should not be applied in combination with any other product. Occlusive dressings should not be applied to the umbilical cord stump, as doing so could increase the absorption of the product through the dermis.

CONTRAINDICATIONS

For the caregiver - This product should not be handled by anyone with a known history of hypersensitivity to chlorhexidine or to any of the excipients.

SPECIAL WARNINGS AND PRECAUTIONS FOR USE

For external use only. Do not inject or swallow.

Keep out of the eyes and ears and do not use over large areas of the body. If SEPIDYL comes into contact with the eyes, wash out promptly and thoroughly with clean water.

This product contains chlorhexidine. There have been reports of hypersensitivity and skin irritation after topical administration of chlorhexidine, including generalized allergic reactions and anaphylactic shock. The prevalence of chlorhexidine hypersensitivity is not known, but available literature suggests this is likely to be very rare. The product should be discontinued and immediate medical help should be sought in case of any symptoms which may indicate an allergic reaction.

If skin irritation or redness occurs, prompt medical advice should be sought.

Treatment with SEPIDYL may be associated with the development of methaemoglobinaemia, via degradation to 4 –chloroaniline, although this has not been observed in clinical trials. This risk is likely to be increased in infants born prematurely, specifically less than 32 weeks gestation or weighing less than 1500 grams. SEPIDYL should be discontinued if symptoms and signs associated with methaemoglobinaemia, such as cyanosis or breathlessness, are observed and immediate medical advice sought.

UNDESIRABLE EFFECTS

The most serious reported adverse reactions to medicinal products or devices containing chlorhexidine are systemic hypersensitivity/anaphylaxis. Signs related to a hypersensitivity reaction include rash, urticaria, angioedema, difficulty in breathing, collapse or loss of consciousness.

PHARMACOLOGICAL PROPERTIES

Pharmacodynamic properties

Pharmacotherapeutic group: antiseptics and disinfectants, ATC code: D08AC02

Mechanism of Action

Chlorhexidine has both bacteriostatic and bactericidal mechanisms of actions, depending on its concentration. It destabilizes the cell wall by interfering with osmosis, once the cell wall is damaged, chlorhexidine then crosses into the cell and damage the cytoplasmic membrane which allows for leakage of components leading to cell death. In high concentrations, chlorhexidine causes the cytoplasm to congeal or solidify.

Product Name:	**Sepidyl**
Width of Leaflet:	135mm
Length of Leaflet:	200mm
Length of top band:	135 x 9.5mm
Color of top band:	Pantone 801 C
Color of text:	Black
Left/Right Margin:	4mm
Artwork code#:	SP-L-1/2
Date of preparation:	24-9-2018
Prepared By:	Sufian Rana
Proof Version:	02

Clinical efficacy and safety

Efficacy has been demonstrated in three community-based randomised controlled trials of 7.1% chlorhexidine gluconate solution. A meta-analysis within a Cochrane review of these studies showed 23% reduction (95% CI 6-37%) in all-cause neonatal mortality in the intervention groups compared to the control groups (dry cord care, soap/water and hand washing). The same meta-analysis showed a reduction in umbilical cord infection ranging from 27 to 56% depending on severity: 27% reduction in skin redness (95% CI 17-36%), 31% reduction in redness with pus or severe redness (95% CI 21-40%), and 56% reduction in severe redness with pus (95% CI 31-72%). A published study of 7.1% chlorhexidine gluconate gel vs. solution showed that the gel was non-inferior to the solution in terms of antimicrobial efficacy.

Single versus multiple applications: The effect of single versus multiple applications was assessed in a Cochrane review. The incidence of moderate and severe omphalitis was reduced with multiple applications, although there was no evidence of difference in overall mortality between the groups.

Antimicrobial studies: In-vitro tests to assess the antimicrobial activity and persistence of effect showed that chlorhexidine gluconate 7.1% w/w gel and solution are comparable.

PHARMACOKINETIC PROPERTIES

Chlorhexidine is cationic in nature and binds strongly to skin. Data relating to topical administration in neonates are limited. After topical application, trace amounts of chlorhexidine may be absorbed percutaneously in preterm newborns.

In newborns and small children bathed in water treated with 4.0 % and 0.4 % chlorhexidine gluconate, respectively, the amount of chlorhexidine found in blood samples and in the faeces was extremely low.

There are no data on metabolism of chlorhexidine following topical administration.

SHELF LIFE

Observe expiry date on the outer pack.

SPECIAL PRECAUTIONS FOR STORAGE

As directed by the Physician.
Keep out of reach of children.
Do not store above 30°C.

خوراک:
ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔
بچوں کی پہنچ سے دور رکھیں۔
۳۰ ڈگری سینٹی گریڈ سے زیادہ درجہ حرارت پر نہ رکھیں۔

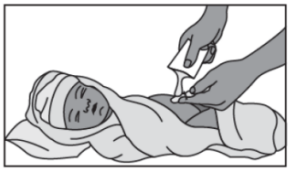
NATURE AND CONTENTS OF CONTAINER

SEPIDYL topical gel is available in 10 gm and 15 gm tubes.

INSTRUCTIONS FOR USE

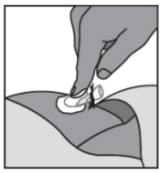
1. Wash your hands carefully **before and after** applying Sepidyl gel, using soap and clean water.

جل لگانے سے پہلے اور استعمال کے بعد ہاتھ کو اچھی طرح صابن اور صاف پانی سے دھوئیں۔



2. Use enough gel from the tube to cover the freshly cut umbilical cord stump and the skin around the base of the umbilical cord within 24 hours after birth.

پیدائش کے ۲۴ گھنٹے کے اندر جل کی مناسب مقدار ناف اور اس کے گردی جگہ پر لگائیں۔



3. Spread the gel on the umbilical cord stump and the skin around the base of the cord using your finger.

جل کو اچھی طرح ناف اور اس کے گردی جگہ پر اپنی انگلی سے پھیلائیں۔

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An OBS Group Company

Code: SP-L-1/2

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