Drugfield Pharmaceuticals Limited

# SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

## (CHLORXY –G®GEL)

**(Chlorhexidine digluconate 7.1% equivalent to chlorhexidine 4% use of 4% chlorhexidine to prevent infection in newborn babies).**

## 1. NAME OF THE MEDICINALPRODUCTION

Chlorxy-G®Gel

## 2. QUALITATIVE AND QUANTITATIVECOMPOSITION

Chlorhexidine digluconate 7.1% $^{w}/_{w}$ (equivalent to 4% $^{w}/_{w}$ chlorhexidine)
Each tube contains chlorhexidine digluconate 7.i% equivalent chlorhexidine. 4%

## 3. PHARMACEUTICAL FORM

Gel

## 4. Clinical particulars

### 4.1 **Therapeutic indication**

Chlorhexidine digluconate 7.1% $^{w}/_{w}$ is indicated for prophylaxis of omphalitis (infection of the umbilical cord) in newborn infants.

### 4.2 **Posology and method of administration**

Posology

The recommended dose is 3gram sachet 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 1.5 kg), the recommended dose is a single 3 gram sachet applied once only in the first 24 hours after birth.

Method of administration

Apply Chlorhexidine digluconate 7.1% $^{w}/_{w}$ Gel 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 Chlorhexidine digluconate 7.1% $^{w}/_{w}$ Gel. Apply adequate content of the sachet 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.

Chlorhexidine digluconate 7.1% $^{w}/_{w}$ Gel should not be applied in combination with other products. Occlusive dressings should not be applied to the umbilical cord stump, as doing so could increase the absorption of the product through the dermis.

### 4.3 **Contraindications**

For the caregiver- This product should not be handled by anyone with known history of hypersensitivity to chlorhexidine (see section 4.4) or to any of the excipients listed in section 6.1

### 4.4 **Warnings & Precautions**

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 Chlorhexidine digluconate 7.1% w/w Gel 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 Chlorhexidine digluconate 7.1% w/w Gel 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 (see section 4.2). Chlorxy-G Gel should be discontinued if symptoms and signs associated with methaemoglobinaemia, such as cyanosis or breathlessness, are observed and immediate medical advice sought.
The use of chlorhexidine solutions, both alcohol based and aqueous, for skin antisepsis prior to invasive procedures has been associated with chemical burns in neonates. Based on available case reports and the published literature, this risk of chemical burns appears to be higher in preterm infants, especially those born before 32 weeks of gestation, and occurs within the first 2 weeks of life (see section 4.2).

4.5 **Interaction**
None known.

4.6 **Pregnancy and lactation**
**Pregnancy**
Not applicable for the intended patient population

**Lactation**
Not applicable for the intended patient population

4.7 **Undesirable effects**
Tabulated list of adverse reactions
Adverse reactions are classified by System Organ Class. Adverse reactions that occurred either during clinical studies or that were spontaneously reported are presented below.
Frequencies were defined as follows:
Very common ≥1/10
Common ≥1/100 to <1/10
Uncommon ≥1/1000 to <1/100
Rare ≥1/10000 to <1/1000
Very rare <1/10000
Not known (cannot be estimated from the available data)
The adverse reactions tabulated below have been associated with post-marketing data from different marketed chlorhexidine formulations (antiseptic solution, antiseptic cream and antiseptic mouthwash). No post-marketing data is available for the 7.1 % w/w gel formulation.

| System organ class | Adverse reaction(s) | Frequency |
|---|---|---|
| Immune system disorders | Hypersensitivity and anaphylaxis | Not known |
| | Allergic skin reactions such as erythema and skin irritation | Not known |

Description of selected adverse reactions
The most serious reported adverse reactions to medicinal products or devices containing chlorhexidine are systemic hypersensitivity/anaphylaxis, see section 4.4. Signs related to a hypersensitivity reaction include rash, urticaria, angioedema, difficulty in breathing, collapse or loss of consciousness.

4.9 **Overdose**
This has not been reported

## 5 Pharmacological properties

### 5.1 Pharmacodynamics properties

Pharmacotherapeutic group: antiseptics and disinfectants, ATC code: D08AC02
Mechanism of action
Chlorhexidine has a wide range of antimicrobial activity. Chlorhexidine is effective against a wide range of gram-negative and gram-positive vegetative bacteria, yeasts, dermatophyte fungi and lipophilic viruses. It is inactive against bacterial spores except at elevated temperatures.
Clinical efficacy and safety
Efficacy has been demonstrated in three non-GSK published community-based randomised controlled trials of 7.1% chlorhexidine digluconate 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 non-GSK published study of 7.1% chlorhexidine digluconate 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 digluconate 7.1% w/w gel and solution are comparable.

### 5.2 Pharmacokinetics 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

digluconate, 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

## 6 **Pharmaceutical particulars**.

### 6.1 List of excipients
Guar gum
Purified water

### 6.2 Incompatibilities
Not applicable.

### 6.3 Shelf life
3 years

### 6.4 Storage conditions
Store below 30°C and away from direct sunlight.

### 6.5 Nature and contents of container
3 g presentation in a foil laminate sachet. Pack sizes of a single sachet wallet or a 7 sachet carton.
Not all pack sizes may be marketed.

### 6.6 **Special precautions for disposal and other handling**
Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

## 7. APPLICANT/MANUFACTURER

Drugfield Pharmaceuticals Limited
Lynson Chemical Avenue Km38,
Lagos-Abeokuta Expressway
Sango-Otta, Ogun State, Nigeria
Tel: +2348033513989
Email:Info@drugfieldpharma.com