SUMMARY OF PRODUCT CHARACTERISTICS

1. Name of the Medicinal Product:
Chlorodin Gel

2. Qualitative and Quantitative Composition:
Chlorhexidine BP 7.1% w/w

For the full list of excipients see section 6.1

3. Pharmaceutical Form:
Gel
Clear, non-greasy, colourless gel, free from visible or gritty particles

4. Clinical Particulars:
4.1 Therapeutic indications:
Umbilical cord infections, pre surgical preparations of skin, wound and general cleansing

4.2 Posology and method of administration:
Wash hands before application. Immediately after cutting the cord, apply Chlorhexidine Digluconate 7.1% w/w Gel to the tip of the cord, the stump and around the base of the stump. Wash hands after application.

4.3 Contraindications:
Irritation of the skin/applied areas

4.4 Special warnings and precautions for use:
For external use only. Avoid contact with eyes. If ingested accidentally, seek professional help.

4.5 Interaction with other medicinal products:
Chlorhexidine is incompatible with anionic agents.

4.6 Pregnancy and lactation:
There is no evidence of any adverse effects on the fetus arising from the use of Chlorodin gel during pregnancy or on infants during lactation. Therefore, no special precautions are recommended.

4.7 Effects on ability to drive and to use machines:

None have been reported or are known.

4.8 Undesirable effects:

In case of hypersensitivity. It may be irritant to the skin. If skin irritation, swelling or redness occur, consult a physician immediately.

Clinical Trial Data

Gastrointestinal Disorders

Very Common:	Tongue coated
Common:	Dry mouth

Nervous system disorders

Common:	Aguesia / dysguesia Glossodynia Oral paraesthesia / hypoaesthesia

Post Marketing Data

Gastrointestinal Disorders

Isolated reports:	Discoloration of the teeth and tongue Irritation of the mouth (see section 4.4) Desquamation / swelling of oral mucosa Parotid gland swelling

Immune System Disorders

Isolated reports:	Hypersensitivity and anaphylaxis

Reporting of suspected adverse reactions

Reporting of suspected adverse reactions: Healthcare professionals are requested to report any suspected adverse reactions via the Pharmacy and Poisons Reporting System (PvERS)
https://pv.pharmacyboardkenya.org

4.9 Overdose:

This has not been reported.
Accidental ingestion: Chlorhexidine taken orally is poorly absorbed. Systemic effects are unlikely even if large amounts are ingested. However, gastric lavage may be advisable using milk, raw egg, gelatin or mild soap. Employ supportive measures as appropriate.

5. Pharmacological Properties:

ATC code: D08AC02

Chlorhexidine is effective against a wide range of Gram negative and Gram-positive vegetative bacteria, yeasts, dermatophyte fungi and lipophilic viruses. It is active against a wide range of important oral pathogens and is therefore effective in the treatment of many common dental conditions.

5.2 Pharmacokinetic properties:
Because of its cationic nature, chlorhexidine bonds strongly to skin, mucosa and other tissues and is thus very poorly absorbed. No detectable blood levels have been found following oral use.

5.3 Preclinical safety data
No additional preclinical data of relevance to the prescriber.

6. Pharmaceutical Particulars:
6.1 List of excipients:
Natrosol
Disodium Edetate(EDTA)
Methyl Paraben
Propyl Paraben

6.2 Incompatibilities:
Hypochlorite bleaches may cause brown stains to develop in fabrics which have previously been in contact with preparations containing chlorhexidine.

6.3 Shelf life:
36 months

6.4 Special precautions for storage:
Store below 30°C in a dry and dark place.
Keep out of the reach of children

6.5 Nature and contents of container:
Pack Size: 10gm, 20gm Chlorodin Gel Leaflets, Chlorodin Gel Aluminum Tube

6.6 Special precautions for disposal and other handling:
N/A

7. Marketing Authorization Holder
Regal Pharmaceuticals Limited
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Email: info@regalpharmaceuticals.com

8. Marketing Authorization Number
H2021/CTD7679/14870

9. Date of First Registration / Renewal of the Registration
20-09-2021

10. Date of Revision of the Text
20-09-2021