

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Ora-lex C ®

Chlorhexidine Gluconate & Benzydamine Hydrochloride Mouthwash.

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Chlorhexidine Gluconate & Benzydamine Hydrochloride Oral Mouthwash with Sprayer.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 15 ml contains

Chlorhexidine Gluconate 18 mg

Benzydamine Hydrochloride 22.5 mg

In a flavored vehicle q.s. (for a full list of excipients, see section 6.1)

3. PHARMACEUTICAL FORM

Liquid preparation, A light pink colour mouth wash liquid

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

ORA-LEX C® is used for mouth and throat antiseptics, for relief of patient's swallowing function and as a symptom reliever in gingival diseases. It can be used for prophylaxis before dental procedure

4.2 Posology and method of administration

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Ora-lex®C Mouthwash

Adult:

The dose of Ora-lex® C Mouthwash is 15ml (1½ tablespoon). Gargle at 1.5 – 3 hour intervals during a day. Chlorhexidine in Ora-lex® C Mouthwash reduces plaque and gingivitis during treatment. If it is used as an alternative to oral hygiene procedures, it should be held in the mouth for at least 1 minute. Teeth should be brushed before use in order to minimize the discoloration induced by chlorhexidine.

Adolescents (12 years of age and above):

Gargle with 5 – 15ml Ora-lex®C Mouthwash for 30 seconds every 1.5 – 3 hours. It should not be used for more than 7 days continuously. In case of burning and stinging sensation, gargle should be diluted with water. Due to insufficient number of clinical studies, Ora-lex®C Mouthwash is not recommended in children under 12 years of age.

Ora-lex®C Mouthwash with sprayer

The dose is 5-10 sprays at 1.5-3-hour intervals during a day. Geriatric population: The same dose as above can be applied to geriatric patients.

Route of administration: For oral administration.

For Ora-lex®C Mouthwash, remove the cap and squeeze until 15ml dispenser fills. Rinse it vigorously around teeth and gums and then spit it out. Do not swallow the contents. Do not wash the mouth, eat or drink anything for the next 20 minutes.

For Ora-lex®C Mouthwash with sprayer, spray about 5-10 sprays in the mouth. Prior to the first usage, it is necessary to press the pump a few times, holding it away from the face, until regular spraying is achieved. The mouth must be opened widely, and the spray must be administered into the oral cavity, by inserting the nozzle of the spray in the mouth. This must be repeated at least 4 times in various areas.

Do not swallow the contents, spit out any residual contents. Do not wash the mouth, eat or drink anything for the next 20 minutes

4.3 Contraindications

It is contraindicated in patients with hypersensitivity to benzydamine and chlorhexidine and to any of the ingredients in Ora-lex®C. It should not be used during pregnancy and lactation

4.4 Special warnings and precautions for use

For external use.

Due to insufficient number of clinical studies, Ora-lex® C is not recommended for Children under 12 years of age.

It is used only in the mouth; its contact with eyes and ears should be avoided. If it contacts with eyes, eyes should be well-rinsed with plenty of water. It may cause reversible color change in mouth, on tongue and teeth. Teeth should be brushed before use in order to minimize the discoloration. Ora-lex® C should not be swallowed and should be expectorated after each use. It is used without dilution. If sore throat is caused by bacterial infection or accompanied by infection, antibacterial treatment can be considered in addition to Ora-lex® C use. As absorbed benzydamine and its metabolites are excreted in urine, possibility of systemic effect should be taken into consideration in patients with severe renal impairment. As absorbed benzydamine is metabolized highly in liver, possibility of systemic effect should be taken into consideration in patients with severe hepatic impairment

4.5 Interaction with other medicinal products and other forms of interaction

Ora-lex®C does not have any known significant drug interaction. Chlorhexidine, one of the drug substances it contains, is incompatible with

some agents: Chlorhexidine salts are incompatible with soap and other anionic compounds.

Chlorhexidine salts are compatible with cationic and nonionic surface active agents; however, when they are co-administered at high concentrations, micelle may reduce chlorhexidine activity due to binding.

Solubility of chlorhexidine salts can be increased with surfactants such as cetrimide and lissapol NX.

It is incompatible with anionic poly-electrodes such as gum arabic, sodium alginate, sodium carboxy methyl cellulose and it is incompatible with starch and gummi tragacanthae; their effects are also reduced with these agents. Chlorhexidine is also incompatible with substances such as brilliant green, chloramphenicol, copper sulphate, fluorescein sodium, formaldehyde, silver nitrate and zinc sulphate

As chlorhexidine interacts with Ca and Mg cations when diluted with hard water, it may precipitate as insoluble salts. As chlorhexidine interacts with Ca and Mg cations when diluted with hard water, it may precipitate as insoluble salts.

Chlorhexidine gluconate is compatible with cetrimide and benzalkonium chloride. These synergistically enhance bactericide effect. Cetrimide prevents precipitation of chlorhexidine with hard waters

Except for chlorhexidine gluconate, chlorhexidine and its salts dissolve better in alcohol than water. Chlorhexidine gluconate solution may precipitate when it is added over alcohol. Ethanol in formulation renders the solution more effective against gram negative micro-organisms. They can be adsorbed during filtration through cellulosic filters.

Drug interactions with benzydamine have not been reported

4.6 Fertility, pregnancy and lactation

General recommendation

Pregnancy category is C

Pregnancy

Ora-lex®C is contraindicated during pregnancy. Animal studies do not indicate effects with respect to pregnancy, embryonal/fetal development, parturition or postnatal development. Potential risk to humans is unknown.

Breastfeeding

Data is not available for breastfeeding women. Therefore, it is contraindicated in breastfeeding women.

4.7 Effects on ability to drive and use machines

Ora-lex® C has no or negligible influence on the ability to drive and use machines

4.8 Undesirable effects

Ora-lex®C is generally well-tolerated and its side effects are minor

There is not any serious side effect and adverse effect reported at the end of clinical studies. Mostly, local side effects are observed. Systemic side effects, generally, are not observed and not serious.

Central nervous system disorders

Very rare: Dizziness, headache and numbness

Gastrointestinal diseases

Common: Oral numbness Very rare: Nausea, vomiting, gag reflex, gastrointestinal diseases

General disorders and administration site diseases

Common: Altered taste, staining of teeth and other oral surfaces, increase in calculus (tartar) formation Tooth staining is harmless and can be minimized through tooth-brushing before administration. Rare: Burning and stinging sensation Very rare: Local dryness, thirstiness, tingling, and feeling of coolness in the mouth

Reporting of suspected adverse reactions Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via pharmacy and poisons board, Pharmacovigilance Electronic Reporting System (PvERS) <https://pv.pharmacyboardkenya.org>.

4.9 Overdose

Ora-lex® C is unlikely to cause adverse systemic effects, even if accidental ingestion should occur. Intoxication is only expected in case of accidental ingestion of large quantities of benzydamine (> 300 mg)

Symptoms associated with ingested overdose of benzydamine are mainly gastrointestinal symptoms and symptoms of the central nervous system. Most frequent gastrointestinal symptoms are nausea, vomiting, abdominal pain and oesophageal irritation.

Symptoms of the central nervous system include dizziness, hallucinations, agitation, anxiety and irritability.

Management

In acute overdose only symptomatic treatment is possible. Patients should be kept under close observation and supportive treatment should be given. Adequate hydration must be maintained.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Benzydamine is an anti-inflammatory analgesic agent structurally unrelated to the steroid group. Benzydamine differs from other non-steroid antiinflammatory agents in that it is a base. At concentrations used for topical treatment, benzydamine exerts local anesthetic effect. The analgesic activity of benzydamine was more reported in models involving experimental inflammation rather than noninflammatory pain.

The mechanism of anti-inflammatory action of benzydamine is not related to stimulation of the pituitaryadrenal axis. Like other non-steroidal antiinflammatory agents, benzydamine inhibits the biosynthesis of prostaglandins under certain conditions, but its properties in this respect have not been fully explained. The stabilizing effect on cellular membranes may be involved in the mechanism of action. Following normal topical application of the medicine, chlorhexidine produces bactericidal effect, followed by a prolonged bacteriostatic action.

Chlorhexidine is a biguanide antiseptic that helps to reduce the development of plaque and gingivitis when usual oral hygiene measures are interrupted. It is a strong base with affinity for oral structures including hydroxyapatite of tooth enamel, pellicle of tooth surface, bacteria and salivary proteins. Chlorhexidine reduces dental plaque deposition and associated gingivitis as characterized by redness, swelling or bleeding of the gingiva. It reduces frequency of aphthous ulcer formation and increases the rate of healing following periodontal surgery. Chlorhexidine is active against a wide range of microorganisms including grampositive, gram-negative bacteria, yeast and some fungi and viruses. Chlorhexidine appears to delay bacterial growth by a delayed surface action. It is absorbed onto microbial cell walls and causes membrane leakage

5.2 Pharmacokinetic properties

Absorption

Absorption: Systemic absorption does not appear to occur following administration of chlorhexidine gluconate topical oral solution as mouth gargle. When it is administered as described, 4% of mouth gargle dose is ingested and some part is absorbed. 90% of the ingested chlorhexidine dose is not absorbed and excreted directly in faeces. Following topical administration of benzydamine hydrochloride, benzydamine is well absorbed into the inflamed oral mucosa where it exerts anti-inflammatory and local anaesthetic effect on administration site. Plasma benzydamine level following use of benzydamine is low and parallel the amount actually ingested

Distribution

Following administration of chlorhexidine gluconate 0.12% topical oral solution as a mouth gargle, approximately 30% of the medicine is retained in the oral cavity. Chlorhexidine is gradually released for up to 24 hours.

Biotransformation: As Chlorhexidine gluconate is poorly absorbed, no detectable blood levels have been found. Benzydamine is metabolized generally by oxidation and conjugation.

Elimination

Chlorhexidine is not accumulated in body and only small amount of it is metabolized. Approximately 10% of the ingested chlorhexidine is excreted via kidneys following absorption; 90% unabsorbed is excreted in faeces. Benzydamine and its metabolites entering in the systemic circulation are excreted largely in the urine

5.3 Preclinical safety data

None available

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

- Sorbitol 70% Liquid • Spearmint Oil
- Color Erythrosine FCF • Citric Acid
- Propylene Glycol • Sodium Citrate
- Peppermint Oil • DM Water
- Acrysol K-140 • Neotame Sweetener

6.2 Incompatibilities

Not applicable

6.3 Shelf life

Ora-lex®C Mouthwash 36 months Ora-lex®C Mouthwash with sprayer 36 months

6.4 Special precautions for storage

Store below 30°C. Protect from direct sunlight, heat & moisture

6.5 Nature and contents of container

Ora-lex®C Mouthwash is available as a 200 ml bottle. Ora-lex®C Mouthwash with sprayer is available as a 30 ml bottle with sprayer

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. MARKETING AUTHORISATION HOLDER

KRISHNA CHEMISTS LTD

3rd Floor Metrix Hardware, Lusaka Road, Industrial Area.

8. MARKETING AUTHORISATION NUMBER(S)

CTD5420

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

18/11/2021

10. DATE OF REVISION OF THE TEXT

18/11/2021