APPROVED PROFESSIONAL INFORMATION LEAFLET: ORALACT

SCHEDULING STATUS **S2**

1. NAME OF THE MEDICINE

ORALACT 0,74 mg/ml Mouthwash

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 1 ml of solution contains 0,74 mg diclofenac free acid

Sugar free

Contains sweetener: Acesulfame 1 mg/ml

Contains sugar alcohol: Sorbitol 0,5 g/ml

Preservative: Sodium benzoate 1 % *w/v*

For the full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Mouthwash

Clear or slightly opalescent red-orange solution with characteristic peach and mint flavour

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Symptomatic treatment of localised inflammatory diseases associated with pain, of the oropharyngeal cavity which may be caused by conditions such as but not limited to pharyngitis; pharyngotonsillitis; tonsillitis; gingivitis; mucositis and mouth ulcers.

May also be used to treat pain and inflammation resulting from minor dental treatment or dental extraction.

May be used to treat oral mucositis resulting from radiotherapy treatment in oncology patients.

4.2 Posology and method of administration

Posology

Treatment of painful, inflammatory conditions of the oropharyngeal cavity (mouth and throat):

Rinse or gargle with 15 ml of solution for 30 seconds twice a day.

Treatment of pain and inflammation resulting from minor dental treatment or extraction:

Rinse or gargle with 15 ml of solution for 1 minute twice a day.

Treatment of pain and inflammation due to oral mucositis following radiotherapy in oncology patients:

Rinse or gargle with 15 ml of solution for 2 minutes three times a day.

Paediatric population

The safety and efficacy of ORALACT in children has not been established.

Elderly

The safety and efficacy of ORALACT in the elderly has not been established.

Patients with renal impairment

The safety and efficacy of ORALACT in patients with renal impairment has not been established.

Patients with hepatic impairment

The safety and efficacy of ORALACT in patients with hepatic impairment has not been established

Method of administration

The required quantity of solution (undiluted or diluted in a small amount of water) should be rinsed around the mouth or used as a gargle and then spat out.

The solution should not be swallowed.

Unless treating oral mucositis resulting from radiotherapy treatment, if symptoms worsen or do not improve after 7 days, further medical assessment may be necessary.

4.3 Contraindications

Hypersensitivity to diclofenac, acetylsalicylic acid, other non-steroidal anti-inflammatory drugs (NSAIDs), or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

If any manifestations of drug reaction with eosinophilia and systemic symptoms (DRESS) occur, ORALACT should be discontinued.

The use of topical preparations, especially if prolonged, can cause the development of sensitisation phenomena. In this case, the treatment should be suspended and appropriate therapy undertaken, if necessary.

ORALACT contains sorbitol and therefore it may have a laxative effect. In addition, patients with the rare hereditary condition of sorbitol intolerance should not take ORALACT.

ORALACT also contains sodium benzoate, which is mildly irritant to the skin, eyes and mucous membranes.

4.5 Interaction with other medicines and other forms of interaction

No interaction studies have been conducted.

4.6 Fertility, pregnancy and lactation

Pregnancy

Adequate and well controlled studies in pregnant women have not been performed thus the safety of ORALACT in pregnancy has not been established. Use of ORALACT in pregnant women is not recommended.

Breastfeeding

It is unknown if ORALACT is excreted in human milk thus the safety of its use in lactation has not been established. Use of ORALACT during breastfeeding is not recommended.

Fertility

No clinical data is currently available.

4.7 Effects on ability to drive and use machines

ORALACT is not known to have an effect on cognitive ability. ORALACT has no or negligible influence on the ability to drive and use machines. However, patients should be advised to exercise caution until they know how ORALACT affects them.

4.8 Undesirable effects

Summary of the safety profile

Clinical studies performed with ORALACT showed, mainly in long-term treatment, the outbreak of: generally mild irritation of the oral cavity; cough.

Table 1: Tabulated summary of adverse reactions

Respiratory, thoracic and mediastinal disorders	
Less frequent:	Cough.
General disorders and administration site conditions	
Less frequent:	Mild irritation of the oral cavity.

Reporting of suspected adverse reactions

Reporting of suspected adverse reactions after authorisation of ORALACT is important. It allows continued monitoring of the benefit/risk balance of ORALACT. Healthcare professionals are asked to report any suspected adverse reactions. Suspected adverse reactions can be reported to Actor Pharma (Pty) Ltd via email: pharmacovigilance@actorpharma.co.za or telephonically on 011 312 3812. Suspected adverse reactions can also be reported to SAHPRA via the “6.04 Adverse Drug Reaction Reporting Form”, found online under SAHPRA’s publications: https://www.sahpra.org.za/Publications/Index/8.

4.9 Overdose

Eventual involuntary swallowing of the dose of solution used for the rinses or gargling causes no harm to the patient since it is equivalent to one fifth / sixth of the dose recommended for systemic administration.
In cases of overdose, patients should be treated symptomatically as required.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacological classification: A 16.5 Ear, nose and throat preparations – Others

Diclofenac is a non-steroidal anti-inflammatory drug (NSAID). Systemically administered diclofenac has analgesic, antipyretic and anti-inflammatory properties.

When used topically diclofenac possesses analgesic and anti-inflammatory properties.

5.2 Pharmacokinetic properties

Spectrofluoroscopy has shown that diclofenac concentrates in the oral mucosa and is then gradually absorbed, thus producing haematic concentrations that are very low and insufficient to express systemic pharmacological effects.

Diclofenac is primarily excreted in the urine, in the form of metabolite, while the remaining part is excreted in bile and faeces.

5.3 Preclinical safety data

TOXICOLOGY

	LD50 per os
MOUSE	1300 mg/kg after 48 hours
	231 mg/kg after 15 days
RAT	1500 mg/kg after 48 hours
	233 mg/kg after 15 days
GUINEA PIG	1250 mg/kg C>

Chronic toxicity after 3 months of oral treatments in rats is practically absent. Three months oral treatment in rats with a dose of 2 mg/kg/day produced practically no chronic toxicity. The studies performed showed no mutagenic, carcinogenic or teratogenic effects of ORALACT.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Choline solution

Sorbitol

Sodium benzoate

Disodium edetate

Acesulfame potassium

Peach flavouring agent

Peppermint oil

Ponceau red E124

Purified water

6.2 Incompatibilities

Not known.

6.3 Shelf life

3 years

6.4 Special precautions for storage

Store at or below 25 °C in a cool, dry place.

Store in the original packaging to protect from light and moisture.

6.5 Nature and contents of container

200 ml transparent amber type 3 glass bottle closed with a plastic child-proof screw cap. Packaged with a 15 ml polypropylene measuring device.

The glass bottle is contained in a cardboard carton.

6.6 Special precautions for disposal

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION

Actor Pharma (Pty) Ltd[1]

Royal Palm Business Estate

Unit 7, 646 Washington Street

Halfway House, Midrand, 1685

Gauteng, South Africa

8. REGISTRATION NUMBER

48/16.5/0130

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

18 May 2022

10. DATE OF REVISION OF THE TEXT

13 April 2023

[1] Company Registration Number.: 2008/008787/07