PROFESSIONAL INFORMATION LEAFLET: ORALACT™ 1,48 mg/ml Throat Spray

SCHEDULING STATUS **S2**

1. NAME OF THE MEDICINE

ORALACT 1,48 mg/ml Throat Spray

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1 spray (corresponding to 0,2 ml) contains 0,3 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

Throat Spray

Clear or slightly opalescent red-orange solution

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.

4.2 Posology and method of administration

Posology

The recommended dose in adults is 2 sprays directly to the affected area three times a day.

If symptoms worsen or do not improve after 7 days when treating localised inflammatory diseases associated with pain, or after 14 days when treating pain and inflammation resulting from minor dental treatment or dental extraction, further medical assessment may be necessary.

<u>Paediatric population:</u>

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

External (oral) use. This product is not intended to be swallowed.

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

During the clinical studies with ORALACT the following side effects were reported:

Mild: Nausea; hypotension; shivering; vision alterations; dyspepsia.

Moderate: Headache; mucous membrane alterations.

Table 1: Tabulated summary of adverse reactions

Psychiatric disorders	
Less frequent:	Headache.
Eye disorders	
Less frequent:	Vision alterations.
Vascular disorders	
Less frequent:	Hypotension, shivering.
Gastrointestinal disorders	
Less frequent:	Nausea, dyspepsia.
General disorders and administration site conditions	
Less frequent:	Mucous membrane alterations.
Frequency not known:	Burning sensation in the mouth.

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 spray solution causes no harm to the patient since the recommended dosage sprayed is much less that that 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

	LD.50 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 chloride
Sorbitol
Sodium benzoate
Disodium edetate
Acesulfame potassium
Ethanol 96 %
Peach flavouring agent
Peppermint oil
Allura red E129
Sodium hydroxide
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

15 ml transparent amber type 3 glass bottle with multidose flacon with sprayer, closed with a polypropylene cap.

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]
Unit 7, Royal Palm Business Estate
646 Washington Street
Halfway House, Midrand, 1685
Gauteng, South Africa

8. REGISTRATION NUMBER

48/16.5/0299

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

18 MAY 2022

10. DATE OF REVISION OF THE TEXT

Not applicable

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

™ ORALACT is a trademark of Actor Pharma (Pty) Ltd

DICTS /PI/01/05.2022