

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Dicloident 0.74 mg/ml Mouthwash (Oromucosal Solution)

Diclofenac 0.74 mg/ml Mouthwash

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

100 ml of the solution contains:

Active substance: 0.074 %w/v Diclofenac free acid.

Excipients with known effect:

Sorbitol (E420) 50 % w/v

Sodium Benzoate (E211) 1% w/v

Ponceau Red E124 0.005% w/v

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Oromucosal solution (Mouthwash)

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Dicloident/diclofenac mouthwash can be used for the symptomatic treatment of local painful inflammatory diseases of the oral cavity and the throat and/or following dental treatment or dental extraction.

4.2 Posology and method of administration

Posology

The recommended dose is 2/3 rinses or gargles per day with 15 ml of oromucosal solution, undiluted or diluted in a little water for 7 days.

For the treatment of mucositis of the oral cavity caused by radiotherapy may be extended to six weeks.

Paediatric population

The safety and efficacy of Diclodent/diclofenac mouthwash on Children has yet to be established: No data are available.

Method of administration

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

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1, or to substances that are chemically closely correlated to them, to acetylsalicylic acid or to other non-steroidal anti-inflammatory drugs.

4.4 Special warnings and precautions for use

Eventual involuntary swallowing of a dose of solution used for the rinses or gargling causes no damage to patient since it is equivalent to one fifth/sixth of the dose recommended for systemic administration. The use of topical preparations, particularly if prolonged, can lead to development of sensitization phenomena. If this occurs, treatment with Diclodent/diclofenac mouthwash should be suspended and suitable treatment instituted if necessary.

Diclodent/diclofenac mouthwash contains Sorbitol. Patients with rare hereditary problems of fructose intolerance should not take this medicine.

Diclodent/diclofenac mouthwash also contains Sodium benzoate, which is mildly irritant to the skin, eyes and mucous membranes and Ponceau 4R, which may cause allergic reactions.

4.5 Interaction with other medicinal products and other forms of interaction

No negative interactions have been reported with other drugs commonly used in the patient treatment.

4.6 Fertility, pregnancy and lactation

Diclodent/diclofenac mouthwash should not be used in pregnancy or lactation unless considered essential by the physician. There are no adequate and well-controlled studies to support its use.

4.7 Effects on ability to drive and use machines

Diclofenac mouthwash has no or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects

Although no undesirable effects that could definitely be attributed to Diclofenac mouthwash were observed during the clinical trials performed with the product, it is possible, particularly in prolonged treatment, that signs of irritation of the oral mucosa, generally, mild, and cough appear. The use of topical preparations, particularly if prolonged, can give rise to sensitization phenomena. If this occurs, treatment with Diclofenac mouthwash should be suspended and suitable treatment instituted if appropriate.

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 the Yellow Card Scheme

Website: www.mhra.gov.uk/yellowcard

4.9 Overdose

No cases of overdose with Diclofenac mouthwash have been reported. Diclofenac mouthwash as Diclodent/diclofenac mouthwash has not been marketed.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: 6.1.1 Medicinal product for application on mouth and oropharynges. Topical application **ATC code:** A01A D11 -Various.

When administered systemically, diclofenac has analgesic, antipyretic and anti-inflammatory properties. When used topically this active substance possesses analgesic and anti-inflammatory properties.

5.2 Pharmacokinetic properties

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

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

Oral diclofenac is rapidly and almost completely absorbed from the gastrointestinal (GI) tract; however, the drug undergoes extensive first-pass metabolism in the liver, with only about 50-60% of a dose as enteric-coated tablets reaching the systemic circulation as unchanged drug.

Following oral administration of a single 25, 50, 75, or 150 mg dose as enteric-coated tablets in healthy adults, average peak plasma diclofenac concentrations of 0.5-1, 1-1.5, 2, and 2.5 mg/mL, respectively within about 1.5-3 hours. The area under the plasma concentration-time curve (AUC) increases linearly with single diclofenac doses of 25-150 mg.

The systemic absorption of mouthwash doses of diclofenac is relatively low compared to oral doses. The systemic bioavailability of diclofenac after 7 days of mouth rinsing b.i.d. with 25 ml of is about 1/10th in terms of AUC and 1/20th to 1/50th in terms of C_{max} of that obtained with the oral administration of 25 mg diclofenac tablets.

This low absorption should greatly diminish the potential for any systemic drug side-effects when diclofenac is administered by this route.

5.3 Preclinical safety data

LD50 *per os*

Mouse	1300Kg after 48 hour
	231 mg/kg after 15 days
Rat	1500kg after 48 hour
	233 mg/kg after 15 days
Guinea Pig	1250 mg/kg after 48 hour

Three months of oral treatment in rats with a dose of 2 mg/kg/day had produced practically no chronic toxicity. The studies performed showed no mutagenic, carcinogenic or teratogenic effects for diclofenac.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sorbitol liquid non crystallising (E420), choline, sodium benzoate (E211), disodium edetate, acesulfame potassium (E950), Peppermint oil, Peach flavour, Ponceau Red E124, purified water.

6.2 Incompatibilities

Not applicable

6.3 Shelf life

3 years

6.4 Special precautions for storage

Store in the original package.

6.5 Nature and contents of container

200ml amber (type III) glass bottle with child resistance polypropylene closure.

6.6 Special precautions for disposal

No special requirements for disposal.

7 MARKETING AUTHORISATION HOLDER

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8 MARKETING AUTHORISATION NUMBER(S)

PL 20117/0112

**9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE
AUTHORISATION**

03/03/2016

10 DATE OF REVISION OF THE TEXT

12/05/2016