

## GELCLAIR® INFORMATION LEAFLET – sachet

### GELCLAIR®

Concentrated Oral Rinse Gel / Oral gel for Mucositis / Protective Oral gel for mucositis relief

### Product Description

Gelclair® is a viscous gel specially formulated to aid in the painful symptoms of mucositis of the oropharyngeal cavity. It forms a protective film that, by adhering to the mucosa of the oropharyngeal cavity, can prevent further irritations thus contributing to the rapid relief of pain.

It is presented as a concentrated gel in sachets for dilution with water.

### Indications

Gelclair® helps the management of painful symptoms of mucositis of the oropharyngeal cavity. Gelclair®, used as a mouthwash, forms a protective film that helps to provide pain relief, soothing mouth lesions including those caused by medication, disease, radiotherapy, chemotherapy, oral surgery, traumatic ulcers caused by dental braces and dentures and ageing.

### Ingredients

AQUA, POLYVINYLPIRROLIDONE (PVP) (9%), MALTODEXTRIN, PROPYLENE GLYCOL, PEG-40 HYDROGENATED CASTOR OIL, HYDROXYETHYLCELLULOSE, AROMA, DISODIUM EDTA, SODIUM HYALURONATE (0.1%), SODIUM SACCHARIN, GLYCYRRHETINIC ACID, PRESERVATIVES (POTASSIUM SORBATE, SODIUM BENZOATE, BENZALKONIUM CHLORIDE)

### Instructions for use

Gelclair® is indicated for children from 4 years of age and adult population. The product should be used 3 times a day before main meals and/or before night rest. Avoid eating or drinking for 30–60 minutes following application.

#### *Adolescents and adults:*

Pour the entire contents of the single-dose Gelclair® sachet into a glass and add approximately 40 ml of water (3 tablespoonfuls). Stir mixture well and use at once immediately after dilution. Rinse around the mouth for at least one minute or as long as possible to coat tongue, palate, throat, inside of cheeks and all oral tissue thoroughly. Gargle and spit out.

#### **Biokosmes S.r.l. – Socio Unico**

Soggetta a Direzione e Coordinamento di Venture Life Group PLC – U.K.

Via dei Livelli, 1 – 23842 Bosisio Parini (LC) – Italy

Tel. +39 0313581085 Fax + 39 0313581082

e-mail: [biokosmes@biokosmes.it](mailto:biokosmes@biokosmes.it) – [www.biokosmes.it](http://www.biokosmes.it)

Sede Legale: 20122 Milano – Via Besana, 10 – Cap. Soc. 100.000 € int. vers.

R.I. Milano / Codice Fiscale / Partita IVA 01430480135 – R.E.A. Milano 1863413



Discard any unused mouthwash.

Do not swallow.

#### *Children:*

Use of Gelclair® in children should be done under the supervision of an adult. For patients unable to rinse and gargle (e.g. young children, patients with deglutition impairment) it is suggested to apply the product directly on the mucosal lesions of the mouth by using a sponge or swab.

#### **Contra-indications**

The use of Gelclair® is contra-indicated in any patient with a known history of hypersensitivity to any of the ingredients.

#### **Precautions and Warnings**

There are no known interactions with medicinal or other products. Please inform your doctor or pharmacist if you are taking or have recently taken any other medicines, even those not prescribed by a doctor, especially in case of sublingual and buccal formulations.

Avoid eating or drinking for 30- 60 minutes following application.

Do not use the product if the sachet is damaged or has reached its expiry date.

The gel may become a little darker and thicker on storage but this does not affect its efficacy or safety.

Store at room temperature, out of direct sunlight.

If no improvement is seen after 7 days of treatment, consult your doctor. The treatment duration should not exceed 30 consecutive days. In case of recurrent oropharyngeal lesions further treatments with Gelclair® may be taken into consideration.

May be used during pregnancy and lactation.

The device does not affect the ability to drive or use machine.

Do not swallow.

KEEP OUT OF THE REACH OF CHILDREN.

#### **Undesirable Effects**

No serious adverse events have been reported to date\*. Minor, reversible, rare, non-serious adverse events referred to local discomfort were collected (e.g. stinging, burning sensation). Use of the product is not, however, advisable for individuals known to be hypersensitive to any of its ingredients, who may experience minor local and transitory side effects after Gelclair application. These side effects mainly consist of local discomfort, stinging and burning sensations.

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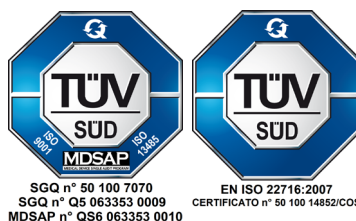
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Tel. +39 0313581085 Fax + 39 0313581082

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\*As per Medical Device Regulation any serious incident that may occur in relation to the device should be reported to the manufacturer and the competent authority of the Member State.

### Accidental Ingestion / Overdose

At the time of producing this leaflet no cases of overdose have been reported; should the maximum daily dose be exceeded please seek medical advice.

Whilst no adverse effects would be expected from accidental ingestion of Gelclair®, ingestion is not recommended; should accidental ingestion occur please seek medical advice.

### Packaging

Pack containing 3 or 15 or 21 x 15 ml sachets of Gelclair®.











Biokosmes s.r.l. - Via Besana, 10 - 20122 Milano, Italy - biokosmes@biokosmes.it

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**CE** 0477



Symbol	Meaning
	Legal manufacturer of medical device
	CE mark issued by Notified Body 0477
	Read carefully instructions for use
	Expiry date
	Batch number
	Unique Device Identifier
	Medical device
	For single use only

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