

## Oral protective gel for mucositis

#### 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 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, PVP, MALTODEXTRIN, PROPYLENE GLYCOL, PEG-40 HYDROGENATED CASTOR OIL, HYDROXYETHYL-CELLULOSE, AROMA, DISODIUM EDTA, SODIUM HYALURONATE, SODIUM SACCHARIN, GLYCYRRHETINIC ACID, PRESERVATIVES (POTASSIUM SORBATE, SODIUM BENZOATE, BENZALKONIUM CHLORIDE)

#### Instructions for use - 180 ml Bottle

Gelclair® should be used 3 times a day or as needed. Avoid eating or drinking for at least 30-60 minutes following treatment.

Pour 15 ml of Gelclair® (1 tablespoonful) into a glass and add approximately 40 ml of water (3 tablespoonfuls). Stir mixture well and use at once. 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.

Discard any unused mouthwash.

Do not swallow.

In patients which are not able to rinse and gargle (e.g. young children) it is suggested to apply the product directly into the mouth by using a sponge or swab.

#### Instructions for use – 15 ml Sachet

Gelclair® should be used 3 times a day or as needed. Avoid eating or drinking for at least 30-60 minutes following treatment.

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. 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.

Discard any unused mouthwash.

Do not swallow.

In patients which are not able to rinse and gargle (e.g. young children) it is suggested to apply the product directly into 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. However, it may reduce the absorption of sublingual drugs; in case of use of this kind of drugs, consult your doctor.

Avoid eating or drinking for at least 30-60 minutes following treatment.

Do not use the product if the bottle or 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. Treatment should be discontinued after 4 weeks.

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 undesirable effects have been reported to date. Use of the product is not, however, advisable for individuals known to be hypersensitive to any of its ingredients.

## Accidental Ingestion / Overdose

At the time of producing this leaflet no cases of overdose have been reported. Whilst no adverse effects would be expected from accidental ingestion of Gelclair®, ingestion is not recommended.

## **Packaging**

Bottle containing 180 ml of Gelclair®.

Box of \_ \_ sachets of 15 ml of Gelclair<sup>®</sup>.

# Manufactured by:

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