

GELCLAIR Concentrated Oral Gel

15 ml SACHET – Information Leaflet

GELCLAIR®

Concentrated Oral Gel

Ingredients: Water, Maltodextrin, Propylene Glycol, Polyvinylpyrrolidone (PVP), Sodium Hyaluronate, Potassium Sorbate, Sodium Benzoate, Hydroxyethylcellulose, PEG-40 Hydrogenated Castor Oil, Disodium Edetate, Benzalkonium Chloride, Flavoring, Saccharin Sodium, Glycyrrhetic Acid.

Patient use form: Concentrated Oral Gel

Contents: 15 mL per single-dose sachet. 1 box contains 15 single-dose sachets.

Therapeutic group: Oral gel for the relief and management of pain.

Indications: Gelclair® has a mechanical action indicated for the management of pain and relief of pain by adhering to the mucosal surface of the mouth, soothing oral lesions of various etiologies, including oral mucositis/stomatitis (may be caused by chemotherapy or radiation therapy), irritation due to oral surgery, traumatic ulcers caused by braces or ill-fitting dentures, or disease. Also indicated for diffuse aphthous ulcers.

Contraindications: The administration of Gelclair® is contraindicated in any patient with a known or suspected hypersensitivity to any of its ingredients.

Special precautions for use: Avoid eating or drinking for at least 30-60 minutes after use. Do not use any sachet that is not intact (torn, split, or otherwise damaged in any way). If no improvement is noticed after 7 days, consult a physician.

Keep out of the reach of children.

Rx Only

Interaction with other medicinal products and other forms of interaction: There are no known interactions with medicinal or other products.

Directions for use: Pour the entire contents of the single-dose Gelclair® sachet into a glass and add 40ml or 3 tablespoonfuls of water. 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. Use 3 times a day or as needed. Avoid eating or drinking for 30-60 minutes following application. If swallowed accidentally no adverse effects are anticipated.

Side effects: The product is not recommended for use in patients with a known or suspected allergy to any of the product's ingredients. Postmarketing reports have included infrequent complaints of burning sensation in the mouth.

Overdose: At the time of producing this leaflet, no cases of overdose have been reported.

Storage: Store at room temperature, out of direct sunlight. The gel may become a little darker and thicker over time, but this does not affect its efficacy or safety. Do not use after the expiration date shown on the box and packet.

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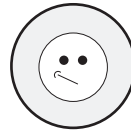
Instructions for Use



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2 Stir mixture well and use at once.



3 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.



4 Gargle and spit out.



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

What is Gelclair[®] and how does it work?

Gelclair[®] gently soothes the pain of oral mucositis and is designed to be non-numbing, non-stinging, and non-drying.

Gelclair[®] is a prescription mouth gel that soothes the pain of oral mucositis for several hours at a time.

Gelclair[®] works by forming a barrier that protects the nerve endings that cause pain. In clinical studies, Gelclair[®] effectively treated pain and provided relief that helped patients eat and drink more easily. You can eat, drink, and take medications while using Gelclair[®].

If you would like more information about oral mucositis and pain treatment with Gelclair[®], please visit www.gelclair.com.