

gelclair[®] Bioadherent 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.

Pharmaceutical form: Concentrated oral gel

Contents: 15 mL per single-use packet. Commercial boxes contain either 15 single-use packets (NHRIC 89141-456-02) or 90 single-use packets (NHRIC 89141-456-03).

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 packet 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.

Warning: Federal law restricts Gelclair[®] to sale by or on the order of a physician or properly licensed practitioner.

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-use Gelclair[®] packet into a glass and add 1 tablespoon of water. If this dilution of Gelclair[®] is too thick, it may be diluted with an additional 1-2 tablespoons of water to achieve the desired thickness. Stir mixture well and use immediately. Rinse around the mouth for at least 1 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. Do not eat or drink for at least 30-60 minutes following treatment. If water is not available, Gelclair[®] may be used undiluted. If Gelclair[®] is swallowed accidentally, no adverse effects are anticipated.

Side effects: At the time of producing this leaflet, no adverse effects have been reported in clinical trials with the use of Gelclair[®]. 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.

Gelclair[®] is a registered trademark of Helsinn Healthcare SA, Lugano, Switzerland.

Manufactured for: Helsinn Healthcare SA, Lugano, Switzerland

Marketed and distributed by: Midatech Pharma US Inc. Raleigh, NC 27615 • 855-273-0468

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 **HEL SINN**
Integrative Care

Instructions for Use:



Pour the entire contents of the single-dose Gelclair® packet into a glass and add 1 tablespoon of water (15 mL)*



Stir mixture well and use immediately



Rinse around the mouth for at least 1 minute to thoroughly coat the tongue, palate, throat, inside of cheeks, and all oral tissue



Gargle and spit out



Wait at least 30-60 minutes before eating or drinking

*If the solution is too thick, it may be diluted with an additional 1 to 2 tablespoons of water to achieve the desired consistency.

For best results, use Gelclair® three times a day, before meals or as recommended by your health care professional.

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.