

# gelclair<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> packet into a glass and add 1 tablespoon of water. If this dilution of Gelclair<sup>®</sup> 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<sup>®</sup> may be used undiluted. If Gelclair<sup>®</sup> 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<sup>®</sup>. 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<sup>®</sup> is a registered trademark of Helsinn Healthcare SA, Lugano, Switzerland.

**Manufactured for:** Helsinn Healthcare SA, Lugano, Switzerland

**Marketed and distributed by:** Fortovia Therapeutics, Inc. Raleigh, NC 27615 • 855-273-0468

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# 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](http://www.gelclair.com).