



Prescribing Information

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 15 single-use packets. (NDC 24477-010-15)

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 1 hour 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 1 hour 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: EKR Therapeutics, Inc., Cedar Knolls, NJ 07927

Date of revision: October 2006

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Special considerations

Patients with severe mucositis pain may require additional dosing for optimal results

Do not eat or drink for at least 1 hour following treatment

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