Gelclair® Oral Gel

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Product name: Gelclair® is manufactured by Sinclair Pharma Limited (Godalming, Surry, England, United Kingdom) and marketed by Cell Pathways, Inc. (Horsham, PA).

Classification: Gelclair is classified as a class I medical device and is available by prescription only.

Indications: Gelclair is a viscous oral gel that has a mechanical action that provides pain relief by adhering to the mucosal surface of the mouth, soothing oral lesions caused by medication, disease, radiotherapy, chemotherapy, irritation related to oral surgery, aging, and trauma caused by mucositis and stomatitis arising from immunosuppression, chemotherapy, and radiation therapy (Sinclair Pharma Limited, 2002; Smith, 2001).

Action: When exposed to the inside of the mouth, Gelclair forms a protective layer over the oral mucosa that soothes irritated tissues and reduces pain. The main ingredients in Gelclair include purified water, maltodextrin, propylene glycol, polyvinylpyrrolidone (a hydrophilic polymer that acts as a muco-adherent and a film-forming agent, which enhances tissue hydration and has been shown to accelerate wound healing in animal models and in human wounds), hyaluronic acid (sodium hyaluronate—a viscous fluid that occurs naturally in the body and promotes healing by hydrating mucus membranes and acting as a protective film-forming, coating substance), and glycyrrhetinic acid, an extract of licorice that mediates healing through its anti-inflammatory properties as a cyclooxygenase inhibitor.

Adverse reactions: No adverse reactions have been noted with the use of Gelclair, even in the event that a patient accidentally swallows the solution.

Interactions: No interactions are known to exist with other medicinal products.

Contraindications: Contraindications of Gelclair administration are in those with a known history of hypersensitivity to any of its ingredients.

Directions for use: Single-dose Gelclair (15 ml) contents are added to 15 ml–45 ml of water. Patients are instructed to rinse or gargle for at least one minute or as long as possible to coat the tongue, palate, throat, and buccal mucosa. Gelclair can be administered three times a day or as needed. Patients should avoid eating or drinking for at least one hour after use. In the unlikely event that water is not available, the product may be used undiluted.

Availability: Gelclair is supplied in boxes of 21 single doses. Each single dose contains 15 ml of Gelclair.

Stability: Gelclair is stored at room temperature, out of direct sunlight. It should not be refrigerated and is stable for up to three years.

Clinical data: Clinical trials have been conducted to evaluate the effectiveness of Gelclair in relieving mucositis symptoms. DeCordi and Martina (2001) found that after three days of Gelclair treatment, patients experienced improvement in severity of mucositis (57%), reduced levels of pain (83%), and noted improvement in ability to eat and drink (83%). Innocenti, Moscatelli, and Lopez (in press) treated 30 patients with painful inflammatory and ulcerative conditions of the mouth and oropharynx with Gelclair. Patients were assessed for mucositis pain using a visual numeric scale ranging from 1–10, with 10 representing the worst pain experienced. A 92% reduction in mean pain scores occurred five to seven hours after the first dose of Gelclair ($p = < 0.005$). Additionally, all of the patients reported a substantial reduction in pain. Forty percent of the patients felt that the optimal effect of a dose of Gelclair persisted for two to three hours, and 57% reported that pain relief lasted longer than three hours. After one week of treatment, 87% of the patients reported improvement from baseline scores related to pain and discomfort on swallowing food, liquids, and saliva. Overall, patients reported that Gelclair was easy to use and well tolerated. Randomized clinical trials are needed to further test the efficacy of Gelclair and compare its effectiveness to other agents used to treat mucositis.

Nursing implications: Mucositis and stomatitis are experienced by 47%–75% of patients with cancer receiving immunosuppressive chemotherapy and irradiation (Borbasi et al., 2002; Shih, Miaskowski, Dodd, Stotts, & McPhail, 2002). Symptoms associated with mucositis are severe pain and inhibition of the functional ability to eat and drink. Patients require opioids for pain management and/or parenteral feeding to maintain weight and nutrition. Opioid use often is accompanied by sedation, nausea, constipation, confusion, and limited activity. In addition, patients and caregivers may harbor fears of addiction. Considerable nursing time is required for mucositis management and patient/caregiver teaching. Although numerous lidocaine or sucralfate

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