



gelclair[®]

Soothing comfort, long-lasting relief

Questions &
Answers

1. What is GELCLAIR?

GELCLAIR is a viscous oral gel designed to aid in the management of lesions or ulcerations within the oral cavity.

Specifically GELCLAIR provides oral pain relief by providing a physical barrier over ulcers or lesions where sensitive nerve endings may be exposed. By coating the mucosal surfaces of the mouth and forming a shield over damaged tissues, GELCLAIR can reduce the irritation caused by consuming solid food and fluids.

In addition to forming a physical barrier over sensitive tissues GELCLAIR provides lubrication and hydration to the oral mucosa.

2. What is GELCLAIR used for?

GELCLAIR can be used as a barrier protection wherever the tissues of the oral mucosa are damaged or sensitised. Damage to the oral mucosa may be a result of:

- Oral mucositis due to cancer treatments.
- Lesions resulting from surgery. (oral, maxillo-facial)
- Diffuse aphthous ulcers.
- Other forms of tissue damage within the oral cavity.

3. What is oral mucositis?

One of the most severe conditions of painful oral lesions is represented by oral mucositis which is characterised by recurrent, erythematous, painful ulcers, and is a common complication of standard and high-dose chemotherapy or radiotherapy for head and neck cancer. Mucositis is a common condition in patients undergoing conditioning prior to bone marrow transplantation and can occur in patients infected with HIV. Mucositis is also a primary symptom of Behcet's disease.

The typical incidence of oral mucositis will vary dependent on the type of cancer therapy received. Approximately 80% of patients receiving radiotherapy to the head and neck may experience some degree of mucositis. In almost half of these patients the degree of mucositis may be quite severe, (grade 3-4).¹

In the case of patients receiving stem cell transplantation between 50% and 100% will experience mucositis as a result of high dose chemotherapy or total body irradiation.¹

Even with standard chemotherapy regimens some degree of oral mucositis occurs in approximately 35 - 40% of patients.^{1,2}



Grade 2 oral mucositis



Grade 3 oral mucositis



Grade 4 oral mucositis

Photographs reproduced by kind permission of Dr Ian Hewson, Royal Australasian College of Dental Surgeons

Many chemotherapy agents are known to induce mucositis - these can be summarised as follows

Markedly mucotoxic agents		
Actinomycin D	Daunorubicin	Methotrexate
Amasacrin	Docetaxel	Mitoxantrone
Bleomycin	Doxorubicin	Pilcamycin
Chlorambucil	Etoposide	Thioguanine
Cisplatin	Floxuridine	Vinblastine
Cytarabine	5-Fluorouracil	Vindesine
Mucotoxic agents		
Carboplatin	Idarubicin	Paclitaxel
Carmustine	Ifosfamide	Procarbazine
Cyclophosphamide	Irinotecan	Dacarbazine
Lomustine	Thiotepa	Dactinomycin
Mechlorethamine	Topotecan	Interferons
Epirubicin	Melphalan	Vincristine
Mercaptopurine	Vinorelbine	Hydroxyurea
Fludarabine	Mithramycin	Interleukin-2
Gemcitabine	Mitomycin	

Adapted from Kostler *et al.* (2001) CA Cancer J Clin³

4. How is oral mucositis graded?

Several grading systems have been developed over the years to assist clinicians in the assessment of oral mucositis. One of the most commonly used systems is that developed by the World Health Organisation (WHO):

WHO Grading Scale of Mucositis	
Grade	Description
0	No symptoms
I	Painless ulcers, erythema or mild soreness
II	Painful erythema, oedema or ulcers but patient can eat
III	Painful erythema, oedema or ulcers and cannot eat
IV	Requires parenteral or enteral nutrition

5. When will mucositis occur and how long will it last for?

The onset of oral mucositis may vary from patient to patient - indeed some patients may not develop oral mucositis at all, in others the onset may vary with different cancer therapies. The following represent a broad overview of the onset and duration of mucositis:

Chemotherapy

The mucotoxic effects of chemotherapy begin shortly after therapy has commenced and peak in severity approximately between day 7 to day 10 with eventual resolution occurring within two weeks.²

Radiotherapy

In standard daily fractionated radiotherapy symptoms occur within the first week of treatment. In patients whose immune system is not compromised oral lesions will usually heal after 3 weeks of radiotherapy finishing.³

6. What are the implications of oral mucositis?

The severe pain that can be associated with mucositis may lead to difficulties in the oral intake of food and fluid which in turn may lead to dehydration and malnutrition. Moreover, patients with oral mucositis show a higher risk of developing infections.

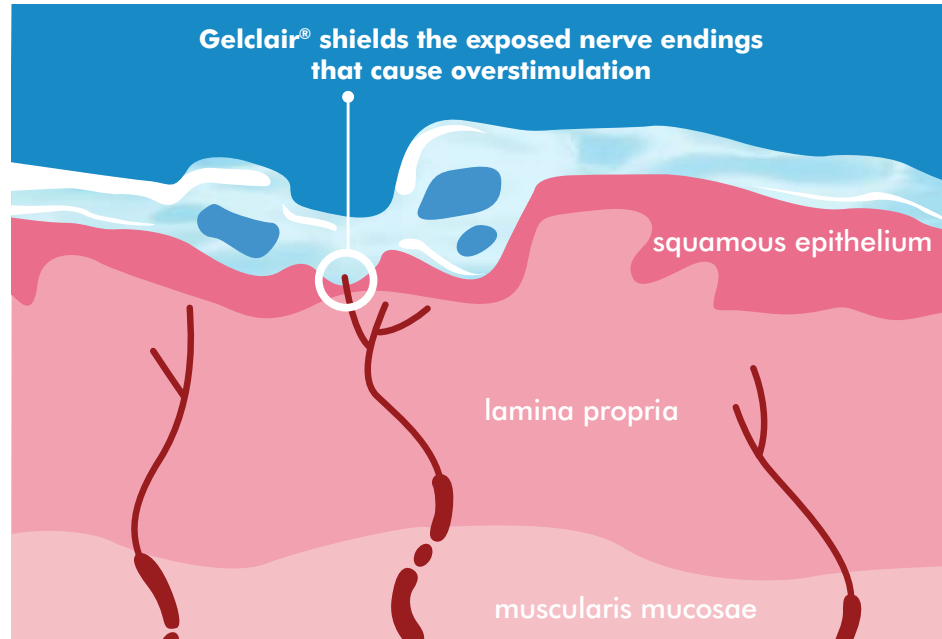
In the case of grades III or IV mucositis it may be necessary for patients to receive intravenous opioid based analgesia as well as parenteral or enteral nutrition. This could require the patient to be admitted into hospital for a period of time.⁴

In some cases the severity of oral mucositis may result in patients' cancer therapy being deferred or interrupted, which may worsen the predicted outcome of treatment.^{4,5}

Clearly the development of oral mucositis as a result of cancer therapies dramatically impacts the quality of life for these patients. It is not uncommon for patients to report problems with their speech and in severe cases sleep may be interrupted.⁴

7. How does GELCLAIR work?

GELCLAIR exerts its pain-relieving effect by forming a protective layer over the oral mucosa and by lubricating, hydrating, and coating the damaged tissues without numbing, stinging, or drying. This protective barrier shields the exposed and sensitised nerve endings in the mucosa from overstimulation and provides rapid oral pain relief.

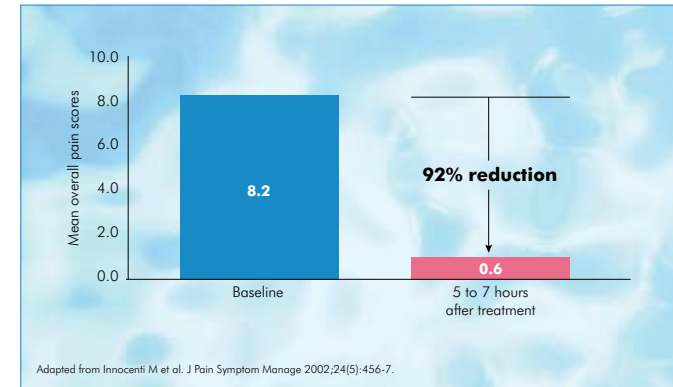


The protection provided by GELCLAIR reduces pain on eating and drinking and therefore may improve hydration and nutrition.⁶

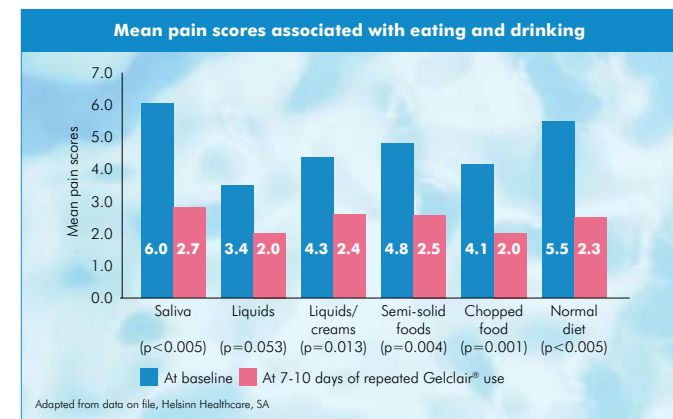
Have the benefits of GELCLAIR been proven?

The effectiveness of GELCLAIR has been evaluated in clinical trials involving patients affected by inflammatory or ulcerative lesions of the oral cavity.

Innocenti *et al*^{5,6} conducted an open-label study in 30 patients suffering from painful inflammatory and ulcerative conditions of the mouth and oropharynx. Patients were evaluated for short-term (5 to 7 hours) and medium-term (after 7 to 10 days of continuous treatment) effects of GELCLAIR on symptoms related to the severity of pain on swallowing saliva, eating, and drinking. In the short term a 92% reduction in mean pain scores was observed ($P < 0.005$) in comparison with the baseline measurements.



In the medium term, an overall improvement in pain and discomfort on swallowing food, liquids, and saliva was reported by 87% of patients.



Another prospective, open-label study (De Cordi *et al*)⁷ was conducted in 30 patients receiving chemotherapy for the treatment of cancer of various origins and suffering oral mucositis.

After 3 days of GELCLAIR treatment, 83% of patients reported a reduction in pain, 83% showed distinct improvement in the ability to eat and drink and 57% of patients experienced an improvement in the severity of mucositis.

A third clinical study was conducted in order to compare the efficacy and safety of GELCLAIR with benzydamine, a non-steroidal anti-inflammatory drug (Flook C *et al*).⁸ The control of pain and the management of symptoms associated with radiation-induced mucositis involving the mouth, oropharynx and hypopharynx were evaluated in 61 patients.

It has been demonstrated that fewer patients administered GELCLAIR suffered from severe pain due to speaking or swallowing liquids and foods. Moreover GELCLAIR caused significantly less pain on application as well as a lower need for opiate medication and artificial feeding in comparison with benzydamine.⁸

8. What is the active ingredient of GELCLAIR?

GELCLAIR acts as a mechanical barrier and is classified as a medical device. As such it has no pharmacologically active ingredient.

9. What does GELCLAIR contain?

The key ingredients of GELCLAIR are polyvinylpyrrolidone, hyaluronic acid, and glycyrrhetic acid. Descriptions of these ingredients are provided below.

Polyvinylpyrrolidone

Polyvinylpyrrolidone is a hydrophilic polymer with muco-adherent and film-forming properties, which enhances tissue hydration and has been shown to accelerate wound healing in animal models and in human wounds.

Hyaluronic acid (sodium hyaluronate)

Hyaluronic acid is a naturally occurring viscous polysaccharide that is widely distributed in the body.

In GELCLAIR, hyaluronic acid acts as a film-forming, muco-adherent agent to aid the physical covering of the oral mucosa. In addition, it may enhance tissue hydration.

Glycyrrhetic acid

Glycyrrhetic acid is a breakdown product of glycyrrhizin, the active component of licorice used as a flavouring agent.

The full list of ingredients is as follows:

Purified water, Maltodextrin, Propylene Glycol, Polyvinylpyrrolidone, Sodium Hyaluronate, Potassium Sorbate, Sodium Benzoate, Hydroxyethylcellulose, PEG-40 Hydrogenated Castor Oil, Disodium Edetate, Benzalkonium Chloride, Flavouring, Saccharin Sodium, Glycyrrhetic Acid.





10. Who can use GELCLAIR?

GELCLAIR is registered as a Class III medical device and contains no ingredient that has a direct pharmacological action. GELCLAIR is registered for use in patients of all ages. Children under the age of 6 years may be unable to rinse or gargle; in this situation GELCLAIR can be applied directly.

GELCLAIR is contraindicated in patients with a known history of hypersensitivity to any of the gel ingredients. GELCLAIR is well tolerated and non-toxic if swallowed accidentally.

11. How should GELCLAIR be used?

Treatment with GELCLAIR should be initiated as soon as signs and symptoms of oral lesions appear.

	Pour the entire contents of the single-dose Gelclair® sachet into a glass and add up to 40mL or two tablespoons of water. If water is not available, Gelclair® may be used undiluted.
	Stir mixture and use at once.
	Rinse around 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 – do not swallow, although if accidentally swallowed, no side-effects are anticipated.

Discard any unused mouthwash.

Use at least three times per day or as needed.

It is recommended that the patient does not eat or drink for at least one hour following treatment.

If patients are performing oral care (e.g. brushing teeth), it should be performed prior to using GELCLAIR.

If being treated with other topical agents (analgesic or anti-infective) they should be used before GELCLAIR since the barrier it forms may prevent other topical agents from reaching the oral mucosa.

Store below 25°C. Do not refrigerate.

12. Can GELCLAIR be used during radiotherapy?

GELCLAIR does not contain alcohol or heavy metals and in addition is oxygen-permeable. As a result GELCLAIR is not expected to interfere with radiotherapy.

13. How often can GELCLAIR be applied?

GELCLAIR can be used at least three times daily - usually to coincide with meal times to provide protection during the consumption of food. Studies have demonstrated that the effects of GELCLAIR can be quite long lasting with the optimal benefit being reported as more than 3 hours.⁶ GELCLAIR can however be used as often as required to relieve pain.

14. Can GELCLAIR be used topically? (directly onto the lesion without dilution)

The easiest and most effective method of applying GELCLAIR is by rinsing around the mouth (for at least one minute). However, if the oral lesions are few in number and easily accessible GELCLAIR may also be applied directly to the site of the lesion. It is recommended in these cases that GELCLAIR is applied undiluted with a cotton bud.

15. Can GELCLAIR be diluted and stored for use later?

It is not recommended that unused GELCLAIR is stored for use later. GELCLAIR is supplied in individual single use sachets and should be diluted and used as required with any excess GELCLAIR being discarded after use.

16. Can GELCLAIR be used for oesophagitis?

GELCLAIR is specifically designed to provide protection in the oral cavity and its method of application by rinsing around the mouth is effective in this regard. Whilst it is recommended that patients do try to gargle with the solution it is questionable as to the degree of oesophageal coating that is achieved. It is unknown if GELCLAIR has any effect on oesophageal mucositis.

It is not recommended that GELCLAIR is swallowed following application to the oral cavity.

17. What happens if you swallow GELCLAIR?

There are no anticipated side effects should GELCLAIR be accidentally swallowed. It is recommended that any excess product is discarded once oral rinsing with the product has been completed.

18. Can GELCLAIR be used in conjunction with other treatments?

As GELCLAIR does not contain any active ingredients within the supplied doses it is not anticipated that there will be interactions with any other treatments.

To date there have been no reports of drug interactions between GELCLAIR and other oral care products.

Should the patient be treated with other topical agents (analgesic or anti-infective) they should be used before GELCLAIR since the barrier it forms may prevent other topical agents from reaching the oral mucosa.

19. Can GELCLAIR be used at the same time as other mouthwashes?

GELCLAIR should be used at least an hour apart from other mouth rinses and immediately after oral hygiene.

Oral hygiene is particularly important before and during cancer therapy, and the practice of using dental floss and the use of saline mouth rinses whenever possible is advocated.

20. How much time should be allowed in using GELCLAIR after using antifungal agents?

There is no data to suggest how long you should wait after applying antifungal medications, prior to applying Gelclair. The answer will depend on upon what kind of oral medication is used and how long it takes for it to be absorbed. Most oral care products are absorbed relatively quickly into the oral mucosa, however it is recommended that at least an hour is allowed following the application of antifungal agents before using GELCLAIR.

21. How can patients purchase GELCLAIR?

Out-patients wishing to purchase GELCLAIR are recommended to contact our preferred supplier – ePharmacy who offer an online and telephone ordering service.

In some centres GELCLAIR may also be available for purchase from the out-patients pharmacy and it is recommended that patients check with their own treatment centre.

To order Gelclair:

www.epharmacy.com.au

Phone: 1300 367 283

Fax: 1300 363 879

Mail: ePharmacy
PO BOX 612
Virginia Queensland 4014

Email: info@epharmacy.com.au



For more information about GELCLAIR please contact
ORPHAN AUSTRALIA on:

Tel: (03) 9769 5744 (Office hours)

Or via: info@orphan.com.au

www.gelclair.com.au

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www.orphan.com.au

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