GELX® ORAL SPRAY

Formulary Guide

GALEN

GelX® Oral spray

Indicated for the treatment and prevention of oral mucositis[1]

- Certified medical device
- Ready-to-use oral spray (100ml)
- Spray nozzle applicator to target hard to reach sites affected by oral mucositis

gelX® ORAL SPRAY

1. Introduction[1]

GelX® is a mucoprotectant brand available in a 100ml oral solution spray. GelX® is certified for the prevention and treatment of oral mucositis (OM) and is suitable for use in all ages and all ethnic cultures.

GelX® has a mild orange flavour and can be sprayed directly onto the lesions. The directional nozzle helps to reach all affected sites in the mouth.

GelX® is a member of the following pharmacotherapeutic group: **Mucoprotectants**

Who gets OM?

- Patients undergoing head and neck radiotherapy, stem cell transplantation and chemotherapy are at a high risk of developing OM. GelX® helps to prevent and treat the effects of OM.
- Studies have shown severe mucositis occurring in 29–66% of patients receiving radiation therapy for head and neck cancer. In these studies, the incidence of OM was especially high in patients with primary tumors in the oral cavity, oropharynx or nasopharynx; those who also received concomitant chemotherapy; those who received a total dose over 5000 cGy, and those treated with altered fractionation radiation schedules.[3]
- For patients receiving high-dose chemotherapy prior to haematopoietic cell transplantation, OM has been reported to be the single most debilitating complication of transplantation.[3]

2. How does it work?[4,5]

Mode of Action

Biomechanical Benefits:

- Provides a bio adhesive barrier for durable protection
- Blocks exposed nerve endings and coats oral lesions to soothe and relieve pain
- Protects ulcerated tissue from further injury and bacterial colonisation

Anti-inflammatory Advantage:

- Adheres to mucosal surface and delivers a bioactive zinc-taurine complex
- Releases bioactive zinc-taurine complex into epithelial cells
- The combined anti-inflammatory properties of zinc and taurine have demonstrated a synergistic biological effect in vitro by regulating COX-2 mediated prostaglandins and inflammatory cytokines

Ingredients

Polyvinylpyrrolidone PVP, a polymer:

- High molecular weight polymer
- Coating and encapsulation of tissues
- Provides a film that is permeable to water

Zinc Gluconate, a mineral salt and Taurine, an amino sulfonic acid:

- Forms a bioactive zinc-taurine complex under physiological conditions
- Provides excellent bacteriostatic qualities without cyto-toxicity seen in other preservative systems
- Effective in addressing mineral deficiency and inflammatory processes associated with oral pain and discomfort
- Found to exert anti-microbial, anti-inflammatory, free radical scavenging, and analgesic effects
- Delays onset of mucositis by inhibiting inflammatory cycle, pain relief through inhibition of COX-2 mediated prostaglandins

GelX® Dosing

3 sprays, 3 times a day

3. Clinical Efficacy

Colita et al, 2015[6]

The Efficacy of Polyvinylpyrrolidone-Zinc Gluconate and Taurine Gel (GelX®) in Prophylaxis and Treatment of Oral Mucositis in Children Treated with Chemotherapy.

This study was set up to evaluate the efficacy of polyvinylpyrrolidone-zn gluconate and taurine as prophylactic or curative treatment for children treated with chemotherapy for haematologic malignant diseases.

This was a single centre prospective and observational study in children with acute leukaemia receiving chemotherapy.

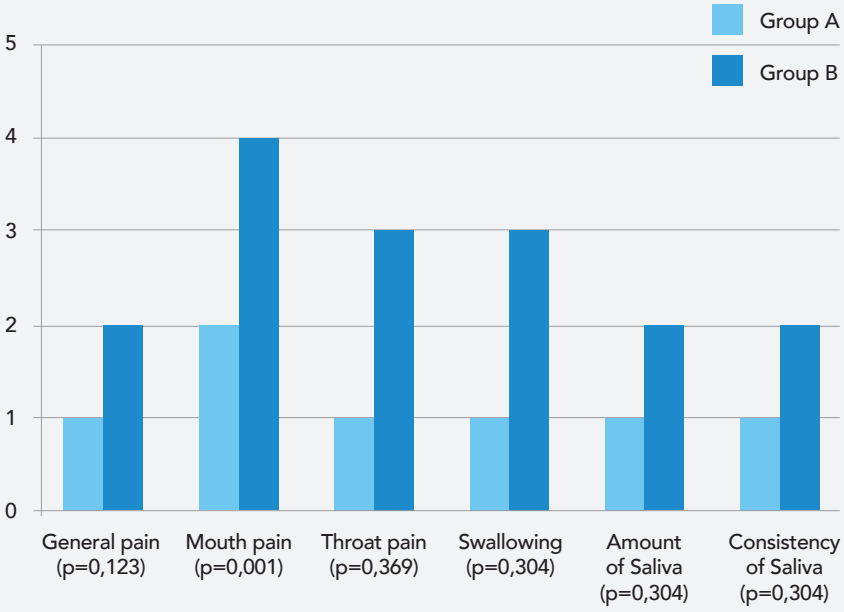
The assessment of OM was done based on the WHO grading as follows 0= absent, 1= soreness and/or erythema, 2= erythema, ulcers and patient can swallow solid food 3= ulcers with extensive erythema and patient cannot swallow food 4= mucositis to the extent that alimentation is not possible.

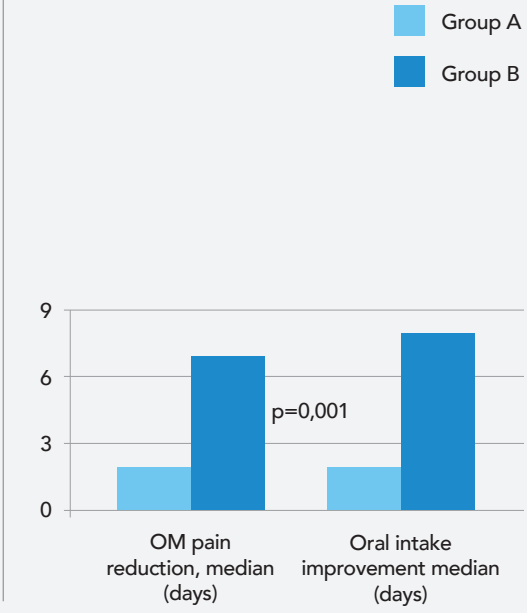
Patient population was in 2 treatment arms Group A Prophylactic arm (8 patients) and Group B Curative arm (7 patients).

Results

GelX® Oral Spray was administered prophylactically or as a curative in this study. The OM maximum grade was higher in the curative group than in the prophylactic group (p=0.018). The patient/parent assessment of mouth pain (p=0.01) and of saliva consistency (p=0.033) were significantly lower in the prophylactic group. There was a significant difference in OM pain reduction (p=0.001), oral intake improvement (p=0.001) and use of systemic analgesics (p=0. 005) in the prophylactic arm.

Median VAS scale assessment of patient for pain and saliva





Conclusions

There was no difference in the median value of tolerability of GelX® between the 2 groups. In the prophylaxis arm, there was a significant reduction of OM severity with better results in quality of life, pain control and oral intake.

3. Clinical Efficacy

Niculita et al, 2020[7]

The Efficacy of Polyvinylpyrrolidone-Zn Gluconate and Taurine (GelX) in the prevention of Oral Mucositis in Haematological Patients.

The study evaluated the results of polyvinylpyrrolidone-zn gluconate and taurine (GelX®) in haematology patients. This was a single centre observational retrospective study analysing 145 patients altogether made up of 99 adults and 46 paediatric patients.

The inclusion criteria consisted of male and female patients aged 2 or older who used GelX® Oral Spray at least once per day during their treatment and had their mucous membranes evaluated during treatment. All patients received GelX® Oral Spray as prophylaxis for OM.

The exclusion criteria consisted of patients who participated in a therapeutic trial on OM in the same period, patients who had active viral, bacterial or fungal infections of the mouth. Patients considered unable to perform oral application of GelX® Oral Spray were also excluded.

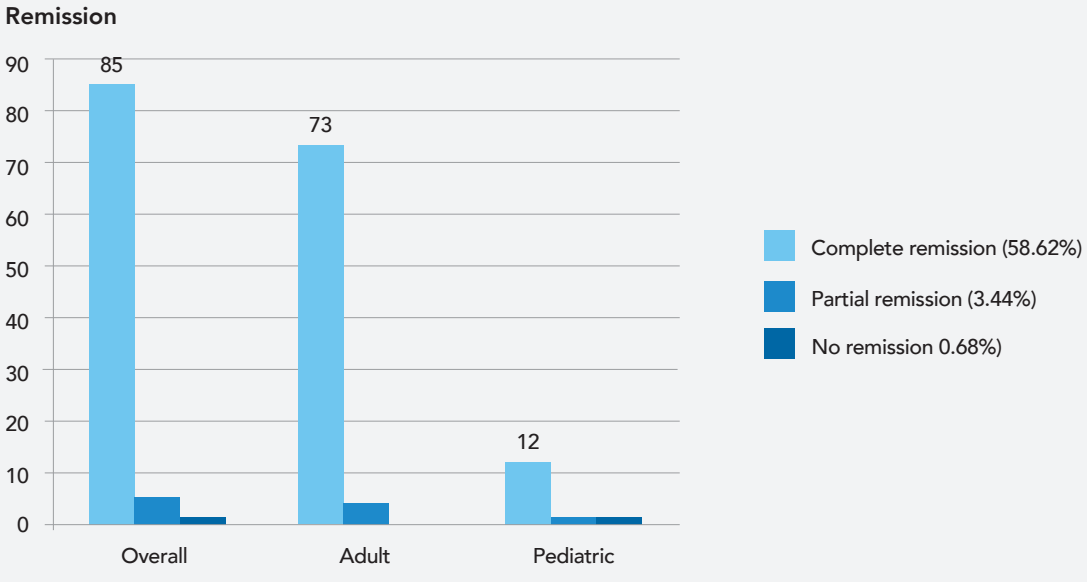
Results

Data was collected from 145 patients made up of 99 adults (68.27%) and 46 children (31.72%) with a female/male sex ratio of 1.15 in adults and 1.09 in paediatric patients. The median age for adult patients was 46 years (range 22-71) and 6 years of age (range of 2-17) for paediatric patients.

The patients' primary diagnosis was leukaemia in 62 patients followed by multiple myeloma (40 patients), lymphoma (37 patients), severe aplastic anaemia (2 patients) as well as sarcoma, neuroblastoma, myelodysplastic syndrome and primary systemic amyloidosis all with 1 patient in each of these categories.

All 145 patients received GelX® Oral Spray for preventing OM. The mean duration of applications was 24 days in the total population, 23 days in adults and 26.5 days in paediatric patients. GelX® Oral Spray was applied 3, 4 or 6 times a day with adults applying one spray and paediatric patients using 2 sprays per application.

Figure 1: GelX® Oral Spray induced a significant remission of OM symptoms



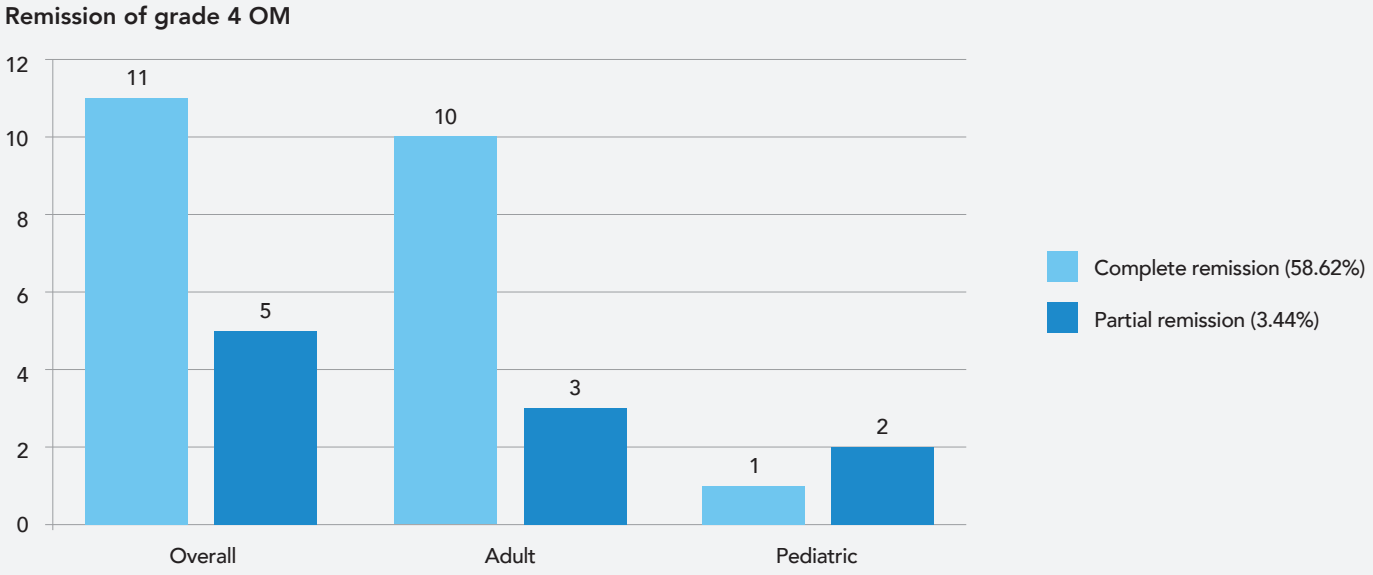
The prevention of OM was achieved in 54 patients (37.24%) [22 adults, 32 children] where patients developed no OM at all. In the remaining 91 patients 93.4% had a complete remission of their OM symptoms (85 patients) and a reduction of OM grade (partial remission) was reached in 5 patients (5.49%). Only one patient had no remission reported. No worsening of OM was reported.

The median duration of OM symptoms from first application to remission was 12 days, as below in figure 2 which was one of the primary endpoints.

A total of 52 patients (40 adults and 12 children) developed severe OM (classed as grade 3 or 4). Grade 4 developed in 16 patients, 11 of them achieved a complete remission (10 adults and 1 child) while 5 patients (3 adults and 2 children) achieved a partial remission of their OM (see figure 2 below).

This study supports prophylactic use of GelX® Oral Spray to minimise the risk of OM secondary to chemo/radiation therapy. 37% of patients did not go on to develop any OM symptoms during their course of treatment. The median duration of OM symptoms in patients treated with GelX® Oral Spray from first application to remission was 12 days. 93.4% of the patients who developed symptoms of OM had a complete remission of symptoms.

Figure 2: GelX® Oral Spray induced a significant improvement of OM symptoms in patients developing Grade 4 OM.



Conclusions

GelX® Oral Spray actively prevented OM and induced a significant remission of OM in patients that already showed OM symptoms. The percentage of patients that showed prevention or remission of OM after receiving GelX® Oral Spray was 99.3% of the total cohort.

No patient had to interrupt their cancer therapy due to OM. There were no adverse events considered related to the use of the product. This retrospective study suggests prophylactic use of GelX® Oral Spray to minimise the risk of OM secondary to cancer therapy.

3. Clinical Efficacy

Dragomir et al, 2015[8]

GelX® Oral Spray in Prevention and Treatment of Chemotherapy-induced Oral Mucositis in Children with Cancer.

This was a single centre, open-label safety and efficacy study aimed at assessing the effectiveness of GelX® Oral Spray in the treatment of OM in children with malignancies treated with high-risk mucotoxic chemotherapy.

Fifteen patients aged between 5 and 16 years old were included who developed severe mucositis (Grade 3 WHO scale) with concomitant neutropenia after the first cycles (1-2) of standard chemotherapy.

GelX® Oral Spray was administered in addition to other therapeutic interventions starting with the early-stage of mucositis for a period of 2 weeks in each chemotherapy cycle and for 4-6 chemotherapy cycles/patient (total 60 cycles).

The grade of OM was evaluated by WHO scale, pain, swallowing and eating difficulty during each chemotherapy cycle, comparing with mucositis symptoms from previous cycles treated with the same therapeutic measures but without GelX® Oral Spray.

Results

Pain was reduced in 80% of patients after the treatment with GelX® Oral Spray. Swallowing difficulties were reduced in 74% of patients, regular feeding with solid food and fluids was not affected during chemotherapy in 12/15 patients and 46 out of 60 cycles, while swallowing difficulties for solid food was recorded only for 3/15 patients for a short period of 2-3 days for 14 out of 60 chemotherapy cycles

Figure 3: Scale of oral mucositis before and after treatment with GelX® Oral Spray

Diagnosis	Ewing Sarcoma (6 patients)		Osteosarcoma (5 patients)		Non-Hodgkin lymphoma (4 patients)		Total (15 patients)	
Cycle of chemotherapy	24		20		16		60	
Oral toxicity	Before GelX	After GelX	Before GelX	After GelX	Before GelX	After GelX	Before GelX	After GelX
Oral toxicity - G1	5	12	3	10	2	6	10 (6%)	28 (47%)
Oral toxicity - G2	11	7	11	6	8	6	30 (50%)	19 (33%)
Oral toxicity - G3	8	5	6	4	6	4	29 (44%)	13 (20%)
Oral toxicity - G4	-	-	-	-	-	-	-	-

Conclusions

Overall with GelX® Oral Spray treatment, the severity of OM was improved, duration of mucositis was shorter, swallowing and eating difficulties were reduced, pain was reduced, there were no delays in treatment caused by severity of OM and no complications related to neutropenia occurred. It was concluded that GelX® Oral Spray prevents severe mucositis and promotes healing and that it is a fast and long-lasting remover of pain caused by OM during high-risk chemotherapy in children with cancer.

Zannier et al, 2019[9]

Effects of Three Products in the Prevention and Treatment of Chemotherapy and Radiation Therapy-induced Oral Mucositis.

The authors carried out a study to evaluate the impact of three different products on OM outcomes of patients who received radio and chemotherapy in solid cancer. Sixty adult patients were randomised into 3 arms, balanced for tumour site and treatment, to receive either GelX® Oral Spray (Group 1), Episil Oral Solution (Group 2) or Gelclair Oral Gel (Group 3).

The primary aim of the study was evaluation of OM onset, severity, reduction or remission and pain relief with the three treatments. Data were analysed from forms completed by patients at baseline and after 16 weeks, and from forms completed by clinicians after 4 weeks and 8 weeks. The patient's safety profile form included 10 items concerning difficulty of speaking, feeding, drinking and change of taste.

Results

The study showed a significant difference among the 3 groups. OM grade of Group 2 after 4 weeks was higher when compared with Group 1 and Group 3. After 4 weeks two cases of grade 4 mucositis had developed in Group 2 compared to none in Group 1 and Group 3. The GelX® Oral Spray group demonstrated an overall better efficacy and grade of safety compared to the other two groups. It was concluded that the study shows how the correct use of anti-mucositis products (accompanied by an appropriate hygienic and dietetic regimen) seems to be effective in the prevention of OM, which is one of the most frequent side effects in patients undergoing chemotherapy.

Safety Data for GelX® Oral Spray

There have been no reported adverse events relating to GelX® Oral Spray use (correct as of June 2022).

The study conducted by Niculita (2020) has reported that there were no adverse events relating to use of GelX® Oral Spray in any of the study participants.

The Zannier (2019) study assessed patient safety as part of the study. They have reported that the patients in the GelX® Oral Spray arm demonstrated an overall better efficacy and grade of safety when compared to the oral mucositis treatments used in the other groups.

4. Cost

Product	List Price[2]	Recommended Dose	Monthly Cost	Daily Cost
GelX® Oral Spray 100ml	£49.21	3 sprays 3 times per day	£49.21	£1.64
Caphosol 32 Doses	£34.28	1 Dose 4-10 times daily	£128.70 - £321.30	£4.29 - £10.71
Caphosol 128 doses	£130.70	1 Dose 4-10 times daily	£122.40 - £306.30	£4.08 - £10.21
Gelclair 21 Sachets	£35.62	3 sachets per day	£152.70	£5.09

Monthly Cost is based on 30 days

Ordering

For ordering enquires, please contact customer.services@galen-pharma.com

Name	Item	Pack	PIP Code
GelX® Oral Spray	100ml	1	413-6198

References

1. GelX® Oral Spray Data Sheet
2. MIMS Online. Accessed August 2023
3. Lalla, R. et al. "Management of oral mucositis in patients with cancer." Dental clinics of North America vol. 52,1 (2008): 61-77, doi:10.1016/j.cden.2007.10.002 Available from: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2266835 [Accessed August 2023]
4. https://gelxus.com/hcp/why-gelx [Accessed August 2023]
5. Data on File. Galen Ltd
6. Colita A. et al. Single center, open-label safety and efficacy. "The efficacy of PVP – zinc gluconate and taurine gel (GelX) in prophylaxis and treatment of oral Mucositis in children treated with chemotherapy" 15 patients GelX Oral Spray, Poster at EHA June 2015, Vienna.
7. Niculita O. et al. The efficacy of Polyvynilpyrrolidone-Zn Gluconate and Taurine in the Prevention of Oral Mucositis in Haematological Patients. Rev. Chim., 71 (8), 2020, 195-205
8. Dragomir M. Single center, open-label safety and efficacy ongoing study. "Prevention and treatment of Chemotherapy-Induced Oral Mucositis in children with cancer"; 15 patients treated with GelX Oral spray; poster presented at the ECCO Congress Sep 2015, Vienna.
9. Zannier F et al. Effects of three products in the prevention and treatment of chemotherapy and radiation therapy-induced oral mucositis. Annals of Oncology annual conference. Submitted Abstracts Basic Science. Volume 30, Supplement 5, v20, October 01, 2019.

Adverse Incidents should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard.

Adverse incidents should also be reported to Galen Limited on 028 3833 4974 and select the customer services option, or email customer.services@galen-pharma.com. Medical information enquiries should also be directed to Galen Limited.

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