Glycerol

Essential medicine status

Section: 13. Dermatological medicines > 13.6. Dermatological medicines > Moisturizers

EMLc | ATC codes: Pending

Indication	Atopic eczema ICD11 code: EA80
INN	Glycerol
Medicine type	Chemical agent
List type	Core (EML) (EMLc)
Formulations	Local > Topical > Cream: 15 to 20%
EML status history	First added in 2025 (TRS 1064)
Sex	All
Age	Also recommended for children
Therapeutic alternatives	The recommendation is for this specific medicine
Patent information	Patents have expired in most jurisdictions Read more about patents.
Wikipedia	Glycerol
DrugBank	Glycerol (Glycerin)

Expert Committee recommendation

The Expert Committee acknowledged the substantial public health burden of atopic dermatitis, its particularly high prevalence in children, and its effects on skin integrity and quality of life. The Committee also noted the challenges faced in many resource-constrained settings to provide affordable access to therapeutic moisturizing agents for the treatment of atopic dermatitis and prevention of symptom worsening and disease flares. The Committee recognized that regular use of therapeutic moisturizers helps maintain skin barrier function, reduces dryness and irritation, and can prevent exacerbations of atopic dermatitis, thereby improving overall disease control. The Committee noted the availability of many different moisturizing products, variably regulated as therapeutics or cosmetics, and recognized the need to prioritize the most effective, best tolerated and affordable therapeutic options. The Committee considered that the rationale used by the applicants to prioritize the proposed glycerol- and urea-based moisturizers was sufficiently robust and evidence-based. The Committee considered evidence from multiple systematic reviews that support the efficacy and safety of topical moisturizers, generally, in the treatment of atopic dermatitis. In consideration of glycerol- and urea-based moisturizers, some evidence suggests that these were associated with improvements in disease severity and prevention of flare-ups. However, the Committee noted that the quality of evidence varied and that the magnitude of clinical benefit was modest in some analyses. The safety profile of glycerol- and urea-based moisturizers was considered favourable. Adverse effects were generally mild and transient. Urea-containing moisturizers were associated with a slightly higher frequency of local reactions compared with glycerol-containing moisturizers, but both were safe for long-term use. The Committee noted that while cost–effectiveness data were not provided, the estimated annual treatment costs were considered a reasonable indicator of feasibility of implementation in national programmes and sufficient to support the decision making. However, affordability remains a challenge in many resource-constrained settings, particularly where moisturizers are imported and taxed as cosmetics. The Committee emphasized the importance of local production and regulatory classification as medicinal products to improve access and affordability. The Committee noted and appreciated the contributions submitted during the public consultation process for the application, indicating support for the proposal to include glycerol- and urea-based moisturizers on the Model Lists. The Expert

Committee therefore recommended the inclusion of glycerol- and urea-based moisturizing creams on the EML and EMLc for the treatment of atopic dermatitis based on evidence of benefit, acceptable safety and public health need. Recommended formulations are creams containing 15% to 20% glycerol and creams containing 5% urea and with regulatory approval as emollients. The Committee emphasized the importance of ensuring access to affordable, quality-assured therapeutic moisturizers as part of comprehensive management of atopic dermatitis, particularly in resource-constrained settings. Any future applications for inclusion of new therapeutic moisturizers should consider glycerol- and urea-based formulations as the standard comparator, given their established efficacy, safety, and affordability profile.

Background

Urea (10% cream and ointment) was added to the EML in 1995 and to the EMLc in 2007 as a keratolytic agent (1, 2). A 5% strength was added in 2011 (3). Glycerol-based topical moisturizers have not previously been considered for inclusion on the Model Lists as topical moisturizers.

Public health relevance

According to the Global Burden of Disease Study, 171 million individuals were affected with atopic dermatitis in 2019, with age-standardized prevalence and incidence rates that were relatively stable from 1990 to 2019. Prevalence rates show some regional trends, with the highest prevalence reported in the Asian Pacific and Central Asian regions, and the lowest prevalence reported in the African region (4). Individuals with atopic dermatitis have a reduced quality of life (5–8), where the stigma associated with its visibility and itch affects sufferers (9, 10). Sleeplessness may lead to poor work functioning and decreased skills (11), school absenteeism and lower learning outcomes in children (12). Untreated atopic dermatitis can be associated with secondary skin and systemic infections (13). Furthermore, eczema is a time-consuming and costly disease to treat (6), similar to the costs of other chronic diseases (14).

Benefits

The application identified seven systematic reviews published between 2015 and 2023 that evaluated the effectiveness and safety of topical moisturizers (15–21). Findings from a 2017 Cochrane systematic review of 77 randomized controlled trials (6603 participants) that evaluated the effects of moisturizers for the treatment of eczema are summarized below (17). The other systematic reviews identified in the application were either published before the Cochrane review or did not report outcomes specifically for glycerol- and urea-based moisturizers. All reviews provided evidence of the beneficial effects of moisturizers generally in the treatment of atopic dermatitis. For the comparison of moisturizers versus no moisturizer, there was low-certainty evidence that moisturizer use was effective in reducing disease severity compared with no moisturizers as assessed using Scoring Atopic Dermatitis (SCORAD) scores (mean difference (MD) −2.42, 95% confidence interval (CI) −4.55 to −0.28; three randomized controlled trials, 276 participants). However, the minimal important difference in SCORAD score (8.7) was not met. For the comparison of all moisturizers versus vehicle, placebo or no moisturizer, there was high-certainty evidence that moisturizers were associated with reduced investigator-assessed disease severity from baseline (standardized MD (SMD) −1.04, 95% CI −1.57 to −0.51; 12 randomized controlled trials, 1281 participants), and moderate-certainty evidence of a reduced risk of eczema flare-ups (risk ratio (RR) 0.33, 95% CI 0.17 to 0.62; six randomized controlled trials, 607 participants). There was low-certainty evidence that moisturizers were associated with lower participant-assessed disease severity (RR 2.46, 95% CI 1.16 to 5.23; five randomized controlled trials, 572 participants), and that moisturizer use was associated with patient-assessed benefit in terms of reduced itch (SMD −1.10, 95% CI −1.83 to −0.38; seven randomized controlled trials, 749 participants). There was low-certainty evidence of no significant differences between treatment groups for patient satisfaction (RR 1.35, 95% CI 0.77 to 2.26; three randomized controlled trials, 296 participants). For the comparison of urea-containing moisturizer versus vehicle, placebo or no moisturizer, there was moderate-certainty evidence of improvement in disease severity as assessed by investigators favouring urea-containing moisturizers (RR 1.40, 95% CI 1.14 to 1.71; one randomized controlled trial, 129 participants). There was low-certainty evidence of improvement in disease severity as assessed by participants favouring urea-containing moisturizers (RR 1.28, 95% CI 1.06 to 1.53; one randomized controlled trial, 129 participants). There was also low-certainty evidence that fewer participants using urea-containing moisturizers experienced a disease flare-up (RR 0.47, 95% CI 0.24 to 0.92; one randomized controlled trial, 44 participants). For the comparison of glycerol-containing moisturizer versus vehicle or placebo, there was high-certainty evidence of improvement in disease severity as assessed by investigators using SCORAD favouring glycerol-containing moisturizer (MD −2.2,

95% CI −3.4 to −0.96; one randomized controlled trial, 249 participants), however, the minimal important difference was not met. There was moderate-certainty evidence of improvement in disease severity as assessed by participants favouring glycerol-containing moisturizers (RR 1.22, 95% CI 1.01 to 1.48; one randomized controlled trial, 134 participants). For the comparison of topical active treatment (corticosteroids or calcineurin inhibitors) plus moisturizer versus moisturizer alone, there was moderate-certainty evidence of improvement in disease severity as assessed by investigators using SCORAD favouring combination treatment (MD −0.87, 95% CI −1.17 to −0.57; three randomized controlled trials, 192 participants) and low-certainty evidence of fewer flare-up (RR 0.43, 95%CI 0.20 to 0.93; one randomized controlled trial, 105 participants).

Harms

In the 2017 Cochrane systematic review, for the comparison of all moisturizers versus vehicle, placebo or no moisturizer, there was moderate-certainty evidence of no significant difference between treatment groups in the number of participants experiencing adverse events (RR 1.03, 95% CI 0.82 to 1.30; 10 randomized controlled trials, 1275 participants). For the comparison of urea-containing moisturizers versus vehicle, placebo or no moisturizer, there was moderate-certainty evidence of an increased risk of adverse events in participants using urea-containing moisturizer (RR 1.65, 95% CI 1.16 to 2.34; one randomized controlled trial, 129 participants). For the comparison of glycerol-containing moisturizers versus vehicle or placebo, there was moderate-certainty evidence of no significant difference between treatment groups in the number of participants experiencing adverse events (RR 0.90, 95% CI 0.68 to 1.19; two randomized controlled trials, 385 participants) (17). Moisturizers are generally safe with a favourable safety profile. The most common adverse effects are mild and transient skin reactions, such as stinging, itching and redness. These reactions are more likely to occur in patients with impaired skin barrier function, such as those with atopic dermatitis. Urea-containing creams may cause more frequent adverse events compared with other moisturizers, but these are typically mild and temporary.

Cost / cost effectiveness

No cost–effectiveness evidence was presented in the application. The application estimated formulation, packaging and production costs for the proposed moisturizers of around 25–50 euros (€) per year for adults and €18–36 per year for children, assuming use of about 70–140 g/week in adults and of 50–100 g/week in children. The application reported that in many resource-limited settings, moisturizing creams are available as imported, over-the-counter cosmetic products and are subject to high taxation, making them unaffordable for many patients.

WHO guidelines

WHO guidelines for the treatment of atopic dermatitis are not currently available. Various regional treatment recommendations and national and international guidelines include recommendations for the use of moisturizers as first-line treatment for atopic dermatitis in adults and children (8,21-23).

Availability

The application reports that the proposed moisturizers are authorized as medicinal products in several European countries, and pharmacopeial standards for glycerol and urea are available. Topical urea formulations are already included on national essential medicines lists of more than 30 countries. One commercial brand of glycerol 15% cream was reported in the application to be available in 32 countries.

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