VI.2 Elements for a Public Summary

VI.2.1 Overview of disease epidemiology

Otic eczema

Skin diseases may predispose to the development of external otitis infections, but can by themselves produce an inflammation in the ear canal. Some topical and systemic dermatological disorders can affect the external ear canal which is known as otic eczema.

Among the systemic diseases that can cause otic eczema there are seborrheic dermatitis, atopic dermatitis, psoriasis or acne, however the most prevalent local disease is the contact dermatitis. Pruritus is the primary symptom for most of these pathologies. The most common dermatological sign is scaling, that can become chronic and produce lichenification affecting the entire pinna.

The cause of the eczematous reaction is unknown, and is often associated in the same patient with allergic rhinitis and bronchial asthma.

An effective treatment for the pruritus and scaling of the external ear canal is the corticosteroid ointment.

VI.2.2 Summary of treatment benefits

Fluocinolone Acetonide is a corticosteroid primarily used in dermatology to reduce skin inflammation and relieve itching, which works by inhibiting the chemicals that cause inflammation and swelling. This drug may help relieve symptoms like scaling, crusting, and dryness, as well as itching and inflammation.

One clinical study has been sponsored by SALVAT in otic eczema. In this study, the clinical efficacy and safety of Fluocinolone Acetonide 250 µg/ml ear drops solution compared with placebo in the treatment of otic eczema were assessed by otoscopic examinations, evaluation on change in itching at end of treatment (mean itching on days 4-8 compared to baseline), and adverse events.

A total of 135 patients aged 18 years or older were included and treated with either Fluocinolone Acetonide 250 µg/ml ear drops solution (n=66) or Placebo (n=69). The full content of the vial was to be instilled in the affected ear canal(s) for 7 consecutive days, twice a day.

Clinical efficacy was superior to that observed with placebo.
Fluocinolone Acetonide 0.025 otic solution was well tolerated when administered topically to adults with otic eczema. The most common adverse events appeared during the study were ear discomfort (5 patients in each treatment group) and otitis externa (5 patients in the Placebo group).

VI.2.3 Unknowns relating to treatment benefits

Children

The use of Fluocinolone Acetonide 250 µg/ml ear drops solution is not recommended in children as clinical data are limited.

Pregnancy

There are no adequate and well-controlled studies in pregnant women with Fluocinolone Acetonide. Therefore, Fluocinolone Acetonide should be used with caution during pregnancy.

VI.2.4 Summary of safety concerns

Important identified risks

Risk	**What is known**	**Preventability**
WORSENING INFECTION (BACTERIAL OR FUNGAL OR VIRAL INFECTIONS)	Infection has been observed rarely (≥1/10,000 to <1/1,000)	If concomitant skin infections are present or develop, an appropriate antifungal or antibacterial agent should be used. If a favorable response does not occur promptly, use of this product should be discontinued until the infection has been adequately controlled.

Important potential risks

HYPOTHALAMIC-PITUITARY-ADRENAL AXIS SUPPRESSION	It is a class effect. Hypothalamic-pituitary-adrenal (HPA) axis is a complex set of direct influences and feedback interactions among three endocrine glands: the hypothalamus, the pituitary gland (a pea-shaped structure located below the hypothalamus), and the adrenal (also called "suprarenal") glands (small, conical organs on top of the kidneys that produce the hormone cortisol). A suppression of HPA axis could result in reduced cortisol response that may cause an impaired stress response and an inadequate host defense against infections. Reversible (HPA axis suppression has occurred in some patients receiving topical corticosteroid at total doses higher than 2 g (approx 1000 folds the highest dose of Fluocinolone Acetonide). However, no HPA axis suppression has been described after otically administered corticosteroids. Considering the low total dose after a treatment with Fluocinolone Acetonide 250 µg/ml ear drops solution, it is unlikely that the systemic exposure of this drug could lead to measurable changes in cortisol levels.	If HPA axis suppression is noted, an attempt should be made to withdraw the drug, to reduce the frequency of application, or to substitute a less potent steroid. Recovery of HPA axis function is generally prompt upon discontinuation of topical corticosteroids. Infrequently, signs and symptoms of glucocorticosteroid insufficiency may occur requiring supplemental systemic corticosteroids.

Missing information

Risk	What is known
Paediatric patients	Children may absorb proportionally larger amounts of topical corticosteroids and thus be more susceptible to systemic toxicity. No data are available in paediatric patients.
Pregnancy	There are no adequate and well-controlled studies in pregnant women with Fluocinolone Acetonide. Therefore, Fluocinolone Acetonide should be used with caution during pregnancy.

VI.2.5 Summary of risk minimisation measures by safety concern

Not applicable.

No additional risk minimisation measures by safety concern are planned.

VI.2.6 Planned post authorisation development plan

No post authorisation studies are planned to be conducted.

VI.2.7 Summary of changes to the Risk Management Plan over time

No changes to the risk management plan over time are anticipated.