





## FORMULATION OF KETAMINE 1% AND AMITRIPTYLINE 1% GEL IN PRURITIC EPIDERMOLYSIS BULLOSA: A CASE REPORT

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## Background

**Epidermolysis bullosa** (**EB**) is a group of rare genetic diseases characterized by **fragility of the skin**, resulting in **painful and itchy blisters**. Although there is no curative treatment for EB, some measures may help to relieve symptoms.

## **Aim and objectives**

## To describe an EB clinical case and evaluate the effectiveness and tolerance of a ketamine and amitriptyline formula.

To develop and validate a topical ketamine and amitriptyline gel (KAG).

Material and methods

A 29-year-old woman with dystrophic pruritic EB in her lower extremities since she was 3. She was previously treated with

methotrexate, oral and topical corticosteroids and cyclosporine. Due to the adverse effects of oral therapy, Dermathology

requested a topical formulation of ketamine and amitriptyline.

A literature research on the efficacy, safety and composition of the formula was conducted. A ketamine 1% with amitriptyline

1% gel was developed and the physical and organoleptic characteristics were analyzed at 0, 14, 28 and 42 days. Clinical follow-

up was carried out during Pharmacy and Dermatology visits to assess the response to the treatment



The literature reported several cases of KAG at different concentrations for treating chronic pruritus and EB. The off-label use

was approved by the Medicines in special situations local Committee.



From the treatment's beginning, the patient showed improvement of the pruritus, good tolerance and satisfaction. After six

weeks, she is ongoing with KAG and applies it every 3 hours.

**Conclusion and relevance** 

In our patient, topical KAG is an effective and safe alternative to consider in the EB treatment. The medium-long term effects will

be assessed through follow-up. During the studied period, the formula developed maintains physical stability.

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