Effectiveness of 3% Topical Imiquimod in Off-label Use for Oral Florida Papillomatosis: A Case Report

L Rendón de Lope*, P Ruiz Huertas, C Donoso-Rengifo, M Murillo Izquierdo, C Castillo Martin, J Cordero Ramos, MD Añorada Fernandez, M Fernandez Gonzalez, ML Moya Martin, Hospital Universitario Virgen Macarena, Pharmacy, Seville, Spain; Hospital Universitario Virgen Macarena, Oral and Maxillofacial Surgery, Seville, Spain

Background. Imiquimod is an immunomodulator, with antitumour activity, indicated for the treatment of genital and perianal warts produced by the human papilloma virus (HPV), actinic keratosis and basal cell carcinoma.

Purpose. Description of a clinical case of papillomatosis (POF) treated with topical imiquimod at 3% in a patient with numerous recurrences after failure of surgical treatment: a 74 years-old woman, diagnosed with POF in 2008, intervened in 2010, presenting numerous recurrences due to non-responses to treatment. In 2011, verrucous carcinoma and proliferative verrucous hyperplasia were detected in biopsy, and it was again intervened for extirpation in 2017 and 2018. After an exhaustive literature review, it was decided to start treatment with 3% topical imiquimod.

Material and methods. The elaboration was carried out using an oral adhesive excipient to prolong the permanence of the drug in oral mucosa and reduce the adverse effects on healthy skin areas, and also liquid petrolatum to increase the interposition between the drug and the excipient. A whitish paste, easy to apply, was obtained. The posology was one application at night, 3 days per week, resting at weekends. Each application assumes a dose of approximately 0.01 g of imiquimod (340 mg of preparation). Hyaluronic acid gel was added in order to reduce the adverse effects of imiquimod on healthy perilesional mucosa.

Results. During the first two weeks of treatment, the patient presented a decrease in the volume of the lesions. After 8 weeks of treatment, the patient presented good tolerance, without adverse reactions or complications, and reduction of lesions. After 16 weeks of treatment, the papillomatosus lesions of the floor of the mouth and lingual tip had disappeared, and a small lesion remained in the lower lip. Currently the patient does not present apparent symptoms, waiting for the result of the biopsy.

Conclusion. The clinical evolution of the patient suggests that the oral application of imiquimod 3% is safe and well tolerated, being effective in the treatment of POF and thus avoiding repeated surgical interventions. In addition, its preparation is associated with a reduced number of lesions and less evidence of pruritus. The case was refractory to all on-label available therapies and has been prescribed topical cidofovir.

Material and methods. Bibliographic research.

Prescription submission for approval of the ethics committee for health and clinical board of the hospital.

Elaboration of master formula sheet and parameterisation of labelling information.

Clinical evaluation and photographic register.

Results. Numerous studies substantiate the prescription, which led to its approval by the referred hospital boards. Cidofovir 3% cream was compounded from injectable cidofovir (vistidine) and incorporated into commercially available fat cream (lipolium). Due to cidofovir’s mutagenic properties and its associated risk by exposure, this preparation was performed with proper protection equipment and using the luer-lock system (syringes and connectors). After 3 months of treatment, topical cidofovir proved to be effective, as the patient presented with a reduced number of lesions and less evidence of pruritus. He referred no symptoms of local irritation (the most reported adverse reaction).

Conclusion. Off-label therapeutic options should be reserved only in specific cases. However, as long as there are no topical options available, compounding pharmacists can be essential in providing an effective and safe formulation. Operator’s safety should not be neglected, and the preparation must be carried out with appropriate precautions/protection equipment.

It should be noted that the success of this treatment required the commitment of a multidisciplinary team, with consequent improvement in patient’s life quality.

References and/or acknowledgements.

To be presented on poster.

No conflict of interest.

Feedback from a Feasibility Study of Allergy Test Preparations in Day Hospitalisation

A Leleux*, S Tombelle, F Danicourt. Dunkerque Hospital Center, Pharmacy, Dunkerque, France

Background. As part of the investigation of anaphylaxis, it is recommended that allergy testing (ATs) be performed in day hospital, because of the anaphylactic risk requiring special hospital surveillance. Skin tests (SKs) and oral provocation tests (OPTs) are currently performed in our hospital in...