EFFECTIVENESS OF 3% TOPICAL IMIQUIMOD IN OFF-LABEL USE FOR ORAL FLORA PAPILLOMATOSIS: A CASE REPORT

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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 papillomatous 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. 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

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 with oral adhesive excipient and its nocturnal application favour the permanence of the drug in the affected area, ensuring the pharmacological effect.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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TOPICAL CIDOFOVIR COMPOUNDING CREAM FOR THE TREATMENT OF DISSEMINATED INFECTION BY MOLLUSCUM CONTAGIOSUM

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Background Cidofovir is a broad-spectrum antiviral agent with activity against several DNA viruses. In Portugal, it has to be imported but it has European Medicines Agency’s approval to treat cytomegalovirus retinitis in specific patient conditions.

A sixty-eight-year-old male patient, diagnosed with disseminated infection by molluscum contagiosum, with idiopathic acquired immunodeficiency CD4+ t-cells and pulmonary cryptococcosis treated three years ago, presented with severe erythroderma. He exhibited countless cutaneous lesions, characterised by severe pruritic millimetre papules which affected the majority of his body, impairing his life quality. The case was refractory to all on-label available therapies and has been described topical cidofovir.

Purpose To share procedures followed after the prescription of a new off-label compounded drug: information research and development of specific procedures for this type of hazardous formulation.

Evaluation of treatment effectiveness, 3 months after the topical cidofovir application in the lower right member.

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.

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