

samples. An important increase in the number of isoforms even with changes in their masses, including the main isoform, was detected.

**Conclusion and relevance** Exposure to light may cause modifications in the nivolumab isoform profile which suggests protein degradation. This work shows the importance of protecting opened vials of the medicine Opdivo from light (and by extension, bags for infusion) when they are at room temperature (up to 25°C).

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3PC-066

#### COMPOUNDING AN EYE DROP FORMULATION OF TOPICAL INSULIN FOR CORNEAL DEFECTS REFRACTORY TO PREVIOUS TREATMENT: EXPERIENCE IN REAL CLINICAL PRACTICE

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**Background and importance** Recent studies suggest the use of topical insulin on the ocular surface to accelerate cicatrization of corneal lesions in diverse ocular pathologies, such as post-operative corneal epithelial erosion, neurotrophic keratitis and refractory corneal ulcers. However, its use has not been extended into real clinical practice.

**Aim and objectives** To describe an eye drop formulation of insulin 1 UI/mL for use in corneal defects refractory to previous treatment, and to evaluate its possible application in regular practice.

**Material and methods** A bibliographical search was performed in Pubmed using the following keywords: topical insulin, corneal ulcers and epithelial defects refractory; 9 results were found. Five references were selected with the most recent publication dates (2017–2020).

The pharmacy and ophthalmology departments reached an agreement to compound an eye drop formulation of topical insulin 1 UI/mL. The preparation was carried out in the pharmacy department in a horizontal laminar flow cabin following an aseptic compounding technique using regular insulin (100 UI/mL) and artificial tears with a polyethylene glycol base. The dilution was then filtered and packaged in light protected eye drop bottles. The risk matrix of sterile preparations of the Sociedad Española de Farmacia Hospitalaria was applied obtaining a low level of risk, which established a validity period of 14 days refrigerated or 48 hours at room temperature.

**Results** The formulation obtained was a transparent sterile liquid, adequate for ocular use. A visual control was

performed during the validity period, with no physical alterations of the product. Currently, nine patients with neurotrophic corneal ulcers or epithelial defects, refractory to medical and/or surgical standard treatment, have been treated. Mean number of days of treatment was 21±7 days. Improvement in pain was observed in every patient and total healing of the lesion was reported in 66% of patients. No adverse reactions were reported.

**Conclusion and relevance** Compounded topical insulin was adequate for ocular use, with no alterations during the validity period. Acceptance by patients was good, achieving quick relief of pain in every patient and total healing of the cornea in most patients. This preparation can be used as a treatment option in corneal defects refractory to previous treatment.

#### REFERENCES AND/OR ACKNOWLEDGEMENTS

**Conflict of interest** No conflict of interest

3PC-067

#### KEY ROLE OF THE HOSPITAL PHARMACY IN A NON-PROFIT STUDY INVOLVING RUXOLITINIB 5 MG CPS: IMPLEMENTATION AND QUALITY ASSURANCE OF AN INVESTIGATIONAL MANUFACTURING PRODUCT

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**Background and importance** Ruxolitinib is a JAK inhibitor indicated for myelofibrosis and polycythaemia vera in adults. The department of haematology started a non-profit study to evaluate ruxolitinib 5 mg in patients affected by Hodgkin's lymphoma. Because the company patent holder was not interested in sponsoring this study, the investigators used their research funds to meet the cost of Jakavi 20 mg tablets, which were cheaper than the other dosages.

**Aim and objectives** The aims of the hospital pharmacy were to improve the pharmaceutical formulation of capsules of ruxolitinib 5 mg, starting with Jakavi 20 mg tablets, consistent with department financial resources, and to conduct uniformity of mass and stability studies of compounding.

**Material and methods** The first step was to measure the volume of a tablet of Jakavi 20 mg to calculate the amount of starch needed to produce 100 capsule size 3 (0.30 mL) ruxolitinib 5 mg. For each batch of 200 capsules, 50 tablets of Jakavi 20 mg and 6 mg of starch were used; 80 samples were allocated to conduct uniformity of mass single dose preparations and stability studies. For the stability test, three samples of 20 capsules for each one, in amber glass bottles at storage temperatures of 25°C to 2°C for 12 months were prepared. Every month, ruxolitinib concentrations were determined by reverse phase HPLC.

**Results** In total, 102 packs of ruxolitinib 20 mg were purchased, instead of 408 packs of ruxolitinib 5 mg. Uniformity of mass studies demonstrated that no more than two of the individual capsule masses deviated from the average mass by more than 10% and none deviated more than twice that percentage. Regarding the stability test, the first 6 months of data showed that the percentage of ruxolitinib has not changed significantly. Therefore, all the aims of the study were achieved.