One *Staphylococcus hominis*CFU was detected on day 14 in one sample stored at 2–8°C. No subsequent microbial growth was found, therefore it was considered contamination

Conclusion and Relevance Tacrolimus 1 mg/mL oral suspension in simple syrup and carboxymethylcellulose 1.5% in a 2:1 ratio is stable when conditioned in polyproplylene syringe for 28 days and stored at room or refrigerator temperature.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

3PC-030 EVALUATION OF EXCIPIENTS USED IN PAEDIATRIC COMPOUNDED FORMULATIONS PRESCRIBED IN A NEONATAL INTENSIVE CARE UNIT

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Background and Importance The absence of marketed medicines adjusted to the pathophysiological profile of the neonate often implies the preparation of personalised compounded medicines. To meet therapeutic needs and improve medicines' stability, several vehicles have been developed and studied for different drugs. The choice of excipients is a critical point in paediatric compounded formulations (PCF), as there are limits inherent to the target population.

Aim and Objectives Evaluation of exposure to PCF excipients, according to individualised medical prescriptions to patients admitted to a Neonatal Intensive Care Unit (NICU) between September 2019 and August 2020, considering the recommended limits. Search for related adverse events (AEs) when limits are exceeded. Propose solutions for the non-conformities detected.

Material and Methods Definition of excipients to be evaluated, search of the respective recommended limits and AE reported.

Ranking PCF containing at least one of the selected excipients and calculation of its concentration in the formulation.

Analysis of prescriptions, calculation of excipient/patient daily intake and evaluation according to age recommendations.

In cases where the limits were exceeded, search the patient's medical record for AE that may be related to exposure to the excipient.

Results Evaluated excipients: benzyl alcohol, benzoic acid/sodium benzoate, ethanol, propylene glycol (PG), propylparaben (PP), polysorbate 80 and sorbitol.

Considering the 10 selected PCF, present in 86 prescriptions corresponding to 172 exposures, only 2 of the evaluated excipients were found: PP and PG. In 52 exposures there was ingestion above recommended limits, 50 of which were of PG in neonates with less than 28 days of age. 5 records of AE described in bibliography with a causal link were found in the medical files.

Conclusion and Relevance In cases of formulations where exceeded excipient limits were detected, an alternative with a different composition or concentration should be investigated. As 50 out of 52 non-compliances were with PG, used as a solvent in the paraben concentrate, this formulation will be tested using water instead of PG. It was not possible to retrospectively confirm a causal assessment related to the AE found as these are common clinical conditions in these patients. Individualisation of medication through compounding is the right direction as it best suits the patient's profile. However, the choice of excipients is crucial for patient safety.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

3PC-032 USE OF ORAL KETAMINE FORMULATION IN PATIENTS WITH CHRONIC REFRACTORY PAIN

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Background and Importance Chronic pain lasts more than three months and includes primary and neuropathic pain. Ketamine provides analgesia and amnesia at a subanaesthetic dose, therefore proposing its use as chronic pain treatment when it is refractory to the standard based on tricyclic antidepressants (TCAs), gabapentinoids, and opioids.

Aim and Objectives To analyse the use of an oral formulation of ketamine prepared and dispensed by hospital pharmacy at a third-level hospital in chronic refractory pain (CRP) treatment.

Material and Methods Observational retrospective study including a cohort of patients with CRP treated with an oral 10 mg/ml ketamine solution at a third-level hospital between January 2021 to December 2021. All of them signed informed consent. A tolerance test with intravenous ketamine was performed on every patient before initiating treatment. Data were collected from clinical history and pharmacy programs. For statistical analysis, continuous variables were categorised according to median (range) or percentage values.

Results 30 patients were included (67% men, median age 48.5 years (18–73)). Chronic pain type was neuropathic in all cases, cancer-associated (37%), trauma-caused neuronal damage (33%), demyelinating (17%), and 14% to other causes. Patients received oral ketamine during a median of 20 months (1–58) and daily dosage varied from 40 mg to 150 mg, the most frequent being 60 mg/d (40%), 90 mg/d (27%) and 120 mg/d (23%). 80% were in adjuvant treatment with opioids; of them, 88% took major opioids. 40% had reached the therapeutic limit by being treated with opioids, TCAs and gabapentinoids without any differences in pain origin. 43% had not included TCAs in treatment.

Treatment was discontinued in 5 patients (17%); 4 due to adverse effects (dizziness, cognitive alterations, tachycardia, hypertension), and 1 due to death unrelated to treatment.

Conclusion and Relevance This study shows oral ketamine analgesic use in neuropathic CRP treatment at 40–150 mg/d; the most frequent 60 mg/d and 90 mg/d. Inferior to those referred to in the literature (up to 400 mg/d). Good tolerance and an acceptable safety profile were observed (17% discontinued) without serious adverse events. As to adjuvant treatment, 80% received opioids and 40% the combination of opioids, gabapentinoid, and TCAs. More studies are needed to evaluate the long-term effectiveness and safety of oral ketamine treatment and to position it in CRP management.

REFERENCES AND/OR ACKNOWLEDGEMENTS
Conflict of Interest No conflict of interest

3PC-034 USE OF A MIXTURE OF BLEOMYCIN, LIDOCAINE AND EPINEPHRINE IN THE TREATMENT OF KELOID SCARS: ON THE SUBJECT OF A CASE

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Background and Importance Keloid scars represent an abnormality in wound repair in predisposed individuals. They are distinguished by an excessive synthesis of connective tissue. The treatment is difficult, recent studies have shown that the mixture of bleomycin, lidocaine and epinephrine (BLE) can be useful in the treatment of these lesions. The addition of lidocaine has an anaesthetic effect and also improves the cytotoxicity of bleomycin. Epinephrine has a vasopressor effect that prevents the passage of bleomycin and lidocaine into the blood.
Aim and Objectives To evaluate the efficacy and safety of the administration of the BLE mixture, by superficial puncture in a patient with keloid scars. Describe the preparation of the mixture in the Pharmacy Service.
Material and Methods Retrospective observational study of a patient to whom the BLE mixture was applied to keloid scars. The variables collected were: sex, age, size and location of the lesions, previous and concomitant treatments and data related to treatment with the BLE mixture (concentration, dose, frequency of administration, duration of treatment, effectiveness and safety). The clinical response to treatment was described with the following scale: complete crushing, very significant crushing, significant crushing. The patient's clinical history and the preparation protocol for the BLE mixture were reviewed.
Results A 14-year-old patient presented with keloid scars in the right cervical, scapular, and left thigh areas. He previously received intralesional punctures of corticosteroids, botulinum toxin and treatment with topical mometasone. The concentration of the BLE mixture was: bleomycin (0.75 g/l), lidocaine (3.5 g/l) and epinephrine (3.5 mg/l). 0.5 to 2 ml was administered in each puncture, monthly, making a total of 4 punctures. The clinical response was described as very significant crushing, with more inactive and whitish scars being observed. No adverse effect was observed.

The mixture was prepared in a vertical laminar flow hood. For this, a vial of bleomycin 15 mg/5 ml, 7 ml lidocaine hydrochloride 1% and 7 ml of diluted adrenaline 0.01 mg/ml were loaded into a 20 ml syringe. It was made up to 20 ml with 0.9% physiological serum.
Conclusion and Relevance The use of the BLE mixture was effective and safe in the treatment of the patient's keloid scars.

REFERENCES AND/OR ACKNOWLEDGEMENTS
Conflict of Interest No conflict of interest

4CPS-001 EMICIZUMAB IN ACQUIRED HAEMOPHILIA TYPE A: A CASE REPORT

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Background and Importance Acquired haemophilia A is a coagulation disorder in which antibodies against factor VIII are produced, interfering with its activity and leading to potentially severe bleeding. Among numerous causes, cancer is a prevailing one. First-line haemostatic treatment until inhibitor eradication consists of bypass agents, including recombinant factor VII activated (rFVIIa) or activated prothrombin complex concentrates (aPCC).
Aim and Objectives We present the case of a 70-year-old male patient diagnosed with metastatic prostate cancer who went to the emergency department of a tertiary referral hospital due to an acute-onset extensive hematoma on the right thigh, with neither personal nor family history of haemophilia.
Material and Methods The patient was diagnosed with paraneoplasic acquired haemophilia. Therefore, immunosuppressive (methylprednisolone + cyclophosphamide) and haemostatic treatment (rFVIIa at 5 mg every 8h) was initiated.

9 days in, off-label use of emicizumab was requested, intended to guarantee a haemostatic level that would allow outpatient management. Emicizumab was administered subcutaneously at 3 mg/kg weekly over 4 weeks and then fortnightly over 16 weeks between January 13th and May 25th, 2022.

Haemostatic was monitored daily during hospitalisation and weekly after discharge through determination of inhibitor activity (Bethesda Units, UB) and FVIII activity (bovine based Chromogenic Factor VIII assay, UI) in blood samples.
Results The patient was successfully treated until the resolution of bleeding and normalised FVIII levels. Over the treatment with emicizumab as the only haemostatic agent (107 days), 8 subcutaneous injections were administered (cost: € 51,255.2).

Having used rFVIIa (5 mg every 12 h) would have entailed 214 intravenous infusions, with a direct cost of € 618,301.64. Thus, emicizumab treatment meant direct cost saving of € 567,046.44.

Moreover, contributing factors to overheads as prolonged hospital stay, expenditure on consumables or staffing should be taken into account. Also risk of vascular access complications and quality of life must be considered.
Conclusion and Relevance Emicizumab has been a safe and cost-effective alternative to rFVIIa in haemorrhage prophylaxis, reducing direct costs by more than 10 times and allowed outpatient management.

Self-administration at home represents a major improvement in acquired haemophilia A quality of life.

Hospital pharmacy and haematology must collaborate to achieve a rational use of resources and an improvement in quality of life.

REFERENCES AND/OR ACKNOWLEDGEMENTS
Conflict of Interest No conflict of interest