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This case has never been reported/published before.

Conflict of Interest No conflict of interest.

5PSQ-121 A REVIEW OF THE EXPOSURE TO POTENTIALLY HARMFUL EXCIPIENTS THROUGH ORAL LIQUID FORMS IN PAEDIATRIC INPATIENTS IN FRANCE

M Bobillot*, V Delannoy, A Trouillard, JM Kinwoski, I Soulairol. *CHU De Nimes- France, Pharmacy, Nimes, France*

10.1136/ejhpharm-2024-eahp.455

Background and Importance Despite growing interests for the use of excipients with described toxicities (excipients of interest., EOI) in children and neonates, even today the lack of paediatric data makes it difficult to establish precise recommendations about quantitative levels of EOI in commercialised paediatric formulations.

Aim and Objectives The primary objective of this work is to identify the EOI present in oral liquid forms used in paediatric departments. The secondary endpoint is to quantify the EOI exposure for often-prescribed molecules (originator formulations and generic brands) used in recommended posology ranges, for different age categories.

Material and Methods A review of medications used in French hospitals has allowed establishing a list of oral liquid forms used for paediatrics and neonatology inpatients. The formulation of each medication has been examined using the summaries of product characteristics (SmPC). Ten of the most prescribed molecules have been selected concerning princeps and generics formulations for a total of 31 formulations. EOI exposure has been calculated and STEP Database and European Médicine Agency (EMA) recommendations were used to evaluate the exposure levels.

Results The analysis involved 219 formulations including 123 active molecules and 140 excipients. Sixteen excipients were present in above 10% of the formulations and nine of them are recognised as EOI (ethanol, propylene glycol, glycerol, sodium benzoate, methyl and propyl paraben, aspartame, sorbitol, saccharose). A total of 95% of all studied formulations involve at least one EOI. The amounts of EOI found in the 10 studied molecules outcome the recommended levels for 45% of the 31 formulations. A rate of 73% of the drugs with neonatalogy marketing authorisation include at least one excipient not recommended in this age category.

Conclusion and Relevance Pediatric and neonates inpatients are receiving a wide range of harmful excipients, among others through the administration of oral liquid forms. Although specific studies tend to enlarge the knowledge about specific use and toxicity of the excipients in paediatrics, too little remains, especially in preterm. When EOI cannot be avoided, quantitative information about their amount in drug formulations should be easily known to help physicians and pharmacist to select the most appropriate drugs and anticipate possible adverse effects or adapt drugs posology.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

5PSQ-122 SEQUENTIAL CHANGE OF DOSING INTERVAL OF PALIPERIDONE PALMITATE BASED ON PLASMA CONCENTRATION MONITORING

F Fuentes Hidalgo*, G Martínez Orea, C García González, A Campello Moñino, JM Del Moral Sánchez, A Ruíz Gómez, N Cano Cuenca, A Candela Fajardo, E Arroyo Domingo, R Bonilla Peñarrubia. *Hospital De La Vega Baja, Pharmacy Department, Orihuela Alicante-Comunidad Valenciana, Spain*

10.1136/ejhpharm-2024-eahp.456

Background and Importance Paliperidone is an antipsychotic used for the treatment of schizophrenia. To increase adherence to treatment and thus reduce the risk of relapse, it was formulated as an extended-release injectable. There are 3 types of formulations: monthly, quarterly and semi-annually. Monitoring of paliperidone plasma concentrations can help to optimise treatment, as patients who do not require dose adjustments may benefit from the longer therapeutic interval formulations (quarterly and semi-annual)

Aim and Objectives To analyse the relationship between the change of presentation of paliperidone palmitate and its pharmacokinetic monitoring

Material and Methods Retrospective observational study in which all patients whose plasma concentrations of paliperidone were determined from January to July 2023 were included. Patients on treatment with oral paliperidone were excluded.

The variables collected were sex, age, current plasma concentrations of paliperidone palmitate, type of paliperidone palmitate formulation used in current treatment, initiation of paliperidone palmitate, presence of previous controls of another type of paliperidone palmitate formulation, previous plasma concentrations of paliperidone palmitate.

Results Sixty-nine patients were included, 69.6% male with a median age of 50 years (20–72).

Of the patients, 42.0% had plasma paliperidone palmitate concentrations within the therapeutic range. Of the patients, 36.3% were on paliperidone palmitate monthly, 42.0% were on paliperidone palmitate quarterly, and 21.7% were on paliperidone palmitate semi-annually.

A change of paliperidone palmitate presentation had occurred in 87.0% of the patients. Of these, only 43.3% had pharmacokinetic monitoring prior to the change of presentation. Of these patients, 46.2% had plasma concentrations in range in the control with the previous presentation of paliperidone palmitate.

Conclusion and Relevance Although the pharmacokinetic determination of plasma concentrations of paliperidone palmitate allows individualising the treatment to each patient, the decision to switch from one formulation of injectable paliperidone palmitate to another with a different dosing interval was not based on the plasma concentrations of the drug in our population.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.