Giorgio Penocchio, Irene Restivo, Francesca Caravaggio, Carla Galloni, Tullio Elia Testa ASST Spedali Civili di Brescia, SC Farmacia Aziendale, p.le Spedali Civili 1, 25123 Brescia

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Compounding of oral Acitretin suspension for paediatric patient with Harlequin Ichthyosis



What was done?

The development of an extemporaneous preparation of Acitretin from the commonly available capsule form. The drug was dispensed in prefilled syringes and administered enterally through the orogastric tube to treat a preterm neonate with a diagnosis of Harlequin Ichthyosis.

Why was it done?

Harlequin Ichthyosis (HI) is a rare congenital disorder of keratinisation characterised by hyperkeratosis and scaling, often associated with underlying inflammation. On 18 April 2022, a newborn diagnosed with HI was hospitalised and clinicians have established the prescription of Acitretin per os (1 mg/kg/d). However, the drug is not available in an appropriate dosage and formulation.

How was it done?

Biological safety cabinet

(teratogenic risk and extreme photosensivity)

2 capsules

of 10 mg

Acitretin

10 mL of a

suspending
agent

= 2 mg/mL 10 mL oral suspension

The procedure involves attaching the Luer lock syringe to the arm with a clamp, capping with a combi-stopper and emptying the contents of the capsules required, transferring the powder quantitatively. Next, add the suspending agent to reach the final volume of 10 mL, close the end of the syringe with the plunger, connect a second syringe using a connector and mix by transferring the contents from one to the other.

What has been achieved?

The suspension was packaged in pre-filled syringes based on the required dose, closed with combi stoppers and placed in a UV bag. Given the lack of stability data, the validity period conferred was 5 days with storage at 2-8°C. The suspension was administered by attaching the syringe to the nasogastric tube and then washing down with water, limiting invasive procedures and consequently the associated skin infections.

What next?

Magistral galenic preparation made it possible to obtain a personalised therapy for a critical patient. Clinical galenics, put into practice thanks to the experience of the preparer pharmacist, represented the only possibility of treatment.





FROM DRUG DESIGN
TO TREATMENT SUCCESS
WHAT REALLY MATTERS
TO PATIENTS?

