

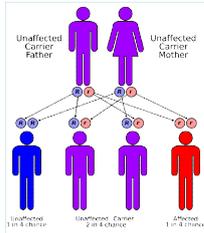
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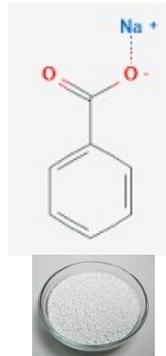
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## Background and importance:

Non-ketotic hyperglycinaemia (NKH) is a rare inborn error of glycine metabolism characterised by accumulation of glycine in body fluids and tissues, resulting in neurometabolic symptoms of variable severity.

**Sodium benzoate** is the sodium salt of benzoic acid that conjugates with nitrogen containing glycine to form the molecule hippurate. **Hippurate** can be excreted by the kidneys, reducing plasma glycine levels. N-methyl-D-aspartate receptor antagonists may ameliorate neurological symptoms although it remains to be established whether they improve long term outcome. Lack of authorised presentations for treatment of rare diseases is an important obstacle that is usually resolved by hospital pharmacy formulations, especially in children.



## Aim and objectives

The aim was to provide an adequate, stable and well accepted oral sodium benzoate formulation for a patient with NKH, to improve her general status

## Material and methods

A 4-year-old girl with severe NKH needed oral treatment with sodium benzoate, although there is no standard oral formulation for children. To find an optimal and suitable solution, a literature search was carried out in the National Library of Medicine's (MEDLINE) database, including terms 'sodium benzoate/chemistry', and 'administration, oral' with no other filter. Our national and regional formulation databases were also checked

## Results

- The patient was initially treated with 16 mL, three times a day, sodium benzoate syrup 112.5 mg/mL, but the volume needed was impossible to swallow by the patient due to her clinical status.
- Subsequently, 2 g sodium benzoate sachets were given with meals (four times a day) but they were not well tolerated.
- We then dispensed a **250 mg/mL suspension** in Ora-Sweet with a stability of 90 days. Despite it being a new formulation for our pharmacy service, glycine levels were reduced from 900–1000 m/L to 500 m/L over 2 months. Currently, her clinical situation is stable, and the patient receives 8 g/24 hours of sodium benzoate which is well tolerated.

## Conclusion and relevance

Sodium benzoate oral suspension dispensed with Ora-Sweet seemed to be an adequate solution to NKH treatment in our patient. Although the formulation is a basic operation for hospital pharmacy services, it is essential, especially in children with rare diseases that need orphan drugs.

PEER REVIEWED	
<p><b>Stability of Extemporaneously Prepared Sodium Benzoate Oral Suspensions</b></p> <p>Johán B. Saldaña, PhD, PharmD<sup>1</sup> / Coordinador Miguel A. Lall, PhD Andrés S. Decker, PharmD David J. Rodríguez, PharmD, BCPH, BCPPS</p>	<p><b>INTRODUCTION</b></p> <p>Extemporaneous (ET) drug preparations are those that are not commercially available. They are prepared by the pharmacist in the pharmacy. The aim of this study was to evaluate the stability of ET sodium benzoate oral suspensions. The study was conducted in a tertiary care hospital. The results show that the stability of ET sodium benzoate oral suspensions is acceptable for up to 90 days at room temperature. The study was conducted in a tertiary care hospital. The results show that the stability of ET sodium benzoate oral suspensions is acceptable for up to 90 days at room temperature. The study was conducted in a tertiary care hospital. The results show that the stability of ET sodium benzoate oral suspensions is acceptable for up to 90 days at room temperature.</p>
<p><b>ABSTRACT</b></p> <p>The stability of extemporaneously prepared sodium benzoate oral suspension in cherry syrup and Ora-Sweet was studied. Oral suspensions of 250 mg/mL sodium benzoate were prepared in either cherry syrup or Ora-Sweet. The 10 mL bottles, 15 grams of Sodium Benzoate Powder USP was dissolved and filtered. The suspension was divided equally into two parts, and each aliquot was added into the appropriate container 100 mL either vial. In the first day, cherry syrup was added to make a final volume of 100 mL. In the second day, Ora-Sweet was added to give a final volume of 100 mL. The process was repeated to prepare three suspensions of each kind and all were stored at room temperature. A 250-µg sample was withdrawn immediately after preparation and again at 7, 14, 28, 56,</p>	<p>...and withdrawal. Withdrawal of ...</p>