

IMPORTANT INFORMATION FOR HEALTHCARE PROFESSIONALS

To: Healthcare Professionals

20/01/2023

**Supply of Calpol 120 mg/5 ml Sugar Free Infant Oral Suspension
PA0330/017/004**

Batch: X4375R, Expiry date: November/2025

Dear Healthcare Professional,

I am writing to you in connection with the supply of the above referenced product, Calpol 120 mg/5 ml Sugar Free Infant Oral Suspension, PA0330/017/004.

We are unable to supply Irish licensed packs at the moment and have obtained approval from the Health Products Regulatory Authority (HPRA) to temporarily supply the corresponding product from the United Kingdom market to fulfil the urgent medical need for the product. These packs are labelled with Calpol Sugar Free Infant Suspension, Batch/Lot No. X4375R, with an expiry date of November 2025.

The pharmaceutical composition of the product is the same, but there are differences in the labelling of the carton and the package leaflet as follows:

Carton

The UK product name is Calpol Sugar Free Infant Suspension. The strength is the same as the Irish licensed product, 120 mg/5 ml, however, the strength (120 mg/5 ml) has not been included in the product name of the UK product on the labelling.

The marketing authorisation holder name and address of the UK product is McNeil Products Limited, HP12 4EG, UK.

The marketing authorisation number (PL15513/0123) on the labelling is for the UK product.

Package leaflet

There are some additional inconsistencies between the UK and Irish package leaflets, notably, in section 3 of the UK package leaflet, in the dosing instructions for babies aged 2-3 months for post-vaccination fever, the instructions imply that a 2.5 ml dose may be administered up to 4 times in 24 hours. The package leaflet for the Irish licensed product recommends no more than 2 doses are administered in 24 hours unless a doctor or nurse has advised otherwise.



Airton Road
Tallaght
Dublin 24

For further details on the product, please refer to the approved Irish summary of product characteristics (SmPC) and package leaflet, which are available on the HPRA website:
www.hpra.ie.

Please ensure all relevant staff *and patients* are made aware of the content of this letter and that the information is communicated to the patients.

If you have any questions, please contact:

Tom Henderson

Phone: 1800 22 00 44

Fax: 01-46653160

Email: crc@its.jnj.com

Yours faithfully,

Tom Henderson
Regulatory Affairs Manager