Perrigo UK
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www.perrigo.co.uk

01 October 2020
Ref: ALLERGY_DHCP

Direct Healthcare Professional Communication

Nytol Liquid Caramel Flavour 10mg/5ml oral solution [Diphenhydramine Hydrochloride]: removal of the allergy indication; should only be sold as an adult sleep aid

Perrigo in agreement with the MHRA would like to inform you of the following:

Summary

- Diphenhydramine should not be used to sedate a child due to the possibility of respiratory depression, lethargy, sleep apnoea and cardiorespiratory arrest
- Nytol Liquid Caramel Flavour 10mg/5ml oral solution is now indicated only as a sleep aid for adults and should no longer be used in children or adults as an antihistamine
- The previous indication as an antihistamine and corresponding dosing information have been removed for newly produced products and new corresponding advice has been added to the packaging
- Current stock coming to pharmacies has been reworked to include an updated carton and leaflet; the existing label has been partially over-stickered with the updated dosing information.

Further information on the safety concern

Nytol Liquid Caramel Flavour 10mg/5ml oral solution is now indicated only as a short-term mild hypnotic (sleep aid) for adults. Its use is not recommended for children under 16 years of age. It was previously approved for allergies, in adults and children.

Concerns were received from the MHRA and pharmacists/pharmaceutical professional bodies about the potential off-label use of this product for sedation in children. In response to these concerns, we have updated the product information to advise healthcare professionals and patients that it should not be used to sedate a child. Warnings have also been added to the carton/label to advise against use in children. Changes have been made to the packaging to make clear that the active ingredient is to be used as a sleep aid in **adults only**.

Perrigo advises that healthcare professionals only recommend Nytol Liquid Caramel Flavour as a sleep aid for adults. New packaging has been approved to reflect the changes to the product information. Existing product held within Perrigo warehouse(s) has been reworked

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into updated cartons and had the leaflet replaced (with the newly approved version); the label has been partially stickered over to include the updated dosing information and respective warnings. These updated products will be available to retailers from mid-September onwards (and until this stock is exhausted); any new batches manufactured will be packaged using the newly approved carton, label and leaflet.

Call for reporting
Please continue to report suspected adverse drug reactions (ADRs) to the MHRA through the Yellow Card Scheme.

Please report:

- all suspected ADRs that are serious or result in harm. Serious reactions are those that are fatal, life-threatening, disabling or incapacitating, those that cause a congenital abnormality or result in hospitalisation, and those that are considered medically significant for any other reason
- all suspected ADRs associated with new drugs and vaccines identified by the black triangle ▼

It is easiest and quickest to report ADRs online via the Yellow Card website – www.gov.uk/yellowcard or via the Yellow Card app available from the Apple App Store or Google Play Store.

When reporting please provide as much information as possible, including information about medical history, any concomitant medication, onset, treatment dates, and product brand name.

Adverse events can also be reported to Perrigo by emailing UKLOCustomerService@perrigo.com or phoning 0203 598 9603.

Communication information
No direct communication to the public is planned.

Annexes:
Text of the revised Product Information (with changes made visible), is annexed for reference.

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Yours sincerely,

01 Oct 2020 09:56 +02:00

X George Nicolas

Signature Certifies Approval

DocuSign

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Perrigo CSCI