



MEDICINES NOTIFICATION

CLASS 4 MEDICINES DEFECT INFORMATION

Caution in Use
Distribute to Retail / Pharmacy / Wholesaler Level

Date: 21 December 2021

EL (21)A/39

Our Ref: MDR 021-12/21

Dear Healthcare Professional and Retailer,

McNeil Products Limited

Benlyn Chesty Coughs Original (P)

PL 15513/0048

Batch No	Expiry Date	Pack Size	First Distributed
V3879R	10/2023	300ml	Not distributed yet
V3880R	10/2023	300ml	Not distributed yet
V4017R	10/2023	300ml	Not distributed yet
V4011R	10/2023	150ml	Not distributed yet
V4016R	10/2023	150ml	Not distributed yet

Active Pharmaceutical Ingredient: Diphenhydramine hydrochloride, Levomenthol

Benlyn Chesty Coughs Non-drowsy (GSL)

PL 15513/0056

V3366R	08/2024	300ml	03-Nov-2021
V3367R	09/2024	150ml	Not distributed yet
V3371R	08/2024	150ml	Not distributed yet
V3260R	09/2024	150ml	Not distributed yet
V3621R	09/2024	150ml	Not distributed yet
V3993R	10/2024	150ml	Not distributed yet

Active Pharmaceutical Ingredient: Guaifenesin, Levomenthol

Brief description of the problem

McNeil Products Limited have identified an error relating to the stated alcohol content for batches of Benlyn Chesty Coughs Original (P) and Benlyn Chesty Coughs Non-Drowsy (GSL) whereby the product labels understate the ethanol values. **The products comply with the defined specifications, including ethanol content and, other than the incorrect ethanol content, all other label information is correct.** However, the amount of ethanol contained within the products is low and hence the related on-pack safety warning, which reads "*The small amount of alcohol in this medicine will not have any noticeable effects.*", is correct.



A table of the current (incorrect) and required (correct) labelling text can be seen below:

Products	Licences	Current labelling text (incorrect)	Required labelling text (correct)
Benylin Chesty Coughs Original (P)	PL 15513/0048	This medicine contains 0.26 mg of alcohol (ethanol) in each 5 ml. The amount in 5 ml of this medicine is equivalent to less than 1 ml beer or 1 ml wine. The small amount of alcohol in this medicine will not have any noticeable effects.	This medicine contains 197 mg of alcohol (ethanol) in each 5 ml. The amount in 5 ml of this medicine is equivalent to less than 5 ml beer or 2 ml wine. The small amount of alcohol in this medicine will not have any noticeable effects.
Benylin Chesty Coughs Non-Drowsy (GSL)	PL 15513/0056	This medicine contains 0.7 mg of alcohol (ethanol) in each 5 ml dose. The amount in a 5 ml dose of this medicine is equivalent to less than 1 ml beer or wine. The small amount of alcohol in this medicine will not have any noticeable effects.	This medicine contains 197 mg of alcohol (ethanol) in each 5 ml. The amount in 5 ml of this medicine is equivalent to less than 5 ml beer or 2 ml wine. The small amount of alcohol in this medicine will not have any noticeable effects.

Advice for healthcare professionals

The impacted products are within specification and there is no issue with product quality. Despite the label error understating the ethanol content, the related label warning is correct. Therefore, the affected batches are not being recalled. Due to the products complying with the specifications, including ethanol content within the product, the batches on hold awaiting distribution will continue to be sold and have been included in this notification for information.

Since the products are within specification, there are no quality issues with the products and all safety warnings including the warning related to the alcohol content are correct, no specific action is required by healthcare professionals or retailers and this notification is being shared for information.

Further Information

For medical information queries please contact: McNeil Products Limited on 01344 864042 or by email to crc@its.jnj.com.

Recipients of this Medicines Notification should bring it to the attention of relevant contacts by copy of this notice. NHS regional teams are asked to forward this to community pharmacists and dispensing general practitioners for information.

Yours faithfully

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