



DRUG ALERT

CLASS 2 MEDICINES RECALL

Action Within 48 hours
Store, Pharmacy and Patient Level Recall

Date: 20 June 2018

EL (18) A/10

Our Ref: MDR 025-06/18

Dear Healthcare Professional,

Bell, Sons & Co.

PL 03105/0066

**Asda Children's Dry Cough Syrup Glycerol Blackcurrant Flavour;
Bell's Healthcare Children's Dry Cough Glycerin 0.75g/5ml Syrup;
Morrisons Children's Dry Tickly Cough Glycerin 0.75g/5ml Oral Solution;
Numark Children's Dry Cough 0.75 g/5 ml Oral Solution;
Sainsbury's Children's Dry Cough 0.75g/5ml Syrup;
Superdrug Children's Dry Tickly Cough Glycerin 0.75 g/5 ml Oral Solution;
Tesco Children's Dry Cough Syrup;
Wilko Tickly Cough 0.75g/5ml Oral Solution**

| Brand & Product Description | Batch Number | D Code | Expiry Date | Pack Size | Date Released |
|--|--------------|----------|-------------|-----------|---------------|
| Asda Children's Dry Cough Syrup Glycerol Blackcurrant Flavour | 274V1 | D10-5120 | 01-Aug-2020 | 200 ml | 27/09/2017 |
| Asda Children's Dry Cough Syrup Glycerol Blackcurrant Flavour | 276V1 | D10-5120 | 01-Oct-2020 | 200 ml | 31/10/2017 |
| Asda Children's Dry Cough Syrup Glycerol Blackcurrant Flavour | 278V1 | D10-5120 | 01-Dec-2020 | 200 ml | 02/01/2018 |
| Asda Children's Dry Cough Syrup Glycerol Blackcurrant Flavour | 283W1 | D10-5120 | 01-Feb-2021 | 200 ml | 19/02/2018 |
| Bell's Healthcare Children's Dry Cough Glycerin 0.75g/5ml Syrup | 280V3 | D10-4315 | 01-Dec-2020 | 200 ml | 04/01/2018 |
| Morrisons Children's Dry Tickly Cough Glycerin 0.75g/5ml Oral Solution | 282W1 | D10-4325 | 01-Jan-2021 | 200 ml | 30/01/2018 |
| Numark Children's Dry Cough 0.75 g/5 ml Oral Solution | 280V1 | D10-4042 | 01-Dec-2020 | 200 ml | 04/01/2018 |
| Numark Children's Dry Cough 0.75 g/5 ml Oral Solution | 288W1 | D10-4042 | 01-Apr-2021 | 200 ml | 27/04/2018 |
| Sainsbury's Children's Dry Cough 0.75g/5ml Syrup | 275V1 | D10-0112 | 01-Sep-2020 | 200 ml | 11/10/2017 |
| Superdrug Children's Dry Tickly Cough Glycerin 0.75 g/5 ml Oral Solution | 280V2 | D10-4695 | 01-Dec-2020 | 200 ml | 04/01/2018 |



| Brand & Product Description | Batch Number | D Code | Expiry Date | Pack Size | Date Released |
|--|--------------|----------|-------------|-----------|-------------------|
| Superdrug Children's Dry Tickly Cough Glycerin 0.75 g/5 ml Oral Solution | 284W1 | D10-4695 | 01-Mar-2021 | 200 ml | 24/03/2018 |
| Tesco Children's Dry Cough Syrup | 277V1 | D10-4271 | 01-Oct-2020 | 200 ml | 31/10/2017 |
| Tesco Children's Dry Cough Syrup | 278V2 | D10-4271 | 01-Dec-2020 | 200 ml | 02/01/2018 |
| Tesco Children's Dry Cough Syrup | 281W1 | D10-4271 | 01-Jan-2021 | 200 ml | 30/01/2018 |
| Wilko Tickly Cough 0.75g/5ml Oral Solution | 275V2 | D10-0310 | 01-Sep-2020 | 200 ml | 11/10/2017 |

Brief description of the problem

Bell, Sons & Co is recalling 15 batches of the cough syrups listed above to patient-level as a precautionary measure due to a small number of reports of mould.

Advice for healthcare professionals

This Drug Alert is provided to healthcare professionals for information in case you receive any queries or ADRs relating to this issue.

This is a GSL product which has been sold from the retail shops Tesco, Asda, Wilkos, Sainsbury, Morrisons, Superdrug in the retailer's livery and one pharmacy chain (Numark, in Numark livery). It has also been supplied in Bell, Sons & Co livery to Poundstretcher and to a number of wholesalers. All retailers and wholesale customers have been notified and stock is already being recalled at store level. Patients are being asked to return bottles from the above batches to the shop they bought it from.

At the time of writing the MHRA has not received any reports of ADRs relating to this issue.

The mould has been identified as *Penicillium decumbens*, *Penicillium corylophilum* and *Penicillium brevicompactum*. Although these moulds may be inactivated in the stomach, there is a low potential risk of systemic infection in younger or immunocompromised children, causing symptoms of infection such as fever.

Penicillium brevicompactum and *Penicillium corylophilum* can produce mycotoxins. Reactions to these mycotoxins are rare in reported literature but there is a low risk they could induce non-specific toxin reactions that could include rashes, breathing difficulties and Gastro-Intestinal (GI) symptoms.

There is also a low risk of allergen-mediated disease either through inhalation or ingestion of *Penicillium* antigens to occur, causing allergic symptoms.

Grocery stores and Numark Pharmacies

Please quarantine and return all stock of this product to your supplier as per the instructions provided by Bell, Sons & Co. If your customers return stock to you, please return it to your supplier.



Wholesalers

Wholesalers are requested to return any remaining stock of this product to their original supplier for credit. Wholesalers who have received affected stock in Bell, Sons & Co livery (Batch 280V3) are listed below:

| Wholesalers | |
|--------------------|-------------------|
| Aprino | Inspira |
| Awan | Lexon |
| B&J Supplies | Mister Discount |
| De Pharma | Rayburn |
| Durham | Roys Of Wroxham |
| Eclipse | Sangers Maidstone |
| Ethigen | Sangers NI |
| GD Cooper | Sigma |
| Heath & Pratt | Trago Mills |
| Homeware | |

Patients and parents

It is important for people to check if they have any bottles from the batches of the blackcurrant cough syrups listed above. If they do, they should not take them or give them to others. They should return any bottles of the batches above to the shop or pharmacy they bought it from. The mould is not always visible so they should return any bottles of the cough syrups from the batches above even if they can't see the mould.

Whilst the possibility of a reaction to the mould is low, if parents are concerned their child has had a reaction they should speak to their GP, pharmacist or other healthcare professional.

As with any medicine, we strongly encourage anyone to report any suspected side effects to the MHRA via our Yellow Card Scheme.

Company contacts for further information

Medical information enquiries

Trevor Price
Pharmacovigilance Manager and Qualified Person for Pharmacovigilance (QPPV)
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Stock enquiries

Jackie Kermode
Sales Office Manager
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Email: Jackie.Kermode@bells-healthcare.co.uk

Recipients of this Drug Alert should bring it to the attention of relevant contacts by copy of this letter. NHS regional teams are asked to forward this to community pharmacists, hospital pharmacists and general practitioners for information.

Yours faithfully

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London, SW1W 9SZ, Telephone +44 (0)20 3080 6574**