

Labelling error leads to retail-level recall of cold and flu medicine



PUBLISHED NOV 11, 2021
BY [GOV.UK](https://gov.uk)

Eleven retailers from around the UK are being asked to recall certain batches of cold and flu capsules due to a mistake on the leaflet and carton that states children aged 12 to 15 years can take a maximum of up to 12 capsules (3.6 grams of paracetamol per day) in any 24-hour period. This labelling is correct for adults aged 16 years and over, but not for children aged 12 to 15 years old.

The incorrect daily dose for 12 to 15 year olds is only slightly higher than the maximum daily dose of 3 grams of paracetamol recommended by the Medicines and Healthcare products Regulatory Agency in this age group. As a result, the UK regulator states that the risk to 12 to 15 year olds from taking the incorrect daily dose is very low and there is no evidence of any harm.

The correct labelling from the company for these products should state a maximum daily dose of 8 capsules per day (2.4 grams of paracetamol) for 12 to 15 year olds, which is slightly lower than the recommendation from the MHRA. Each pack has 16 capsules containing 300mg of paracetamol, which provides two days of treatment at the maximum dose.

The company are currently correcting their labelling and the products have been taken off shelves until this is completed.

Dr Alison Cave, MHRA Chief Safety Officer said:

I want to reassure people that, while this recall is aimed at retail level only, patient safety is at the centre of all our decision-making.

If you or your child are aged 12 to 15 years, have recently

used these capsules and have not experienced any side effects, there is no cause for concern. If you currently have one of these packets at home, please take note of the corrected dose in this age group and talk to your pharmacist if you are unsure of these changes.

If you have any other questions, please speak to your healthcare professional and report any adverse reactions via the Yellow Card scheme.

As is usual for paracetamol-containing products, the leaflet states that patients should only take the maximum dose for a short period of time, and longer-term use should first be discussed with a healthcare professional.

The MHRA has launched a review of the labelled dosage for all paracetamol-containing medicines with an indication for this age group.

For batch numbers affected, please see the Class 2 recall notice.

Media enquiries

News centre

MHRA

10 South Colonnade

London

E14 4PU

Email newscentre@mhra.gov.uk

During office hours: 020 3080 7651 (08:30 - 17:00)

Out of office hours: 07770 446 189 (17:00 - 08:30)

Office hours are Monday to Friday, 8:30am to 5pm. For real-time updates including the latest press releases and news statements, see our Twitter channel at

Press release distributed by Media Pigeon on behalf of GOV.UK, on Nov 11, 2021. For more information subscribe and follow us.

Media Assets

Embedded Media

Visit the [online press release](#) to interact with the embedded media.

<https://mediapigeon.io/newsroom/govuk/releases/en/labelling-error-leads-to-retail-level-recall-of-cold-and-flu-medicine-13516>

GOV.UK

Newsroom: <https://mediapigeon.io/newsroom/govuk>

Website: <https://www.gov.uk/>

Primary Email: publiccorrespondence@cabinetoffice.gov.uk

Social Media

Twitter - <https://twitter.com/cabinetofficeuk>

Instagram - <https://www.instagram.com/cabinetoffice>

Linkedin - <http://www.linkedin.com/company/cabinet-office>

Youtube - <http://www.youtube.com/user/cabinetofficeuk>

Flickr - <http://www.flickr.com/photos/cabinetoffice/>
