



28<sup>th</sup> October 2016

**Mucodyne Paediatric Syrup 250 mg/5 mL (Carbocisteine Oral Liquid): new double-strength presentation - check dose volume to ensure appropriate dose is given**

Dear Healthcare Professional,

In January 2015, Sanofi informed you of the discontinuation of Mucodyne Paediatric Syrup due to manufacturing problems.

**Summary**

- Mucodyne Paediatric Syrup has been re-launched and has double the concentration of the active ingredient carbocisteine per millilitre compared with the previous formulation
- To reduce the risk of accidental overdose, dose volumes must be checked to ensure the appropriate dose is administered, especially if they have used Mucodyne Syrup in the past.


**Further information on the safety concerns and the recommendations**

New presentation:

- Mucodyne Paediatric Syrup has double the concentration of carbocisteine per millilitre of syrup compared with the withdrawn product
- The concentration of the new paediatric presentation is 250 mg/5 mL
- The paediatric syrup is presented in a 125 mL bottle
- A graduated 5 mL non-sterile plastic syringe is included to aid accurate measurement of dose volume and oral administration (see below images)

New packaging:

- Packaging has been revised with marking on the outer box and labelling to indicate the new strength (see pack images)
- A revised Patient Information Leaflet (PIL) specific to the paediatric formulation is included. Patients should be encouraged to read the revised PIL to ensure that the correct dose is given using the syringe provided, especially if they have used Mucodyne syrup in the past.

Revised outer carton	Revised bottle label
<p><b>Mucodyne®</b>  <b>250mg/5ml</b>  <b>Paediatric Syrup</b>  <b>Carbocisteine</b></p> <p>Oral Use</p> <p><b>New Strength</b></p> <p><b>125ml</b></p> <p><b>SANOFI</b> </p>	<p><b>Mucodyne®</b>  <b>250mg/5ml</b>  <b>Paediatric Syrup</b>  <b>Carbocisteine</b></p> <p>Each 5ml of oral solution contains 250mg of carbocisteine. Also contains sucrose, ethanol, sodium and methyl parahydroxybenzoate (E218). See enclosed leaflet for further information. Take as directed by your doctor. Always read the leaflet before taking this medicine. Keep out of the sight and reach of children. Store below 25°C.</p> <p>Oral Use</p> <p><b>New Strength</b></p> <p>125ml</p> <p><b>POM</b> PL: 04425/0204  MA Holder:  Sanofi, One Onslow Street,  Guildford, Surrey GU1 4YS, UK</p> <p>Packaging code - laetus code</p> <p><b>Leatus code</b></p> <p>BN:  EXP:</p>

### **Call for reporting**

#### **Reporting of suspected adverse reactions**

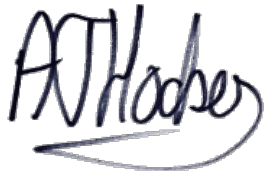
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via Yellow Card Scheme at: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard)

Adverse events arising from the use of medicines manufactured by Sanofi may also be reported to the Sanofi UK Pharmacovigilance department at: Sanofi, One Onslow Street, Guildford, Surrey, GU1 4YS, UK. - Tel: 01483 554242, Fax: 01483 554806, Email: [uk-drugsafety@sanofi.com](mailto:uk-drugsafety@sanofi.com)

**Company contact point**

Should you have any questions or require additional information, please call Medical Information at Sanofi, One Onslow Street, Guildford, Surrey, GU1 4YS, UK - Tel: 0845 372 7101, Email: [uk-medicalinformation@sanofi.com](mailto:uk-medicalinformation@sanofi.com). For questions relating to order of product: Sanofi Customer Services – 0800 854 430, (9am – 5.15pm Monday-Thursday, 9am – 4pm Friday).

Yours faithfully,

A handwritten signature in black ink that reads "A.H. Hockey". The signature is written in a cursive style with a large, sweeping underline that extends to the left and then curves back under the name.

Dr Andrew Hockey FFPM  
Medical Head - General Medicines  
Sanofi UK