28th 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.

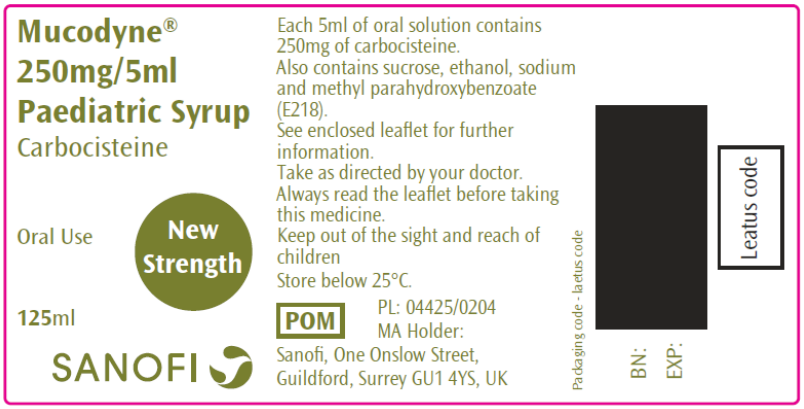
Further information on the safety concerns and the recommendations

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- Mucodyne Paediatric Syrup has double the concentration of carbocisteine per millilitre of syrup compared with the withdrawn product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
	

Call for reporting

Reporting of suspected adverse reactions

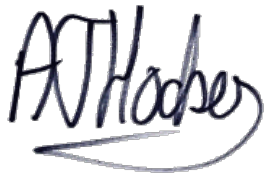
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via Yellow Card Scheme at: www.mhra.gov.uk/yellowcard

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

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. For questions relating to order of product: Sanofi Customer Services – 0800 854 430, (9am – 5.15pm Monday-Thursday, 9am – 4pm Friday).

Yours faithfully,



Dr Andrew Hockey FFPM
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