

14 October 2010

Dear Healthcare Professional,

Re: Rhinathiol 2% (carbocisteine) Children and Infant Syrup - Contraindication in children below 2 years old

Sanofi-aventis had recently been informed by the French Regulatory Agency's (Afssaps) on a latest evaluation of pharmacovigilance data which indicated the risk of aggravation of respiratory symptoms in connection with the use of products with mucolytic and fluidifying properties to treat bronchial secretion in children below 2 years old. This has led the French authorities to conclude that the benefit risk ratio of the above mentioned class of drugs in children less than 2 years of age is no longer favourable and the contraindication of these products in this group of children is required as a precautionary measure. Sanofi-aventis Singapore Pte Ltd will be adopting and extending this decision of contraindicating the use of carbocisteine in children below 2 years old to Rhinathiol 2% Children and Infant Syrup.

Background

The pharmacovigilance investigation conducted by AFSSAPS covered the therapeutic class of mucolytics and agents that fluidify bronchial secretions. The decision by AFSSAPS followed as result of this investigation revealed a risk of respiratory congestion in infants due to the functional features of their air passages and thoracic cavity (small caliber bronchi, immature bronchial surfaces that limit the lung's capacity to remove mucus flow).

Actions to be taken by Sanofi-aventis Singapore

At Sanofi Aventis, it is our mission to ensure ongoing monitoring and management of the safety profile of all of our pharmaceutical products. Thus, we wish to bring to your attention the package insert for Rhinathiol 2% Children and Infant syrup will be updated to reflect this new contraindication. The packaging for Rhinathiol 2% Children and Infant Syrup will subsequently be changed and the product will be renamed as Rhinathiol 2% Children Syrup. The new packaging with the revised package insert is estimated to be implemented in Singapore in February 2011.

Package Insert Update

The package insert for Rhinathiol 2% Children and Infant Syrup will be updated with the following information:

1. Posology and method of administration:

Children aged 2 to 5 years: one 5ml measuring spoon twice a day.

Children aged over 5 years: one 5ml measuring spoon three times a day.

2. Contraindications:

This drug MUST NOT BE USED IN THE FOLLOWING SITUATIONS:

- *Known allergy to one of the ingredients of the medicine (particularly methyl parahydroxybenzoate and other parabens),*
- *Infants (under 2 years of age), as there is a risk of worsening the airway congestion.*

New Product Name

The packaging of Rhinathiol 2% Children and Infant Syrup will be changed and renamed as:

Rhinathiol 2% Children Syrup

The local introduction of the new product packaging with new package insert for Rhinathiol 2% Children Syrup is estimated to take place in February 2011. In the mean time, it is important that all healthcare professionals take into consideration the above information when prescribing or dispensing Rhinathiol 2% Children and Infant Syrup to their patients.

Call for reporting

Healthcare professionals are encouraged to report suspected adverse reactions associated with the use of Rhinathiol 2% Children and Infant Syrup to Sanofi-Aventis Singapore Pte Ltd at tel: +65 6226 3836, fax: +65 6334 2539 or to the Vigilance Branch, Health Products Regulation Group, Health Sciences Authority at tel:6866 3538, fax:6478 9069.

Communication information

If you have any further questions or require additional information, please contact our Medical Information department at Sanofi-Aventis Singapore Pte Ltd; tel: +65 6226 3936.

Yours sincerely,



Dr Shahnun Ahmad
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