

PRAC considers risk of severe allergic reactions with ambroxol- and bromhexine-containing medicines to be small

Update of product information is recommended

The EMA's Pharmacovigilance Risk Assessment Committee (PRAC) has completed a review of medicines containing ambroxol or bromhexine. This follows concerns over the risk of allergic reactions with these medicines, which are widely used as expectorants (to help clear mucus from the airways).

The PRAC considers that the risk of allergic reactions is small, but has recommended that the product information for these medicines should be updated with further information on severe allergic reactions, and that severe skin reactions (SCARs) should be introduced as a side effect. SCARs include conditions such as erythema multiforme and Stevens-Johnson syndrome.

Read more on the hyperlink:

http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2015/01/news_detail_002248.jsp&mid=WC0b01ac058004d5c1