



## SFDA SAFTEY COMMUNICATION

July 13<sup>th</sup>, 2014

**Subject: Risk of hypersensitivity reactions of products containing ambroxol and bromhexine.**

The Saudi Food and Drug Authority would like to inform the healthcare professionals and the public that after reviewing the safety profile for products containing ambroxol and bromhexine (secretolytic agents of acute and chronic bronchopulmonary diseases), it has been found that these drugs might be associated with rare but severe allergic reactions such as anaphylactic shock. The signs and symptoms of these reactions may include rash, itchy eyes, angioedema (swelling of the deeper layers of the skin) and breathing difficulties. Healthcare professionals should be aware of the risk of hypersensitivity reactions associated with these drugs and counsel patients about how to recognize the possible signs and symptoms. Patients should seek emergency medical attention immediately if they develop any signs and symptoms of a serious allergic reaction while taking these drugs.

The Saudi Food and Drug Authority (SFDA) continues to monitor the safety of pharmaceutical products in Saudi Arabia. For further information please contact us using the following information:

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