



SFDA SAFETY COMMUNICATION

17-01-2016

Saudi Food and Drug Authority (SFDA) –Potential Risk of Serious Hypersensitivity Reactions Related to Salicylic Acid or Benzoyl Peroxide Containing Products

Saudi Food and Drug authority (SFDA) would like to notify health care professionals and consumers that some skincare products for acne treatment, that contain benzoyl peroxide or salicylic acid, can cause rare but serious hypersensitivity reactions, known as anaphylactic reaction.

There have been several internationally reported cases of hypersensitivity reactions related to these products, and no reported death. The symptoms include fainting, breathing problems, throat tightness, low blood pressure or swelling of the eyes, face, lips or tongue.

Consumers should stop using these products and get an immediate medical help if any of those symptoms occurs. Consumers should also stop using these products when they experience itching or hives.

SFDA emphasizes that these hypersensitivity reactions are not the same as mild skin irritations include redness, burning, peeling, and mild swelling that can occur at the application site and are already mentioned in most products' labels.

Report Adverse Drug Events (ADRs) to the SFDA

The SFDA urges both healthcare professionals and patients to report ADRs resulted from using any medications to the SFDA either online, by regular mail or by fax, using the following contact information:

National Pharmacovigilance and Drug Safety Center (NPC)

Saudi Food and Drug Authority-Drug sector

3292 Northern Ring Road

Al Nafal District
Riyadh 13312 – 6288
Kingdom of Saudi Arabia
Toll free number: 8002490000
Tel: 01 2038222 ext. 2317, 2356, 2340, 5769
Fax: 01 2057662
Email: NPC.Drug@sfda.gov.sa