

SFDA
Safety Communication

[15/11/2022]

The Potential Risk of Dependence and Abuse with the Use of products containing Pseudoephedrine and/or Dextromethorphan

The Saudi Food and Drug authority (SFDA) would like to notify healthcare professionals about the safety labeling changes for cough and cold medicines containing pseudoephedrine and/or dextromethorphan. This safety concern was triggered by some local cases of dependence.

Dextromethorphan suppresses the cough reflex by directly acting on the cough center in the medulla. While pseudoephedrine acts as a decongestant by stimulating alpha-adrenergic receptors of vascular smooth muscle.

The SFDA reviewed the current evidence including published literature and post-marketing data on the potential risk of dependence and abuse with the use of products containing pseudoephedrine and/or dextromethorphan. Our review found two systematic reviews, one retrospective study, two case reports, and 11 local cases suggesting a possible association between pseudoephedrine and/or dextromethorphan containing products and the risk of dependence/abuse. Most cases were young male patients. Moreover, we identified 1258 spontaneous case reports (1,136 cases for dextromethorphan and 122 cases for pseudoephedrine) in the World Health Organization (WHO) database.

Therefore, the SFDA requests to update the product information of pseudoephedrine and/or dextromethorphan as following:

- **Products containing Pseudoephedrine:**

Special warnings and precautions for use:

As with other CNS stimulants, pseudoephedrine sulphate carries the risk of abuse. Increased doses may ultimately produce toxicity. Continuous use can lead to tolerance resulting in an increased risk of overdosing.

- **Products containing Dextromethorphan:**

Special warnings and precautions for use:

Drug dependence, tolerance, and potential abuse:

Prolonged use of product containing dextromethorphan such as this product may lead to drug dependence (addiction), even at therapeutic doses. The risks are increased in individuals with current or past history of substance misuse disorder (including alcohol misuse) or mental health disorder (e.g., major depression). Caution is particularly recommended for adolescents and young adults as well as in patients with a history of drug abuse or psychoactive substances.

Undesirable effects:

Psychiatric disorders: drug dependence (frequency unknown).

Call for reporting:

The SFDA urges both healthcare professionals and patients to report ADRs related to use of any drug/vaccine to the SFDA using the following contact information:

The National Pharmacovigilance Centre (NPC):

Call Center: 19999

E-mail: npc.drug@sfd.gov.sa

Website: <https://ade.sfd.gov.sa>

Risk Minimization Measures:

