SFDA
Safety communication

July 28, 2022

SFDA Recommendations for Healthcare Professionals regarding Hypersensitivity Reaction Cases Reported with Levothyroxine Containing Products

The Saudi Food and Drug Authority (SFDA) would like to aware healthcare professionals about cases of hypersensitivity reaction reported with the new formulation of Euthyrox® (levothyroxine) worldwide.

Merck Company was introduced new formulation of Euthyrox® in March 2020 in Saudi Arabia. The new modification to the formulation's excipients included removal of the non-active ingredient lactose, and replacement with mannitol and citric acid. These excipients are commonly safe and used in tablet formulations.

Hypersensitivity reactions to Euthyrox® product are rare, but it could occur due to the active ingredient or excipients such as citric acid, mannitol, or gelatin. These reactions generally appear as generalized urticaria, angioedema, eczematiform skin eruption, and rash.

Levothyroxine is used to treat hypothyroidism. Currently, two brand of levothyroxine containing products are registered in Saudi Arabia as shown in the below table:

Scientific Name	Trade Name	Pharmaceutical Company	Excipients
LEVOTHYROXINE	EUTHYROX® 0.05 mg Tablet	Merck Healthcare	○ Maize starch ○ Citric acid ○ Croscarmellose sodium ○ Gelatine ○ Magnesium stearate ○ Mannitol
	EUTHYROX® 0.025 mg Tablet		
	EUTHYROX® 0.15 mg Tablet		
	EUTHYROX® 0.1 mg Tablet		
	ELTROXIN® 0.05 mg Tablet	Aspen Pharma Trading Limited	○ Microcrystalline cellulose ○ Pregelatinised starch (maize starch 1500) ○ Magnesium stearate ○ Talc ○ Colloidal anhydrous silica
	ELTROXIN® 0.1 mg Tablet		

Advice to healthcare providers:

- Monitor carefully your patients (thyroid function tests and experience of adverse events) after switching to a new brand or new formulation of levothyroxine containing products.
- Oral desensitization protocol can be used for patients with hypersensitivity reactions to levothyroxine containing products until achieving the target daily therapeutic dose, **if there is no alternative therapy available.**
- Report any adverse events including hypersensitivity reaction and lack of efficacy with the use of levothyroxine containing products to the SFDA.

Call for reporting:

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

The National Pharmacovigilance Centre (NPC):

Call Center: 19999

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

Website: https://ade.sfda.gov.sa