

Date: 14-09-2023

Direct Healthcare Professional Communication

Notification of typing error in Torvacol 40mg (atorvastatin) mentioned on the side panel

Dear Healthcare professional,

The Jordanian Pharmaceutical Manufacturing in agreement with the Saudi Food and Drug Authority (SFDA), would like to inform you of the following:

Summary:

We have discovered a typing error between the main panel (40mg) and the strength mentioned on the side panel of the outer package (20mg). The typing error is only on one side (Arabic):

This issue occurred in specific batches **refer to attachment #1** which were previously released in the Saudi market.

Description of the issue as detailed in the table below:

Incorrect Description (Showing on the package side label)	Correct Description	Corrective action Upon SFDA recommendation:
كل قرص تورفاكول 20 يحتوي على أتروفاستاتين 20 ملغم على هيئة أتروفاستاتين كالسيوم.	كل قرص تورفاكول 40 يحتوي على أتروفاستاتين 40 ملغم على هيئة أتروفاستاتين كالسيوم.	1. Permeant adhesive label to cover and correct the wrong information in existing stocks. 2. Artwork correction for upcoming shipments.

List of MAH product:

Active substance	Brand name
Atorvastatin as atorvastatin calcium	Torvacol 40mg Film Coated Tablet

Call for reporting for adverse reactions

As a reminder, there is a need to report any suspected adverse reaction to the national pharmacovigilance center (NPC)

- Fax: +966-11-205-7662
- SFDA Call Center: 19999
- E-mail: npc.drug@sfda.gov.sa
- Website: <https://ade.sfda.gov.sa>

Company contacts point

Pharmacovigilance Manager:

Al-Jawhara Al-Azman

The Jordanian Pharmaceutical Manufacturing (JPM)
Al Khazan Street Al-Khaldiya Building -12th Floor
Riyadh - Kingdom of Saudi Arabia
Landline: +966114041703
Mobile: +966590008191

Name of QPPV and the stamp

Al-Jawhara Ibrahim Al-Azman



د. الجوهرة إبراهيم العزمان

مدير التيقظ الدوائي



Attachment #1 :Batch numbers for Torvacol 40 mg Atorvastatin

2106079	2212074
2107058	2212075
2111035	2212076
2207044	2212077
2209045	2212078
2211049	2212079
2211050	2212080
2211051	2212081
2211052	2212086
2211053	2212087
2212069	2303017
2212070	2303049
2212071	2303050
2212072	2305039
2212073	