



Ref. #: SAU-PV-005/2020

Date: 06 May 2020

Subject: Megamox® 625mg tablets is associated with a typographic error in the units for the weight of the product stated on the aluminum foil.

Dear Healthcare Professional,

Please note that Jazeera Pharmaceuticals Industries (JPI) (part of Hikma Pharmaceuticals), the marketing authorization holder (MAH) of amoxicillin trihydrate and clavulanic acid (Megamox®) would like to inform you of the following:

Summary

The Saudi Food and Drug Authority (SFDA) has concluded that amoxicillin trihydrate and clavulanic acid (Megamox®) tablets is associated with a typographic error in weight unit in Arabic text on the aluminum foil which stated "جرام" (grams) instead of "ملجم" (milligrams). The affected batches are mentioned in Attachment #1.

Background on the error concern

This error will not likely to have risk on the product integrity, safety, strength, purity and quality.

Health care professionals should consider this dosing unit when prescribing and dispensing amoxicillin trihydrate and clavulanic acid (Megamox®).

Call for reporting

As a reminder, there is a need to report any suspected adverse reactions to the National Pharmacovigilance Center (NPC):

- SFDA call center: 19999
- Toll free phone: 8002490000
- E-mail: npc.drug@sfda.gov.sa
- Website: <http://ade.sfda.gov.sa/>
- Fax: +966-11-2057662

Pharmacovigilance department:

- Name of QPPV: Norah Al-Suwaidan
- Telephone: +966(11) 4173731 Ext: 1086
- Email: jpimedical@hikma.com

Sincerely,

Local QPPV

Norah Mohammed Al-Suwaidan



Attachment #1: The following batches contain the described typographic error in weight units:

S.I	Description	Batch	Mfg. Date	Exp. Date
1	Megamox 625 Mg Tab/ 20 ORG	195040	01.01.2019	01.01.2021
2	Megamox 625 Mg Tab/ 20 ORG	195041	01.01.2019	01.01.2021
3	Megamox 625 Mg Tab/ 20 ORG	195056	01.01.2019	01.01.2021
4	Megamox 625 Mg Tab/ 400 bulk std	195059	30.01.2019	01.01.2021
5	Megamox 625 Mg Tab/ 20 ORG	195101	01.03.2019	01.03.2021
6	Megamox 625 Mg Tab/ 400 bulk std	195102	01.03.2019	01.03.2021
7	Megamox 625 Mg Tab/ 20 w/p	195127	01.03.2019	01.03.2021
8	Megamox 625 Mg Tab/ 7 FMS	195128	01.03.2019	01.03.2021
9	Megamox 625 Mg Tab/ 400 bulk std	195129	01.03.2019	01.03.2021
10	MEGAMOX 625 TAB /400 TAB BULK MOI	195130	01.03.2019	01.03.2021
11	Megamox 625 Mg Tab/ 20 ORG	195143	01.04.2019	01.04.2021
12	Megamox 625 Mg Tab/ 20 ORG	195151	01.04.2019	01.04.2021
13	Megamox 625 Mg Tab/ 20 ORG	195154	01.03.2019	01.03.2021
14	MEGAMOX 625 TAB /400 TAB BULK MOI	195156	01.04.2019	01.04.2021
15	MEGAMOX 625 TAB /400 TAB BULK MOH	195179	01.05.2019	01.05.2021
16	MEGAMOX 625 TAB /400 TAB BULK MOH	195180	01.05.2019	01.05.2021
17	MEGAMOX 625 TAB /400 TAB BULK MOH	195181	01.05.2019	01.05.2021
18	MEGAMOX 625 TAB /400 TAB BULK MOH	195182	01.05.2019	01.05.2021
19	MEGAMOX 625 TAB /400 TAB BULK MOH	195183	01.05.2019	01.05.2021
20	MEGAMOX 625 TAB /400 TAB BULK MOH	195184	01.05.2019	01.05.2021
21	MEGAMOX 625 TAB /400 TAB BULK MOH	195186	01.06.2019	01.06.2021

22	MEGAMOX 625 TAB /400 TAB BULK MOH	195187	01.06.2019	01.06.2021
23	MEGAMOX 625 TAB /400 TAB BULK MOH	195188	01.06.2019	01.06.2021
24	MEGAMOX 625 TAB /400 TAB BULK MOI	195213	01.05.2019	01.05.2021
25	MEGAMOX 625 TAB /400 TAB BULK MOH	195214	01.05.2019	01.05.2021
26	MEGAMOX 625 TAB /400 TAB BULK MOH	195238	01.06.2019	01.06.2021
27	MEGAMOX 625 TAB /400 TAB BULK MOH	195239	01.07.2019	01.07.2021
28	MEGAMOX 625 TAB /400 TAB BULK MOH	195240	01.07.2019	01.07.2021
29	MEGAMOX 625 TAB /400 TAB BULK MOH	195241	01.07.2019	01.07.2021
30	MEGAMOX 625 TAB /400 TAB BULK MOH	195242	01.07.2019	01.07.2021
31	MEGAMOX 625 TAB /400 TAB BULK MOH	195254	01.07.2019	01.07.2021
32	Megamox 625 Mg Tab/ 20 ORG	195275	01.07.2019	01.07.2021
33	MEGAMOX 625 TAB /400 TAB BULK MOI	195276	01.07.2019	01.07.2021
34	MEGAMOX 625 TAB /400 TAB BULK MOI	195279	01.07.2019	01.07.2021
35	MEGAMOX 625 TAB /400 TAB BULK MOH	195280	01.07.2019	01.07.2021
36	MEGAMOX 625 TAB /400 TAB BULK MOI	195316	01.08.2019	01.08.2021
37	MEGAMOX 625 TAB /400 TAB BULK MOH	195319	01.09.2019	01.09.2021
38	MEGAMOX 625 TAB /400 TAB BULK MOH	195348	01.09.2019	01.09.2021
39	Megamox 625 Mg Tab/ 20 ORG	195363	01.09.2019	01.09.2021
40	Megamox 625 Mg Tab/ 400 bulk std	195364	01.09.2019	01.09.2021
41	MEGAMOX 625 TAB /400 TAB BULK MOH	195365	01.09.2019	01.09.2021
42	MEGAMOX 625 TAB /400 TAB BULK MOH	195370	18.11.2019	18.11.2021
43	Megamox 625 Mg Tab/ 7 FMS	195387	01.09.2019	01.09.2021
44	Megamox 625 Mg Tab/ 20 ORG	195388	01.09.2019	01.09.2021

45	Megamox 625 Mg Tab/ 20 ORG	195389	01.09.2019	01.09.2021
46	MEGAMOX 625 TAB /400 TAB BULK MOH	195390	01.09.2019	01.09.2021
47	Megamox 625 Mg Tab/ 400 bulk std	195392	01.09.2019	01.09.2021
48	MEGAMOX 625 TAB /400 TAB BULK MOH	195437	19.11.2019	19.11.2021
49	MEGAMOX 625 TAB /400 TAB BULK MOH	195438	20.11.2019	20.11.2021
50	MEGAMOX 625 TAB /400 TAB BULK MOH	195439	21.11.2019	21.11.2021
51	MEGAMOX 625 TAB /400 TAB BULK MOH	195441	26.11.2019	26.11.2021
52	MEGAMOX 625 TAB /400 TAB BULK MOH	195442	27.11.2019	27.11.2021
53	MEGAMOX 625 TAB /400 TAB BULK MOH	195443	28.11.2019	28.11.2021
54	MEGAMOX 625 TAB /400 TAB BULK MOH	195444	01.12.2019	01.12.2021
55	MEGAMOX 625 TAB /400 TAB BULK MOH	195445	02.12.2019	02.12.2021
56	MEGAMOX 625 TAB /400 TAB BULK MOH	195446	06.12.2019	06.12.2021
57	MEGAMOX 625 TAB /400 TAB BULK MOH	195447	07.12.2019	07.12.2021
58	MEGAMOX 625 TAB /400 TAB BULK MOH	195448	09.12.2019	09.12.2021
59	MEGAMOX 625 TAB /400 TAB BULK MOH	195449	12.12.2019	12.12.2021
60	MEGAMOX 625 TAB /400 TAB BULK MOH	195450	15.11.2019	15.11.2021
61	Megamox 625 Mg Tab/ 20 ORG	195451	22.11.2019	22.11.2021
62	Megamox 625 Mg Tab/ 400 bulk std	195457	12.12.2019	12.12.2021
63	MEGAMOX 625 TAB /400 TAB BULK MOH	195472	12.12.2019	12.12.2021
64	Megamox 625 Mg Tab/ 400 bulk std	205018	27.01.2020	27.01.2022
65	Megamox 625 Mg Tab/ 20 ORG	205035	21.02.2020	21.02.2022
66	Megamox 625 Mg Tab/ 20 ORG	205036	21.02.2020	21.02.2022
67	Megamox 625 Mg Tab/ 20 ORG	205037	23.02.2020	23.02.2022

68	Megamox 625 Mg Tab/ 400 bulk NUPCO	205051	23.02.2020	23.02.2022
69	Megamox 625 Mg Tab/ 400 bulk NUPCO	205073	08.03.2020	08.03.2022
70	Megamox 625 Mg Tab/ 7 FMS	205084	19.03.2020	19.03.2022
71	MEGAMOX 625 TAB /400 TAB BULK MOH	205085	19.03.2020	19.03.2022
72	MEGAMOX 625 TAB /400 TAB BULK MOH	205111	25.03.2020	25.03.2022
73	MEGAMOX 625 TAB /400 TAB BULK MOH	205112	29.03.2020	29.03.2022
74	MEGAMOX 625 TAB /400 TAB BULK MOH	205113	31.03.2020	31.03.2022
75	MEGAMOX 625 TAB /400 TAB BULK MOH	205114	03.04.2020	03.04.2022
76	Megamox 625 Mg Tab/ 400 bulk NUPCO	205130	31.03.2020	31.03.2022