

Date: 31/10/2022

Idacio® (Adalimumab), Clarification of outer pack Stickers

Dear Healthcare Professional,

Fresenius Kabi in agreement with the Saudi Food and Drug Authority would like to inform you of important information for Idacio:

Summary

- The outer pack of Idacio of batch numbers: 16RE4372 and 16RD4334 have incorrect Arabic translation of the following sentence “solution for injection” was written in Arabic as “محلول للتسريب الوريدي” instead of “محلول للحقن”, to correct that; the stickers have been applied stating “محلول للحقن” in the outer packs of both pre-filled pen and pre-filled syringe of Idacio.
- The dosage form of Idacio is “solution for injection”, “محلول للحقن”.

Further information on the safety concern and the recommendations

Idacio is TNF blockers used to treat immune-system diseases, such as Crohn’s disease, ulcerative colitis, rheumatoid arthritis, ankylosing spondylitis, psoriatic arthritis, and plaque psoriasis.

We are confirming that this concern is related ONLY to batch numbers 116RE4372 and 16RD4334 and the concern has been solved with our manufacturing facilities to avoid any inconvenience.

Call for reporting

You can help provide more information on the safety of this medicine for National Pharmacovigilance Centre (NPC) by one of the following:

- SFDA Call Center: 19999
- E-mail: npc.drug@sfd.gov.sa
- Website: <https://ade.sfda.gov.sa/>
-

Company contacts point

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