

## DIRECT HEALTHCARE PROFESSIONAL COMMUNICATION (DHPC)

7 November 2024

## CalSource Forte effervescent tablets - Calcium 500 mg - Labelling Information Error

## Dear Healthcare Professional,

Haleon KSA in agreement with the Saudi Food and Drug Authority would like to inform you of the following:

- Summary
- It has been recently brought to the attention of Haleon that the CalSource Fort effervescent tablets product in market has a labelling error on the outer packaging.
- The error appears as misspelling under the ingredients section of the outer packaging as the dosage of "Calcium lactate-gluconate 1132 gm" instead of "Calcium lactate-gluconate 1132 mg".
- The identified misprint does not impact the usual product dosage and recommendation.
- Further information on the safety concerns and the recommendations

Haleon totally understand that this labelling error could cause confusion to some healthcare professionals in terms of identifying the correct ingredient dosage. Therefore, this letter has been developed and distributed to explain the issue and avoid any confusion.

Haleon would like to confirm that the identified error appears only on the outer pack. However, the product insert leaflet and rest of labelling information are accurate and represent the correct dosage of ingredients within the pack.

- To report any adverse event(s):

Kingdom of Saudi Arabia

-National Pharmacovigilance center (NPC)

Reporting Hotline: 19999 E-mail: npc.drug@sfda.gov.sa Website: https://ade.sfda.gov.sa

- Haleon Arabia Limited - Head Office, Jeddah

Mobile: +966-53-553-3647 Email: <u>mystory.sa@haleon.com</u>

P.O. Box 48034, Jeddah 21572, Saudi Arabia

للإبلاغ عن أي آثار جانبية:

المملكة العربية السعودية - المركز الوطني للتيقظ (NPC)

رحر الوطني للنيقط (NPC) الاتصال بالرقم الموحد: 19999

البريد الإلكتروني: npc.drug@sfda.gov.sa الموقع الإلكتروني: https://ade.sfda.gov.sa

- هاليون العربية المحدودة - المكتب الرئيسي، جدة.

جوال: 3647-553-553+96+ البريد الإلكتروني: <u>mystory.sa@haleon.com</u>

ص.ب. 48034، جدة 21572، المملكة العربية السعودية

- Haleon Products

Product Name	Active ingredients
CalSource Forte effervescent Tablets	Calcium lactate gluconate 1132 mg + Calcium carbonate 875 mg

Yours respectfully,

For and on behalf of Haleon,

Hosam M Bin Homed

Local Safety Responsible - KSA

Hosam M. Bin Homed

Electronically signed by: Hosam M Bin Homed Reason: I am signing this document as author and attest to its accuracy, completeness and integrity. Date: Nov 7, 2024 17:39 GMT+3