

13 March 2025

KISQALI® (Ribociclib): change of storage conditions

Dear Healthcare professional,

Novartis Saudi Arabia in agreement with the **Saudi Food and Drug Authority (SFDA)** would like to inform you of the new proposed **storage conditions for KISQALI (Ribociclib)**,

Summary new storage conditions for KISQALI (Ribociclib)

- **KISQALI (Ribociclib)** will need to be **stored refrigerated between 2°C and 8°C** with **shelf life of 18 months**.
- It is important that patients are informed that they must store **KISQALI (Ribociclib) between 2°C and 8°C**.
- The product information ([summary of product characteristics and package leaflet](#)) has been updated to **reflect the new storage conditions**.

Background

- The **storage conditions and shelf-life for KISQALI (Ribociclib)** have been updated to ensure the quality of the product throughout its shelf-life, the update is still under Saudi FDA review process and expected to be approved soon, while the **Current ambient stock** should be stored as per instructions in the applicable product information.
- These **changes do not impact any outcomes** when it comes to the **efficacy and safety of Ribociclib**, it just means storage conditions may differ. Therefore, patients can continue to **use Ribociclib safely in metastatic breast cancer patients**.

Indication

Advanced or metastatic breast cancer

Kisqali is indicated for the treatment of adults with hormone receptor (HR)- positive, human epidermal growth factor receptor 2 (HER2)-negative (locally) advanced or metastatic breast cancer in combination with:

- an aromatase inhibitor as initial endocrine therapy or
 - Fulvestrant as initial endocrine therapy or following prior endocrine therapy in postmenopausal women or in men.
- In pre- or perimenopausal women or in men the endocrine therapy should be combined with a luteinising hormone-releasing hormone (LHRH) agonist.

Request

At the time being, there will soon be **two different presentations** of KISQALI available. We request you to:

- **Prioritize depleting the ambient presentation of KISQALI (Ribociclib) for advanced/metastatic breast cancer patients before** distributing or using the **cold chain presentation**.
- Once the Early Breast Cancer (eBC) indication is approved by the SFDA, Novartis will initiate the return of ambient pack quantities along with the cold chain presentation.

Call for reporting

Any suspected adverse events should be reported to:

Novartis Saudi Ltd

Toll Free Number: 8001240078

Phone: +966112658100

Fax: +966112658107

Email: adverse.events@novartis.com Or by

online: <https://report.novartis.com/>



The National Pharmacovigilance Centre (NPC- Saudi Food and Drug Authority (SFDA))

Unified Contact Center: 19999

Email: npc.drug@sfda.gov.sa

Or by online: <https://ade.sfda.gov.sa>



Novartis contact point:

Novartis Saudi Patient Safety Department Details and Contacts	
Patient Safety Generic Email adverse.events@novartis.com Toll Free: 8001240078	
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Sincerely,

Hajer Alsaleh

Patient safety manager /QPPV

Novartis Saudi