Direct Healthcare Professional Communication

July 2025

Kisqali® (ribociclib) 200 mg film coated tablet: Observed Patient Enrolled on Kisqali Patient Support Program with Early Breast Cancer (off-label use)

Dear Healthcare Professional,

Novartis, in agreement with the General Administration for Pharmaceutical Vigilance of the Central Administration for Pharmaceutical Care at The Egyptian Drug Authority, would like to inform you of the following:

Summary:

- Novartis has become aware that a number of patients have been enrolled into the Novartis Patient Support Program (PSP) named “Enaya” that have taken Kisqali for early Breast Cancer (eBC), which is an indication not currently approved in Egypt, i.e., off-label indication.
- Kisqali® (ribociclib) 200 mg film coated tablet available in the Egyptian market is locally approved for the treatment of patients with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative (locally) advanced or metastatic breast cancer (mBC) in combination with an aromatase inhibitor or fulvestrant.
- Kisqali was recently approved in the EU and US for eBC patients, with changed storage conditions and shelf life.
- In Egypt, ribociclib (KISQALI®) should not be prescribed to eBC patients until the eBC indication receives regulatory approval.
- Accordingly, starting 20-May-2025, for new patients seeking PSP enrollment, Novartis require a written confirmation by the treating physician that the patient is seeking Kisqali for mBC. Only patients with mBC will be able to enroll in the Kisqali PSP “Enaya”.
- Patients already enrolled within “Enaya” PSP with a confirmed eBC diagnosis (off-label) will not be able to continue participation in the PSP and their accounts will need to be deactivated. Please discuss with your impacted patients to help their transition off the Kisqali PSP.

Background

Novartis initiated an internal review of its current PSP “Enaya” for patients taking lower doses than 600mg/day which is the recommended starting dose for Advanced/metastatic Breast Cancer (mBC). Upon this review, it was identified that a number of patients enrolled within the PSP were treated with Kisqali for eBC which is not an approved indication in Egypt raising an off-label use concern.

As a result, and to ensure the appropriate and safe use of Kisqali®, Novartis, in agreement with the Pharmaceutical Vigilance General Administration at the Egyptian Drug Authority, are providing the above recommendation in order to reinforce the current approved indication.

The purpose of this letter is to inform you about the identified off-label use and to remind you that Kisqali is approved for patients with advanced or metastatic breast cancer and is not intended for the treatment of eBC in the context of the PSP “Enaya”. This information should be considered in clinical practice and prescribing behavior going forward.

Given the eBC indication is not currently approved in Egypt, patients currently on Kisqali for this indication will no longer be part of the program. As the prescriber, please discuss with your patients to help their transition off the Kisqali PSP. To enable an appropriate transition out of the Enaya PSP for the impacted patients with eBC, Novartis will align with the Egyptian Drug Authority a phasing out period of up to 6 months.

Please contact Novartis' Medical Affairs department if you have questions or concerns regarding the off-boarding of your patient from the Kisqali PSP.

Call for reporting

Healthcare professionals are asked to report any suspected adverse reactions via the Egyptian reporting system:

Name: General Administration for Pharmaceutical Vigilance

Email: pv.followup@edaegypt.gov.eg

Online reporting: : https://vigiflow-eforms.who-umc.org/eg/med

QR Code:

Hotline: 15301