



IMPORTANT MEDICINE INFORMATION

28 May 2024

Dear Healthcare Professional

DEREGISTRATION OF APPROVED INDICATIONS FOR GAVRETO® (PRALSETINIB) AND REMOVAL FROM THE SOUTH AFRICA PHARMACEUTICAL MARKET

Roche Products (Pty) Ltd in collaboration with South African Health Products Regulatory Authority (SAHPRA) would like to inform you about deregistration of approved indications for Gavreto® (pralsetinib) and the removal from the South African pharmaceutical market.

Summary

- Gavreto® (pralsetinib) is a prescription medicine indicated to treat certain cancers caused by abnormal rearranged during transfection (RET) genes.
- The product will be deregistered from the South African pharmaceutical market due to development discontinuation in the country and other parts of the world.
- Healthcare professionals should consider alternative therapy options, for newly identified patients with RET-driven tumors.
- The planned deregistration and removal of Gavreto® (pralsetinib) from the South African pharmaceutical market is not based on any new clinical efficacy or safety information, and the known and established benefit-risk profile of the medicine in its approved indications remains unchanged.
- Gavreto® (pralsetinib) will be deregistered upon distribution of this dear healthcare professional letter.

Background

Gavreto® (pralsetinib) is indicated for the treatment of adult patients with:

- RET-fusion positive, locally advanced or metastatic non-small cell lung cancer.
- Locally advanced or metastatic RET-mutant medullary thyroid cancer.
- Locally advanced or metastatic RET-fusion positive thyroid cancer who require systemic therapy and who are radioactive iodine-refractory (if radioactive iodine is appropriate).

Gavreto® (pralsetinib), developed and marketed by Blueprint Medicines Pharmaceutical Company, globally, is registered by Roche Products (Pty) Ltd in South Africa.

On the 8th of January 2024, Blueprint Medicines Pharmaceutical Company, provided a public update on Gavreto® (pralsetinib), announcing their decision to discontinue global marketing and development of this product in all territories excluding the United States and Greater China. This discontinuation means that ongoing clinical trials will be closed.

In light of this background, Roche Products (Pty) Ltd came to a decision, in February 2024, to terminate a global collaboration agreement with Blueprint Medicines Pharmaceutical Company, to develop and commercialise Gavreto® (pralsetinib).

Advise to healthcare professionals

- Healthcare professionals are requested to explore other treatment options for newly identified patients eligible for treatment with this product.
- Healthcare professionals are urged to report any adverse drug reactions (ADRs) or product quality issues associated with medicines marketed by Roche Products (Pty) Ltd to global.irt_sahubtcs@roche.com or to SAHPRA by completing an ADR reporting form accessible via this link <https://www.sahpra.org.za/document/adverse-drug-reactions-and-quality-problem-reporting-form/> and send it to adr@sahpra.org.za.
- Healthcare professionals may report via this eReporting link <https://primaryreporting.who-umc.org/ZA> available on the SAHPRA website (www.sahpra.org.za).
- Additionally, reporting can be done via Med Safety App. The App can be downloaded into a smart mobile phone through Google Play or Apple App Store. For more information on Med Safety App, please visit <https://medsafety.sahpra.org.za/>.
- For more information on ADR reporting, please contact the SAHPRA Pharmacovigilance unit at pvqueries@sahpra.org.za.
- For further information and clarity regarding this communication please contact REAL (Roche Ethical Assistance Line) at 0800 21 21 25 or P O Box 1469, Halfway House, 1685 or <https://www.roche.co.za/>.

References

1. Press release: <https://ir.blueprintmedicines.com/news-releases/news-release-details/blueprint-medicines-regain-global-rights-GAVRETO-pralsetinib>
2. Press release: <https://ir.blueprintmedicines.com/news-releases/news-release-details/blueprint-medicines-highlights-2024-corporate-strategy-and>

Yours sincerely,
Roche Products (Pty) Ltd

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