



LAO PEOPLE 'S DEMOCRATIC REPUBLIC
PEACE INDEPENDENCE DEMOCRACY UNITY PROSPERITY

MINISTRY OF HEALTH
FOOD AND DRUG DEPARTMENT
TEL (856 21) 214013, 214014
FAX: (856 21) 214015.

Certificate of Drug Registration
Registration Number:05-LM-10023-26

ALIERDATINI

Dosage Form	TABLET
Active Ingredients	ERDAFITINIB 4mg
Description	This product is a orange tablets, 56 tablets per bottle.
Size of packaging unit	56 TABLET
Indications	See Annex
Manufacturer	LAOS ALLIANCE PHARMACEUTICAL GROUP COMPANY SAYSETHA DEVELOPMENT ZONE, SAYSETHA DISTRICT, VIENTIANE CAPITAL, LAO PDR

This Certificate is issued to attest that the product described above has met the minimum standards required for drug registration undertaken by the Food and Drug Department in Lao PDR.

This certificate expires, unless previously suspended or revoked, on **30 June 2031**

Note: All boxes and packaging for importations must bear the Lao Registration No. **05-LM-10023-26**

At, Vientiane, **May 25, 2026**



ດຣ. ສຸກສິມຄວນ ຈັນທະມາດ



Registration Number:05-LM-10023-26

ALIERDATINI

ANNEX

INDICATIONS

• ALIERDATINI is a kinase inhibitor indicated for the treatment of adult patients with locally advanced or metastatic urothelial carcinoma (mUC) with susceptible FGFR3 genetic alterations whose disease has progressed on or after at least one line of prior systemic therapy.

• ALIERDATINI ເປັນສານຢັບຢັງ Kinase ທີ່ໃຊ້ສໍາລັບການປິ່ນປົວຄົນເຈັບຜູ້ໃຫຍ່ທີ່ເປັນມະເຮັງ ເຍືອເມືອກທາງເດີນທໍ່ສົ່ງຍ່ຽວ ທີ່ມີການແຜ່ລາມ (mUC) ມີການກາຍພັນຂອງຈຸລັງ FGFR3 ທີ່ໄວຕໍ່ຢາ ເຊິ່ງເຮັດໃຫ້ພະຍາດ ໄດ້ມີການແຜ່ລາມໄປແລ້ວ ຫຼື ພາຍຫຼັງຈາກທີ່ມີການບໍາບັດຢ່າງເປັນລະບົບດ້ວຍເຄມີ ຢ່າງຕໍ່າ ໝຶ່ງຮອບ.