



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-10020-26

ALIAVATINI

Dosage Form	TABLET, FILM COATED
Active Ingredients	AVAPRITINIB 100mg
Description	This product is a white film coated tablet?round. It is packaged in an HDPE bottle containing 30 tablets per bottle.
Size of packaging unit	30 TABLETS
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-10020-26**

At, Vientiane, **23 May 2026**



ວຽກ. ສຸກສິມຄວນ ຈັນທະມາດ



Registration Number:05-LM-10020-26

ALIAVATINI

ANNEX

INDICATIONS

ALIAVATINI is a kinase inhibitor indicated for:

Gastrointestinal Stromal Tumor (GIST)

- the treatment of adults with unresectable or metastatic GIST harboring a platelet-derived growth factor receptor alpha (PDGFRA) exon 18 mutation, including PDGFRA D842V mutations.

Advanced Systemic Mastocytosis (AdvSM)

- the treatment of adult patients with AdvSM. AdvSM includes patients with aggressive systemic mastocytosis (ASM), systemic mastocytosis with an associated hematological neoplasm (SMAHN), and mast cell leukemia (MCL).

- ເປັນຢາຢັບຢັງ kinase inhibitor ທີ່ນຳໃຊ້ສຳລັບຮັກສາ:

- ມະເຮັງເນືອງອອກສະໄຕຣມອລໃນກະເພາະອາຫານ

- ການປົວສຳລັບຜູ້ໃຫຍ່ທີ່ເປັນມະເຮັງເນືອງອອກສະໄຕຣມອລໃນກະເພາະອາຫານ (GIST) ທີ່ບໍ່ສາມາດຜ່າຕັດອອກໄດ້ ຫຼື ມີການແຜ່ລາມ

ເຊິ່ງມີການກາຍພັນຂອງຕົວຮັບທີ່ກ່ຽວກັບປັດໃຈໃນການຈະເລີນເຕີບໂຕຈາກເມັດເລືອດ (PDGFRA) exon 18, ລວມທັງການກາຍພັນຂອງ PDGFRA D842V.

ພາວະຈາກການສະສົມຂອງຈຸລັງ Mastocytosis ໃນເຍື່ອເນືອກຕ່າງໆແບບຮຸນແຮງ (AdvSM) (Advanced Systemic Mastocytosis):

- ໃຊ້ປົວປົວຄົນເຈັບຜູ້ໃຫຍ່ທີ່ເປັນ AdvSM (Advanced Systemic Mastocytosis) ມະເຮັງເມັດເລືອດທີ່ມີຄວາມຮຸນແຮງເຊັ່ນ: ມະເຮັງເມັດເລືອດຂາວ (ASM)

ເນືອງອອກທີ່ເກີດໃນຈຸລັງຂອງລະບົບເລືອດ (SMAHN) ແລະ ຈຸລັງມະເຮັງເມັດເລືອດຂາວ (MCL).