HEALTHCARE PROVIDERS REMINDER CARD

Erivedge® Reminder for Healthcare Providers.

Contraindication to:

- Women who are pregnant or breastfeeding
- Women of childbearing potential who do not comply with the Erivedge® Pregnancy Prevention Programme

Female patients of childbearing potential must:

- Take monthly pregnancy test even if patient becomes amenorrhoeic.
- Always use recommended contraception while taking Erivedge® and for 24 months after their final dose.
- Not breast-feed during treatment and for 24 months after their final dose.

Consult healthcare provider immediately during treatment and for 24 months after their last dose:

- If they become pregnant or think for any reason that they may be pregnant.
- If they miss their expected menstrual period.
- If they stop using birth control.
- If they need to change birth control during treatment.

Male patients must:

- Use condoms (with spermicide if available) when having sex with a female partner while taking Erivedge® and for 2 months after their final dose.
- Not donate semen during treatment and for 2 months after the final dose of this medicine.

Notify a healthcare provider if their female sex partner becomes pregnant while they are taking Erivedge® or within 2 months after their last dose.

Healthcare providers must:

- Assess pregnancy status, counsel the patient for teratogenicity risk, and refer the patient and female partner to a specialist.
- Report all confirmed pregnancies to Roche.

All patients must:

- Never give this medicine to another person.
- Return the unused capsules at the end of the treatment (disposal will depend on local requirements).
- Not donate blood during treatment and for 24 months after their final dose.

Prescriber's role in the Erivedge® pregnancy prevention programme

- Educate patients about the risks of teratogenicity associated with exposure to Erivedge® during pregnancy.
- Ensure that patients are capable of complying with the requirements for the safe use of Erivedge®.
- Ensure that patients who are women of childbearing potential have a negative medically supervised pregnancy test within a maximum of 7 days prior to initiating treatment (day of pregnancy test = day 1) and have monthly medically supervised pregnancy tests during treatment.
- Ensure that for patients who are women of childbearing potential, prescriptions of Erivedge® should be limited to 28 days of treatment and continuation of treatment requires a new prescription.
- Ensure that patients who are women of childbearing potential are able of complying with contraceptive measures during Erivedge® treatment and for 24 months after their final dose.
- Since Erivedge® is present in semen, every male patient must understand the risks to the unborn child and use condoms (with spermicide if available), even if he has had a vasectomy, during sex with female partners during treatment and for 2 months after final dose, to prevent exposure to Erivedge®.
- Provide your patient with the brochure "Erivedge® Pregnancy Prevention Programme: Information for patients taking Erivedge®", which contains information and advice about taking Erivedge®
- Report any pregnancies to Roche.
- Refer the patient to a specialist physician in the event of pregnancy.

Further information on Erivedge® side effects, pregnancy prevention and all other instructions can be found in the Erivedge® PI and Patient Leaflet on the Ministry of Health website or on the Roche website at www.roche.co.il..

Any suspected adverse events should be reported to the Ministry of Health according to the National Regulation by using an online form https://sideeffects.health.gov.il/ or by email (adr@MOH.HEALTH.GOV.IL).

Or to Roche Affiliate Safety Reporting contact information:

Israel.DrugSafety@roche.com, Phone: 09-9737722 Fax: 09-9737736

This card and its contents were approved by the Ministry of Health in May 2021.