Erivedge® Reminder

FOR HEALTHCARE PROVIDERS

Material created by Roche

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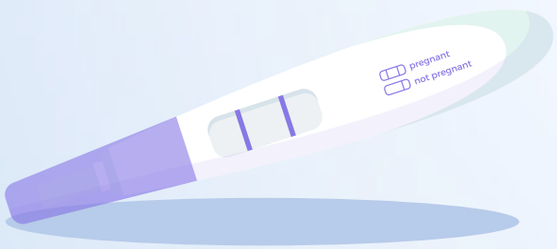
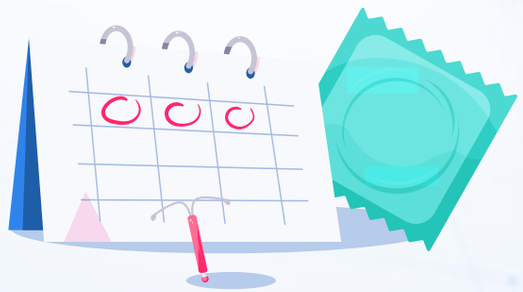
Contraindicated in:

- 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:



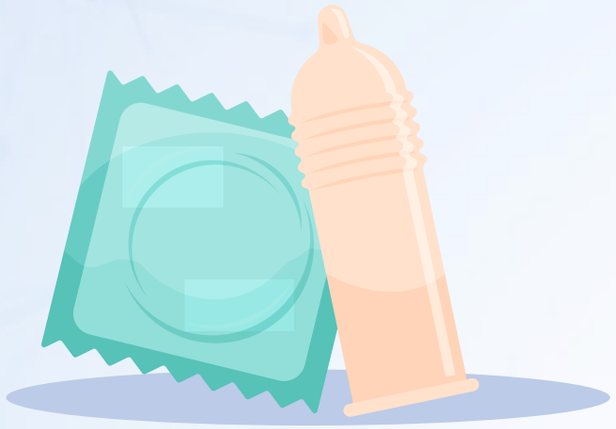
- **Take monthly pregnancy test** even if patient becomes amenorrhoeic.



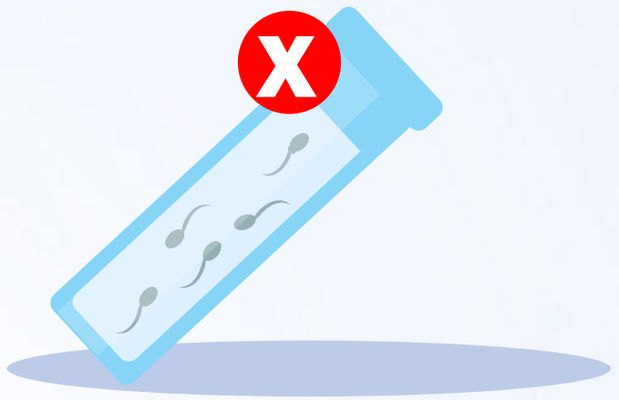
- **Always use recommended contraception** while taking Erivedge® and for 24 months after their final dose.

- **Not breast-feed during treatment** and for 24 months after their final dose.

Male patients must:



- **Use condoms (with spermicide if available)** when having sexual relations 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.

THE PATIENT MUST CONTACT YOU URGENTLY IF A PREGNANCY IS SUSPECTED IN A FEMALE PATIENT OR IN A FEMALE PARTNER OF A MALE PATIENT.

You 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®.**

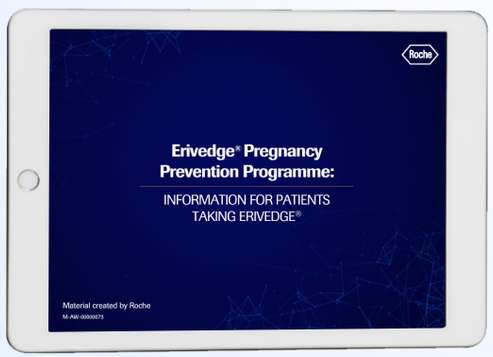
- Ensure that patients who are women of **childbearing potential have a negative medically supervised pregnancy test** within a maximum of 7 days prior to initiating treatment **(day of pregnancy test = day 1) and have monthly medically supervised pregnancy tests during treatment.**

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.

- 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 and pregnancy prevention can be found in the Erivedge® SmPC and Package Leaflet.