

Erivedge® Patient Counselling Guideline

WARNING: EMBRYO-FOETAL DEATH AND SEVERE BIRTH DEFECTS

Erivedge® may cause embryo-foetal death or severe birth defects when administered to a pregnant woman. Hedgehog pathway inhibitors such as Erivedge® have been demonstrated to be embryotoxic and/or teratogenic in multiple animal species and can cause severe malformations, including craniofacial anomalies, midline defects and limb defects. Erivedge® must not be used during pregnancy.

For All Patients

I understand that:

- Erivedge® may cause serious birth defects and can cause the death of a unborn child.
- I must not give Erivedge® to another person. Erivedge® is only prescribed for me.
- I must keep Erivedge® out of the sight and reach of children.
- I must not donate blood while taking Erivedge® and for 24 months after the last dose.
- I must return the unused capsules at the end of the treatment.

For Women Who Could Become Pregnant

I understand that:

- I must not take Erivedge® if I am pregnant or plan to become pregnant.
- I must not become pregnant while taking Erivedge® and for 24 months after my final dose.
- My healthcare provider talked with me about recommended forms of birth control.
 - I must use 2 recommended forms of birth control at the same time while I am taking Erivedge®.
 - Unless I commit to not having sexual intercourse at any time (abstinence).
- I must have a negative pregnancy test conducted by my healthcare provider within a maximum of 7 days (day of pregnancy test = day 1) before starting Erivedge® and each month during treatment.
- I must talk to my healthcare provider immediately during treatment and for 24 months after my last dose:
 - If I become pregnant or think for any reason that I may be pregnant
 - If I miss my expected menstrual period
 - If I stop using birth control
 - If I need to change birth control during treatment
- In case of pregnancy during treatment with Erivedge®, I must stop treatment immediately.
- I must not breast-feed while I am taking Erivedge® and for 24 months after my last dose.
- My healthcare provider will report any pregnancy to Roche, the maker of Erivedge®.

For Male Patients

I understand that:

- I must always use a condom when having sex with a woman while I take Erivedge® and for 2 months after my last dose, even if I have had a vasectomy.
- I will tell my healthcare provider if my female sex partner becomes pregnant while I am taking Erivedge® or within 2 months after my last dose.
- I should not donate semen at any time during treatment and for 2 months after my final dose of this medicine.

Report Pregnancy and Adverse Events to Roche at hong_kong.drug_safety@roche.com