



Erivedge[®]

PATIENT COUNSELING

GUIDELINE

Material created by Roche

M-AI-0000285 (v2.0.1)



WARNING: EMBRYO-FETAL DEATH AND SEVERE BIRTH DEFECTS

- ◆ Erivedge[®] **may cause embryo-fetal 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 donate blood while taking Erivedge[®] and for 24 months after the last dose.



I must not give Erivedge[®] to another person. Erivedge[®] is only prescribed for me.



I must return the unused capsules at the end of the treatment.



I must keep Erivedge[®] out of the sight and reach of children.



For women who could become pregnant:

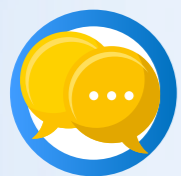
I understand that:



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.

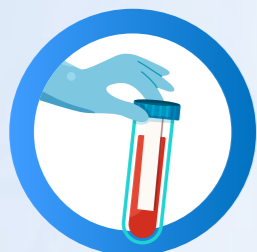
- ◆ I must use 2 recommended forms of birth control at the same time while I am taking Erivedge[®].
- ◆ Unless I commit to not having sexual intercourse at any time (abstinence).



I must 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.

 **For women who could become pregnant:**



- ◆ **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.



- ◆ **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 sexual relations 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 sexual 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 cac.farmacovigilancia@roche.com