茲收到"**Erivedge: Important Safety Information for Healthcare Professionals**"一份，已 充分了解使用Erivedge可能產生的風 險及病患執行避孕措施之必要。

- 醫院: _____
- 科別: _____
- 醫師姓名: _____
- 簽名& Date: _____

Erivedge: Important Safety Information for Healthcare Professionals About Risk of Embryo-foetal Death and Severe Birth Defects

Contraindication:
Breast-feeding women during the course of treatment and for 24 months after the last dose due to the potential to cause serious developmental defects in breast-fed infants and children.

Special warnings and precautions for use

Embryo-foetal death or 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 midline defects, missing
digits, and other irreversible malformations in the developing embryo or foetus. Erivedge must not be used during pregnancy, except in severe life- threatening cases, where the potential benefit to the patients outweighs the risk to the foetus.

Please see Package Insert for Important Safety Information.

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Erivedge: Important Safety Information for Healthcare Professionals About Risk of Embryo-foetal Death and Severe Birth Defects

Erivedge may cause embryo-foetal death or severe birth defects if administered during pregnancy. Erivedge must not be used during pregnancy, except in severe life-threatening cases where the potential benefit to the patient outweighs the risk to the foetus. It is very important that patients understand the risks associated with Erivedge. Women of childbearing potential* must use 2 forms of acceptable contraception including one acceptable barrier method with spermicide (where available), during therapy and for 24 months after completing therapy.

It is important that healthcare professionals (HCPs) and their patients understand the risks to the embryo or foetus and know what precautions are necessary to prevent pregnancy

- For women of childbearing potential,* a pregnancy test should be performed at a medical office or laboratory within 7 days prior to initiating Erivedge treatment and monthly during treatment

*A woman of childbearing potential is a female who can get pregnant (this includes young girls who have started to develop secondary sexual characteristics but do not have menstrual periods, and all females who have had at least 1 menstrual period in the last 12 months). Female patients who meet at least 1 of the following criteria are not considered women of childbearing potential:

- Fifty years old or older and naturally amenorrheic for 1 year or more
- Permanent premature ovarian failure confirmed by specialist gynaecologist
- Previous bilateral salpingo-oophorectomy or hysterectomy
- XY genotype, Turner's syndrome, or uterine agenesis

Your role as HCP is to:

Educate patients about the risk of embryo-foetal death or severe birth defects associated with the use of Erivedge.
Confirm that women of childbearing potential have had a pregnancy test performed at a medical office or laboratory within 7 days prior to initiating Erivedge treatment and monthly during treatment.
Provide contraceptive advice to your patients.
Instruct female patients to take precautions against pregnancy during treatment and for 24 months after their last dose of Erivedge.
Instruct male patients to use condoms with spermicide (where available) with a female partner during treatment with Erivedge and for 2 months after the last dose.
Report any pregnancies to Roche Drug Safety and encourage patients to report information regarding the pregnancy immediately.

Please see Package Insert for Important Safety Information.

If a pregnancy occurs

If a female patient or female partner of a male patient becomes pregnant during or following treatment, you should:

- Instruct the patient to notify the pregnant female's treating physician immediately to seek further evaluation and counseling
- Report the pregnancy to Roche Drug Safety at (02) 2715-3111
- Encourage your patient to share information about the pregnancy when contacted by Roche Drug Safety

Recommended forms of birth control

You should instruct patients to always use contraception unless they choose abstinence (no sexual intercourse). Please see below for acceptable forms of birth control that are appropriate for use during treatment with Erivedge.

Women of childbearing potential should use 2 acceptable forms of birth control at the same time (one of which must be a barrier method) during treatment and for 24 months after the last dose.

Male patients must use condoms with spermicide (where available), even after vasectomy, during sexual intercourse with women throughout treatment duration, and for 2 months after the last dose to avoid pregnancy and exposing an unborn embryo or foetus to Erivedge.

Acceptable forms of birth control	
<u>Primary contraception</u>	<u>Barrier contraception</u>
Combination hormonal	Any male condom with spermicide (where vailable)
Subcutaneous hormonal implant	Diaphragm with spermicide (where available)
Hormonal patch	
Hormonal contraceptives (levonorgestrel-releasing intrauterine system,	
Tubal sterilization	
Intrauterine device (IUD)	
Vasectomy	

Antibiotics and St. John's wort may make hormonal birth control less effective.

Please see Package Insert for Important Safety Information.

TELL ALL PATIENTS while they are taking Erivedge that they should:

- Not donate blood while taking Erivedge and for 24 months after the last dose
- Not share medication with anyone
- Keep medication out of the reach of children

TELL FEMALE PATIENTS while they are taking Erivedge and for 24 months after the last dose they should:

- Not breast-feed while taking Erivedge
- Not become pregnant
- Not have unprotected sex. They should use 2 forms of acceptable birth control at the same time

TELL MALE PATIENTS while they are taking Erivedge and for 2 months after the last dose they should:

- Not have unprotected sex. They should use condoms with spermicide (where available) when they have sex

Notes

For more information

About Erivedge

Visit: www.roche.com.tw

To report a pregnancy

Roche Drug Safety: (02) 2715-3111

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