

# Erivedge® (vismodegib)

## Pregnancy Prevention Programme

*Important information for men and women taking Erivedge® about pregnancy prevention and contraception*

- Erivedge® may cause severe birth defects
- It may lead to the death of a baby before it is born or shortly after being born
- You or your partner must not become pregnant while taking this medicine
- You must follow the contraceptive advice described in this brochure

**This brochure gives you a summary of important safety information and advice about taking Erivedge®. This brochure does not replace the advice given to you by a healthcare professional (doctor, pharmacist or nurse). Read it carefully before you start taking Erivedge® and keep it in case you need to read it again.**

**Please also read the Patient Information Leaflet inside each carton of Erivedge® capsules for important information about taking this medicine.**

**If there is anything that you do not understand, or if you have any more questions, please talk to your healthcare professional.**

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See the end of section 7 for how to report side effects.

This educational material is provided by Roche Products Limited and is mandatory as a condition of the Marketing Authorisation in order to further minimise important selected risks.

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▪ Erivedge® may cause severe birth defects

▪ It may lead to the death of a baby before it is born or shortly after being born

▪ You or your partner must not become pregnant while taking this medicine

▪ You must follow the contraceptive advice described in this brochure

Read the specific instructions given to you by your doctor, particularly on the effects of Erivedge® on unborn babies.

# 1. What is Erivedge® and how does it work?

*Erivedge® is an anti-cancer medicine containing the active substance vismodegib. It is used to treat adults with a type of skin cancer called basal cell carcinoma.*

It is used when the cancer:



has spread to other parts of the body and is causing noticeable symptoms (called symptomatic “metastatic” basal cell carcinoma)



has spread into areas nearby (called “locally advanced” basal cell carcinoma) and your doctor decides that treatment with surgery or radiation is inappropriate

Basal cell carcinoma develops when DNA in normal skin cells becomes damaged and the body cannot repair the damage. This damage can change how certain proteins in these cells work and the damaged cells become cancerous and begin to grow and divide.

Erivedge® is an anti-cancer medicine that works by controlling one of the key proteins involved in basal cell carcinoma. This may slow or stop the cancer cells from growing, or may kill them. As a result, your skin cancer may shrink.

## 2. Who cannot take Erivedge®?

*Some people cannot take Erivedge®. Do not take this medicine if any of the following apply to you. If you are not sure, talk to your doctor or pharmacist.*

### Do not take Erivedge® if you:



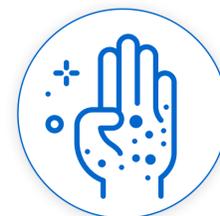
are **pregnant**, think you may be pregnant, or are planning to become pregnant during treatment or for 24 months after your final dose



are **breastfeeding** or plan to breastfeed during the course of treatment or during the 24 months after your final dose



are a woman who could become pregnant and you are **not using** recommended birth control (contraception, see section 6) or you do not refrain from sexual intercourse during treatment and for 24 months after the final dose



have an **allergic** reaction to this medicine or any of the ingredients

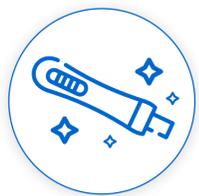


if you are also taking St John's Wort (*Hypericum perforatum*) a herbal medicine used for depression

## 3. Biological Mechanisms and risk of birth defects

*The Hedgehog pathway plays an essential role during development of the unborn baby. Animal studies with the active substance vismodegib show severe malformations such as missing and/or fused digits, head and face abnormality, and retardations.*

## 4. Before you start taking Erivedge®



If you are a woman who could become pregnant, you must have a pregnancy test performed by a healthcare professional within a maximum of 7 days of starting your treatment with Erivedge®



As a patient you must review the Erivedge® patient counselling guidelines with your prescriber

# 5. During and after Erivedge® treatment

Erivedge® may harm a child before or after it is born.



Do not become pregnant during treatment and for 24 months after your final dose, a monthly pregnancy test must be taken during treatment



Do not breastfeed during treatment and for 24 months after your final dose



Do not donate blood during treatment and for 24 months after your final dose



Keep Erivedge® out of the sight and reach of children



Use recommended contraception as described in this brochure



Never give this medicine to another person



Return any unused capsules to your pharmacist at the end of the treatment

# 6. Pregnancy and Erivedge®

## 6.1: If you are a woman taking Erivedge® who could become pregnant

Erivedge® may cause severe deformities during development of an unborn child if you become pregnant during treatment and for 24 months after your final dose.



Do not become pregnant during treatment and for 24 months after your final dose, a monthly pregnancy test must be taken during treatment



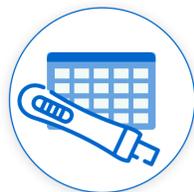
Do not breastfeed during treatment and for 24 months after your final dose



If you are pregnant, you must not start taking Erivedge®



You must have a pregnancy test performed by a healthcare professional to make sure you are not pregnant within a maximum of 7 days before you start taking Erivedge® (day of pregnancy test = day 1)



You must take a pregnancy test every month during treatment



If you are thinking about getting pregnant, talk to your healthcare professional about it



You must not become pregnant while you are taking Erivedge® and for 24 months after your final dose



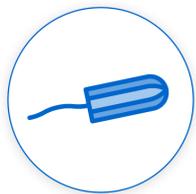
It is very important that you use 2 recommended forms of contraception from the table opposite, one of which must be a barrier method (one barrier method and one highly effective form of contraception)



You must use contraception during Erivedge® treatment and for 24 months after your final dose, unless you commit to not having sex at any time (complete abstinence)



If your periods stop during the course of treatment, you must still use recommended contraception during treatment and for 24 months after discontinuation of Erivedge®



If your periods stop prior to the start of treatment with Erivedge® as a result of previous anti-cancer medication, you must still use recommended contraception during treatment and for 24 months after discontinuation of Erivedge®



Talk to your doctor about the best contraceptive methods for you



You must stop taking Erivedge® and immediately inform your healthcare professional if you miss a menstrual period or you suspect you are pregnant

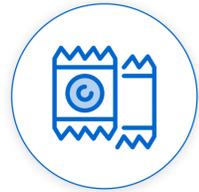
**Recommended forms of contraception**

You must use 2 forms of contraception. Use 1 form of contraception from **each** of the columns below.

<b>Barrier methods</b>	<b>AND</b>	<b>Highly effective forms of contraception</b>
<ul style="list-style-type: none"> <li>▪ male condom with spermicide</li> <li><b>OR</b></li> <li>▪ diaphragm with spermicide</li> </ul>		<ul style="list-style-type: none"> <li>▪ hormonal depot injection OR</li> <li>▪ intrauterine device (“the coil” or IUD) <b>OR</b></li> <li>▪ tubal sterilisation <b>OR</b></li> <li>▪ vasectomy</li> </ul>

Talk to your healthcare professional if you are not sure which forms of contraception to use, or if you need more information.

## 6.2: If you are a man taking Erivedge®



The active ingredient in this medicine can pass into semen and may expose your female sexual partner to the drug. To avoid potential exposure during pregnancy, you must always use a condom (with spermicide, if available) even after a vasectomy, when you have sex with a woman during treatment and for 2 months after your final dose if your sexual partner is pregnant or a woman of childbearing potential



You should not donate semen during treatment and for 2 months after the final dose

Talk to your healthcare professional if your female partner suspects that she is pregnant while you are taking Erivedge® and for 2 months after your final dose.

## 6.3: If you suspect a pregnancy

You must talk to your healthcare professional immediately if you or your sexual partner misses a period, have unusual menstrual bleeding, suspect a pregnancy, or are pregnant



**Female patients:** talk to your doctor and stop taking Erivedge® immediately if you suspect a pregnancy while taking this medicine and for 24 months after your final dose



**Male patients:** talk to your doctor if your female partner suspects that she is pregnant while you are taking Erivedge® and for 2 months after your final dose

## 7. Common side effects of Erivedge®

*The Patient Information Leaflet has a full list of the known side effects of this medicine.  
It is important to know what side effects you may have during your treatment.  
Talk to your doctor if you experience any side effects while taking Erivedge®.*

### Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in the package leaflet. You can also report side effects directly via the Yellow Card Scheme at **[www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard)**, or search for MHRA Yellow Card in the Google Play or Apple App Store.

You should also report side effects to Roche Products Ltd by emailing the Roche Drug Safety Centre at [welwyn.uk\\_dsc@roche.com](mailto:welwyn.uk_dsc@roche.com) or calling +44 (0) 1707 367554.

By reporting side effects you can help provide more information on the safety of this medicine.