

## The Erivedge Contraception Plan

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### Important information regarding contraceptives and prevention of pregnancy for men and women taking Erivedge

- Erivedge may cause severe birth defects and the death of the fetus or the newborn.
- You or your partner should avoid pregnancy during the course of treatment with this medication.
- You must adhere to the guidelines for the prevention of pregnancy described in this brochure.

#### Introduction:

This brochure provides a summary of important safety information and guidelines for taking Erivedge. Read them carefully and save it for future reference. You must use Erivedge according to your doctor's instructions.

In addition, read the patient package insert attached to the medication package for important information about taking this medication. If there is anything that you don't understand, or if you have any further questions, refer to your physician or pharmacist.

Please note that Erivedge may affect reproductive ability in women. There are a number of women whose menstrual cycle ceased after they took Erivedge. In such cases, it is unknown whether the menstrual cycle will reappear. Please consult your physician if you wish to preserve your future reproductive ability.

**This brochure does not replace the patient package insert included with the product. For complete information regarding the medication, please refer to the patient package insert.**

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## 1. Introduction:

- Erivedge may cause severe birth defects and the death of the fetus or the newborn.
- You or your partner must avoid pregnancy during the course of treatment with this medication.
- You must adhere to the guidelines for the prevention of pregnancy described in this brochure.

Read the explicit orders given to you by your doctor, particularly those regarding the effect of Erivedge on the fetus.

### 1.1 What is Erivedge and how does it work?

Erivedge is an anti-cancer medication which contains the active ingredient vismodegib.

It is used to treat adults with a type of skin cancer called basal cell carcinoma. Erivedge is given in cases in which the cancer has spread to other parts of the body (is metastatic) or in which the cancer has spread to nearby organs (is locally advanced) and has recurred after surgery, or cannot be treated by either surgery or radiation.

Basal cell carcinoma develops when the DNA in normal skin cells is damaged and the body cannot repair the damage. This damage may cause a change in the functioning of several proteins in the damaged cells, which become cancerous and start to proliferate and divide. Erivedge is an anti-cancer medication which binds to and blocks one of the key proteins involved in this type of skin cancer. This activity may slow or stop the growth of the cancer cells or enable their killing, and as a result, it may cause your skin cancer to shrink.

## 2. Who cannot take Erivedge?

Some individuals cannot take Erivedge. Do not take this medication if any of the following applies to you. If you are unsure, refer to your physician or pharmacist

Do not take Erivedge if:

- You are **pregnant** or think you may be pregnant; or if you are planning to become pregnant during the course of the treatment or within 24 months of taking the last dose.
- You are **breastfeeding** or if you are planning to breastfeed during the course of the treatment or within 24 months of taking the last dose.
- You are a woman who can become pregnant and you do not use the recommended contraceptives (Contraceptives, section 6.1) or you do not abstain from sexual intercourse throughout the course of the treatment or during the 24 months after the last dose is taken.
- You are **allergic** to the active ingredient (vismodegib) or to any other ingredient of the medication.
- You are also taking *Hypericum perforatum* (St. John's wort) - a herbal medication used to treat depression.

### **3. Biological mechanisms and the risk of harm to the fetus**

The Hedgehog pathway plays an important role in fetal development. Animal studies with the active ingredient vismodegib have demonstrated the formation of severe deformities such as missing or fused fingers, abnormal structure of the head and face and retardation.

### **4. Before you start taking Erivedge**

If you are a woman who can become pregnant, you must take a pregnancy test under the supervision of a medical staff member during the 7 days prior to the start of treatment with Erivedge.

### **5. During and after the treatment:**

Erivedge may harm the fetus or the newborn.

- Do not become pregnant during the course of the treatment or within 24 months of taking the last dose. You must take a pregnancy test every month.
- Do not breastfeed during the course of the treatment or during the 24 months after the last dose is taken.
- Do not donate blood during the course of the treatment or within 24 months of taking the last dose.
- Keep the medication out of the reach and sight of children.
- Use the contraceptives recommended in this information brochure.
- Do not donate sperm during the course of the treatment or within two months of taking the last dose.
- Do not give this medication to any other person.

### **6. Pregnancy and Erivedge**

#### **6.1 If you are a woman who can become pregnant and taking Erivedge:**

Erivedge may cause severe defects during the course of fetal development if you become pregnant during the course of the treatment or within 24 months of taking the last dose.

- If you are pregnant, it is forbidden for you to start treatment with Erivedge
- You must perform a pregnancy test under the supervision of a medical staff member during the 7 days prior to the start of treatment with Erivedge. (the day the pregnancy test is taken = day 1)
- You must take a pregnancy test every month throughout the course of the treatment.
- If you are planning a pregnancy, you must consult your doctor.
- Do not become pregnant during the course of the treatment or during the 24 months after the last dose is taken.
- It is very important to use 2 of the contraceptives listed in the table below. One of them must be an obstructive method of contraception.

Recommended contraceptives		
You must use <b>2</b> means of contraception. Use one contraceptive <b>from each column</b> .		
<b>Obstructive contraceptives</b>	<b>combined with</b>	<b>Highly effective contraceptives</b>
<ul style="list-style-type: none"> <li>• A male condom which contains spermicide, <b>or</b></li> <li>• A diaphragm which contains spermicide</li> </ul>		<ul style="list-style-type: none"> <li>• A hormone-releasing injection <b>or</b></li> <li>• An intrauterine contraceptive device (IUD) <b>or</b></li> <li>• Tubal ligation <b>or</b></li> <li>• A vasectomy</li> </ul>
Consult your doctor if you are unsure which contraceptives you should use, or if you need more information.		

- You must use contraceptives (or abstain from sex) throughout the course of the treatment with Erivedge and during the 24 months after the last dose is taken, unless you commit to abstaining from sexual intercourse during this period (complete abstinence from sex).
- If your menstrual period has stopped during the course of the treatment, you must continue using contraceptives throughout the treatment with Erivedge and during the 24 months after the last dose is taken.
- If your menstrual period has stopped before the start of treatment with Erivedge, you must continue using contraceptives throughout the treatment with Erivedge and during the 24 months after the last dose is taken.
- Talk to your doctor about the contraceptives most suitable for you.
- You must stop taking Erivedge and inform your doctor immediately if your menstrual period is delayed and you suspect that you may be pregnant.

### 6.2 If you are a man taking Erivedge

- The active ingredient in this medication may pass to the sperm and expose your sexual partner to it. In order to prevent exposure to the active ingredient during pregnancy, you must use a condom (which contains a spermicide, if possible) at all times, even if you have undergone a vasectomy, during sexual intercourse with a woman throughout the course of the treatment and during the 2 months after the last dose is taken.
- Do not donate sperm during the course of the treatment or during the two months after the last dose is taken.
- Consult the attending physician if there is a concern that your partner has become pregnant during the course of the treatment or during the two months after the last dose is taken.

### 6.3 If there is a suspicion of pregnancy

You must immediately consult your doctor if your menstrual period or your sexual partner's menstrual period is delayed; or if there is any unusual bleeding between menstrual periods, a suspicion of pregnancy or a pregnancy.

- Female patients - Consult your doctor and stop taking Erivedge immediately if you suspect you might be pregnant during the course of the treatment or during the 24 months after the last dose was taken.
- Male patients- Consult your doctor if your partner suspects that she is pregnant during the course of the treatment with Erivedge or during the 24 months after the last dose was taken.

## **7. Side effects of Erivedge**

- The patient package insert contains a complete list of all of the known side effects of the medication. It is important to be familiar with the side effects, since you may experience them during the course of the treatment. Inform your attending physician in case of any side effect.
- Side effects may be reported to the Ministry of Health using the online form for the reporting of adverse events on the homepage of the Ministry of Health, at [www.health.gov.il](http://www.health.gov.il), or by clicking on the link: <https://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffectMedic@moh.gov.il> or to Roche company at the following email address [Israel.DrugSafety@roche.com](mailto:Israel.DrugSafety@roche.com)