

ERIVEDGE PREGNANCY PREVENTION PROGRAMME

Important information for men and women
taking Erivedge regarding contraception and
contraceptives

- Erivedge could cause serious birth defects and death of the unborn or newborn child.
- You or your partner must not become pregnant during treatment with this medicine.
- You must follow the contraception guidelines presented in this brochure.

Introduction:

This brochure contains a summary of important safety information and guidelines about taking Erivedge. Read it carefully and keep it in case you will want to read it in the future. Use Erivedge in accordance with your doctor's instructions.

Also read the Patient Package Insert attached to the medicine package for important information about taking the medicine. If there is anything that you don't understand or if you have additional questions, please ask the doctor or pharmacist.

This brochure is not a substitute for the Patient Package Insert attached to the preparation. For full information about the medicine, see the Patient Package Insert attached to the preparation.

Table of Contents:

1. Introduction
 - 1.1 What is Erivedge and how does it work?
2. Who may not take Erivedge?
3. Biological mechanisms and the risk for birth defects
4. Before you begin taking Erivedge
5. During and after treatment:
6. Pregnancy and Erivedge
 - 6.1 If you are a woman of childbearing potential taking Erivedge
 - 6.2 If you are a man taking Erivedge
 - 6.3 If pregnancy is suspected
7. Side effects of Erivedge

1. Introduction

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Read the explicit instructions given to you by your doctor, particularly about the effect of Erivedge on unborn children.

1.1 What is Erivedge and how does it work?

Erivedge is an anti-cancer medicine, containing the active ingredient vismodegib.

It is used in adults to treat a type of skin cancer called basal cell carcinoma. Erivedge is given for conditions in which the cancer has spread to other parts of the body (metastatic) or for cancer that has spread to surrounding areas (locally advanced) and has come back after an operation or cannot be treated with an operation or with radiotherapy.

Basal cell carcinoma develops when the DNA of normal skin cells is damaged and the body is unable to repair the damage. This damage can cause a change in the function of a number of proteins in the damaged cells and they become cancerous and begin to grow and divide. Erivedge is an anti-cancer medicine that binds to and blocks one of the key proteins involved in this type of skin cancer. This action may slow or stop the cancer cells from growing, or enables their killing and, as a result, can lead to shrinkage of your skin cancer.

2. Who may not take Erivedge?

Some people may not take Erivedge. Do not take Erivedge if any of the following applies to you. If you are unsure, refer 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 during the 24 months after you take your final dose.
- You are breastfeeding or are planning to breastfeed during treatment or during the 24 months after you take your final dose.
- You are a woman of childbearing potential and are not using the recommended forms of contraception (see Contraception, section 6.1) or you are not abstaining from sexual relations during treatment and for 24 months after taking your final dose.
- You are allergic to the active ingredient vismodegib or to any of the other ingredients of the medicine.
- You are also taking Hypericum perforatum (St. John's wort) - a herbal medicine for the treatment of depression.

3. Biological mechanisms and the risk for birth defects

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

4. Before you begin taking Erivedge

If you are a woman of childbearing potential, you must take a medically supervised pregnancy test during the 7 days before starting Erivedge treatment.

5. During and after treatment:

Erivedge could harm an unborn or newborn child.

- Do not become pregnant during treatment or during the 24 months after you take your final dose. During treatment, a pregnancy test must be performed every month.
- Do not breastfeed during treatment or during the 24 months after you take your final dose.
- Do not donate blood during treatment or during the 24 months after you take your final dose.
- Keep the medicine out of the reach and sight of children.
- You must use the contraceptive methods recommended in this information brochure.
- Do not donate sperm during treatment or during the 2 months after you take your final dose.
- Do not give this medicine to anybody else.
- You must return any capsules that are left over at the end of treatment to the pharmacy.

6. Pregnancy and Erivedge

6.1 If you are a woman of childbearing potential taking Erivedge:

Erivedge could cause severe defects during development of the unborn child if you become pregnant during treatment or during the 24 months after you take your final dose.

- If you are pregnant, you must not start treatment with Erivedge.
- You must take a medically supervised pregnancy test to confirm that you are not pregnant during the 7 days before starting treatment with Erivedge. (The day that you take the pregnancy test = Day 1)
- You must take a pregnancy test every month during treatment.
- If you are planning to become pregnant, you must consult with a doctor.
- Do not become pregnant during treatment or during the 24 months after you take your final dose.
- It is very important to use two of the recommended contraception methods detailed in the table below. One of them must be a barrier method, and the other must be a highly effective method of contraception.

Recommended Methods of Contraception

Use **2** methods of contraception. Use one method of contraception from each **column**.

Barrier Method of Contraception

- Male condom with spermicide
- OR**
- Diaphragm with spermicide

**in combination
with**

A Highly Effective Method of Contraception

- Hormone-releasing injection
- OR**
- Intrauterine device (IUD)
- OR**
- Tubal ligation
- OR**
- Vasectomy

Consult with a doctor if you are uncertain about which methods of contraception to use or if you need further information.

- You must use contraception (or abstain from sex) during treatment with Erivedge and for 24 months after taking your final dose, unless you commit to not having sexual intercourse (abstinence) during this period (complete abstinence from sex).
- If your menstrual periods stop during treatment, you must continue to use the recommended methods of contraception during treatment with Erivedge and for 24 months after taking your final dose.
- If your menstrual period stopped before you began treatment with Erivedge as the result of previous anti-cancer treatments, you must continue to use the recommended methods of contraception during treatment with Erivedge and for 24 months after taking your final dose.
- Talk to your doctor about the most appropriate methods of contraception for you.
- You must stop taking Erivedge and immediately report to your doctor if your menstrual period is late and you suspect that you are pregnant.

6.2 If you are a man taking Erivedge

- The active ingredient in this medicine can pass into your sperm and expose it to your sexual partner. In order to prevent possible exposure to the active ingredient during pregnancy, you must always use a condom (with spermicide if possible), even after vasectomy, when having sexual intercourse with a female partner during treatment and for 2 months after taking your final dose.
- Do not donate sperm during treatment or during the 2 months after you take your final dose.
- Consult with your doctor if you suspect that your partner has become pregnant during treatment or within 2 months after taking your last dose.

6.3 If pregnancy is suspected

Speak with your doctor immediately if your or your sexual partner's menstrual period is delayed, if there is abnormal bleeding between periods, suspected pregnancy or pregnancy.

- Female patients - Consult with your doctor and stop taking Erivedge immediately if you suspect that you are pregnant during treatment with Erivedge or during the 24 months after you take your final dose
- Male patients - Consult with your doctor if your partner suspects that she is pregnant while you are taking Erivedge or during the 2 months after you take your final dose

7. Side effects of Erivedge

- The Patient Package Insert contains a complete list of all known side effects of the medicine. It is important to be familiar with the side effects that you may experience during treatment. If you have a side effect, report this to your doctor. Precise instructions can be found in the drug leaflet on the Ministry of Health website or on the Roche website at www.roche.co.il
- Side effects can be reported to the Ministry of Health using the online form for reporting side effects that can be found on the homepage of the Ministry of Health website www.health.gov.il or by entering the link: <https://sideeffects.health.gov.il/> or to Roche by email to Israel.DrugSafety@roche.com