

## Package leaflet: Information for the patient

### Erivedge® 150 mg hard capsules

vismodegib

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 must not become pregnant while taking this medicine. You must follow the contraception advice described in this leaflet.

The name of your medicine is Erivedge 150 mg hard capsules but will be referred to as Erivedge throughout this leaflet.

#### Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

#### What is in this leaflet

1. What Erivedge is and what it is used for
2. What you need to know before you take Erivedge
3. How to take Erivedge
4. Possible side effects
5. How to store Erivedge
6. Contents of the pack and other information

#### 1. What Erivedge is and what it is used for

##### What Erivedge is

Erivedge is an anti-cancer medicine and contains the active substance vismodegib.

##### What Erivedge is used for

Erivedge is used to treat adults with a type of skin cancer called advanced basal cell carcinoma. It is used when the cancer:

- has spread to other parts of the body (called “metastatic” basal cell carcinoma)
- has spread to areas nearby (called “locally advanced” basal cell carcinoma) and your doctor decides that treatment with surgery or radiation is inappropriate.

##### How Erivedge works

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 down or stop the growth of the cancer cells, or may kill them. As a result, your skin cancer may shrink.

#### 2. What you need to know before you take Erivedge

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

Read carefully and follow the instructions of the patient brochure given to you by your doctor.

##### Do not take Erivedge

- if you are **allergic** to vismodegib or any of the other ingredients of this medicine (listed in section 6).
- if you are **pregnant**, think you may be pregnant, or are planning to become pregnant during the course of treatment or during the 24 months after your final dose of this medicine. This is because Erivedge may harm or cause the death of your unborn baby.
- if you are **breast-feeding** or plan to breast-feed during the course of treatment or during the 24 months after your final dose of this medicine. This is because it is unknown whether Erivedge can pass into your milk and cause harm to your baby.
- if you are able to become pregnant but are unable or unwilling to follow the necessary pregnancy prevention measures that are listed in the **Erivedge Pregnancy Prevention Programme**.
- if you are also taking St John’s wort (*Hypericum perforatum*) – a herbal medicine used for depression (see “Other medicines and Erivedge”).

More information on the issues above is found in the sections “Pregnancy, breast-feeding and fertility” and “Contraception – for men and women”.

Do not take this medicine if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking Erivedge.

##### Warnings and precautions

Talk to your doctor or pharmacist before taking Erivedge if you have questions on the information in this section:

- You should not donate blood at any time during treatment and for 24 months after your final dose of this medicine.
- If you are male, you should not donate semen at any time during treatment and for 2 months after the final dose.
- Serious skin reactions have been reported in association with Erivedge treatment. Stop using Erivedge and seek medical attention immediately if you notice any of the symptoms described in section 4.
- Never give this medicine to anyone else. You should return unused capsules at the end of your treatment. Talk to your doctor or pharmacist regarding where to return the capsules.

##### Children and adolescents

The use of Erivedge in children and adolescents under the age of 18 years is not recommended. This is because it is not known if it is safe or effective in this age group. Erivedge can cause bones to stop growing and lead to premature onset of puberty (before age 8 years in girls or age 9 years in boys). This can happen even after stopping Erivedge. Problems with growing teeth and bones were seen in animal studies with this medicine.

##### Other medicines and Erivedge

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

This also includes non-prescription medicines, vitamins and herbal medicines.

Some medicines may affect how Erivedge works, or make it more likely that you will have side effects. Erivedge can also affect how some other medicines work.

In particular, tell your doctor if you take any of the following medicines:

- rifampicin – used for bacterial infections,
- carbamazepine, phenytoin – used for epilepsy,
- ezetimibe and statins, such as atorvastatin, fluvastatin, pravastatin, rosuvastatin, simvastatin – used for high cholesterol,
- bosentan, glibenclamide, repaglinide, valsartan,
- topotecan – used for certain types of cancer,
- sulfasalazine – used for certain inflammatory disorders, and especially,
- St. John’s wort (*Hypericum perforatum*) – a herbal medicine used for depression, since you must not use it at the same time as Erivedge.

##### Pregnancy, breast-feeding and fertility

###### Pregnancy

Do not take Erivedge if you are pregnant, think you may be pregnant, or are planning to become pregnant during the course of treatment or during the 24 months after your final dose of this medicine.

You must stop treatment and inform your doctor straight away if: you miss or think you have missed a period, or you have unusual menstrual bleeding, or suspect you are pregnant. If you do become pregnant during the treatment with Erivedge, you must stop the treatment and inform your doctor immediately.

Erivedge may cause severe birth defects. It may also lead to the death of the unborn baby. Specific instructions (the Erivedge Pregnancy Prevention Programme), given to you by your doctor contain information particularly on the effects of Erivedge on unborn babies.

###### Breast-feeding

Do not breast-feed during your treatment and for 24 months after your final dose of this medicine. It is not known if Erivedge can pass into your breast milk and harm your baby.

###### Fertility

Erivedge may affect a woman’s ability to have children. Some women taking Erivedge have stopped having periods. If this happens to you, it is not known if your periods will come back. Talk to your doctor if you wish to have children in the future.

##### Contraception – for men and women

###### For women taking Erivedge

Before starting the treatment, ask your doctor if you are able to become pregnant. Even if your periods have stopped, it is essential to ask your doctor if there is any risk that you could become pregnant.

If you are able to become pregnant:

- you must take precautions so that you do not become pregnant while taking Erivedge
- use 2 methods of contraception, one highly effective method and one barrier method (please see the examples below)
- you need to continue contraception for 24 months after your final dose of this medicine – because Erivedge may remain in your body for up to 24 months after your final dose.

Method of recommended contraception: Talk to your doctor about the best two contraception methods for you.

Use one highly effective method, such as:

- a contraceptive depot injection
- an intra-uterine device (“the coil” or IUD)
- surgical sterilisation.

You must also use one barrier method, such as:

- a condom (with spermicide, if available)
- a diaphragm (with spermicide, if available).

Your doctor will make sure to test you for pregnancy:

- within a maximum of 7 days before starting treatment – to make sure that you are not already pregnant
- every month during treatment.

You must tell your doctor immediately during the course of treatment or during the 24 months after your final dose of this medicine if:

- you think your contraception has failed for any reason,
- your periods stop,
- you stop using contraception,
- you need to change contraception.

###### For men taking Erivedge

Erivedge can pass into semen. Always use a condom (with spermicide, if available) even after a vasectomy, when you have sex with a female partner. Do this during treatment and for 2 months after your final dose of this medicine.

You should not donate semen at any time during treatment and for 2 months after your final dose of this medicine.

##### Driving and using machines

Erivedge is unlikely to affect your ability to drive, use any tools or machines. Talk to your doctor if you are not sure.

##### Erivedge contains lactose and sodium

Erivedge contains a type of sugar called lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

This medicine contains less than 1 mmol sodium (23 mg) per capsule, that is to say essentially ‘sodium free’.

#### 3. How to take Erivedge

Always take Erivedge exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

##### Taking this medicine

- The recommended dose is one capsule each day.
- Swallow the capsule whole with a drink of water.
- Do not crush, open or chew the capsule, to avoid unintended exposure to the capsule contents.
- Erivedge can be taken with or without food.

##### If you take more Erivedge than you should

If you take more Erivedge than you should, talk to your doctor.

##### If you forget to take Erivedge

Do not take a double dose to make up for a forgotten dose, but resume with the next scheduled dose.

##### If you stop taking Erivedge

Do not stop taking this medicine without talking to your doctor first as this could make your treatment less effective.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

#### 4. Possible side effects

Like all medicines, Erivedge can cause side effects, although not everybody gets them.

Erivedge may cause severe birth defects. It may also lead to the death of a baby before it is born or shortly after being born. You must not become pregnant while taking this medicine (see section 2, “Do not take Erivedge” and “Pregnancy, breast-feeding and fertility”).

Other side effects are presented in order of severity and frequency:

**Very common** (may affect more than 1 in 10 people):

- loss of monthly periods in women of childbearing age,
- loss of appetite and weight loss,
- feeling tired,
- muscle spasm,
- diarrhoea,
- hair loss (alopecia),
- rash,
- a change in the way things taste or the complete loss of taste,
- constipation,
- vomiting or feeling like you want to vomit (nausea),
- upset stomach or indigestion,
- joint pain,
- pain (in general) or pain in your arms, legs,
- itchiness.

**Common** (may affect up to 1 in 10 people):

- pain in your chest, back or side,
- lack of energy or weakness (asthenia),
- loss of water from the body (dehydration),
- muscle, tendon, ligament, bone pain,
- stomach pain,
- loss of taste,
- abnormal hair growth,
- eyelashes falling out (madarosis)
- changes in blood tests, which include increased values in liver tests or increased values in creatine phosphokinase (a protein mainly from muscle).

#### Frequency not known

- Bones stop growing (epiphyses premature fusion)
- Premature puberty (precocious puberty)
- Liver injury
- Serious skin reactions:
  - Reddish target-like macules or circular patches often with central blisters on the trunk, skin peeling, ulcers of mouth, throat, nose, genitals and eyes. The skin reactions are often preceded by fever and flu-like symptoms (Stevens- Johnson syndrome, toxic epidermal necrolysis).
  - Widespread rash, fever, and enlarged lymph nodes (DRESS-syndrome or drug hypersensitivity syndrome).
  - Red, scaly widespread rash with bumps under the skin and blisters accompanied by fever at the initiation of treatment (acute generalised exanthematous pustulosis).

#### Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme Website: [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**. By reporting side effects you can help provide more information on the safety of this medicine.

#### 5. How to store Erivedge

- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date, which is stated on the bottle and carton after EXP. The expiry date refers to the last day of that month.
- Do not store above 30 °C.
- Keep the bottle tightly closed in order to protect from moisture.
- If this medicine becomes discoloured or shows any other signs of deterioration, please contact your pharmacist who will advise you on what to do.
- Do not throw away any medicines via wastewater or household waste.
- At the end of your treatment you should return all unused capsules. This will prevent misuse and help to protect the environment. Talk to your pharmacist or doctor regarding where to return the medicine.

#### 6. Contents of the pack and other information

##### What Erivedge contains

- The active substance is vismodegib. Each hard capsule contains 150 mg of vismodegib.
- The other ingredients are:
- Capsule contents: microcrystalline cellulose, lactose monohydrate, sodium lauril sulfate, povidone (K29/32), sodium starch glycolate (Type A), talc and magnesium stearate.
- Capsule shell: iron oxide red (E172), iron oxide black (E172), titanium dioxide, gelatine,
- Printing ink: shellac glaze and iron oxide black (E172).

##### What Erivedge looks like and contents of the pack

The capsules have a pink opaque coloured body marked “150 mg” and a grey cap marked “VISMO” in black edible ink. They are available in bottles with a child-resistant closure containing 28 capsules. Each pack contains one bottle.

##### Product Licence Holder and Manufacturer

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**Erivedge 150 mg hard capsules**  
**PL 45985/0349**

**POM**

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As part of the Erivedge Pregnancy Prevention Programme, all patients will receive a:

- Patient Brochure

Please refer to this document for further information.

**Blind or partially sighted?**  
**Is this leaflet hard to see or read?**  
**Call +45 63 95 27 00**  
**to obtain the leaflet in a format**  
**suitable for you.**