

SCHEDULING STATUS

S4

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

Erivedge[®], 150 mg Hard gelatin capsules

Read all of this leaflet carefully before you start using Erivedge

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or pharmacist.
- Erivedge has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

- **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 Erivedge.**
- **You must follow the contraception advice described in this leaflet.**

WHAT ERIVEDGE CONTAINS

- The active substance is vismodegib. Erivedge contains 150 mg vismodegib per hard capsule.
The other ingredients are inactive ingredients: microcrystalline cellulose, lactose monohydrate, sodium lauryl sulfate, povidone, sodium starch glycolate (Type A), talc, magnesium stearate (non-bovine).
- Capsule shell: iron oxide red (E172), iron oxide black (E172), titanium dioxide, gelatine.
- Printing ink: shellac glaze and iron oxide black (E172).

Contains sugar: Lactose.

WHAT ERIVEDGE IS USED FOR

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.

Erivedge contains the active substance vismodegib.

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.

BEFORE YOU TAKE ERIVEDGE

Your doctor will counsel you on the Erivedge Pregnancy Prevention Programme. You and your partner will be required to sign the Verification of Counselling form to acknowledge that you have understood the conditions of use.

Do not take Erivedge

- if you are **allergic** to vismodegib or any of the other ingredients of 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. This is because Erivedge may harm or cause the death of your unborn baby.
- if you are **breastfeeding** or plan to breastfeed during the course of treatment or during the 24 months after your final dose of this medicine.
- 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 “Taking other medicines with Erivedge”).

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

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

Take special care with Erivedge

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 Erivedge.
- If you are male, you should not donate semen at any time during treatment and for 6 months after the final dose.
- Your doctor will check your skin regularly for a type of cancer called “cutaneous squamous cell carcinoma’ (cuSCC). It is not known if cuSCC is related to treatment with Erivedge. Usually this type of lesion appears on sun-damaged skin, remains local and can be cured. Tell your doctor in case you notice any changes in your skin.
- Never give Erivedge 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 unused capsules.

Use in children

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. Problems with growing teeth and bones were seen in animal studies with Erivedge.

Pregnancy, breastfeeding and fertility

Erivedge exposure during pregnancy can cause embryo-foetal death and severe birth defects. Erivedge can cause your baby to die before it is born (be stillborn) or cause your baby to have severe birth defects.

Please see warning (patient counselling information) at the beginning of this leaflet.

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 Erivedge.

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.

Breastfeeding: Do not breastfeed 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 your ability to have children, which applies to both men and women. 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
- you must 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 Erivedge – 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 of these highly effective methods, such as:

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

In addition, you must also use one barrier method, such as:

- a condom (with spermicide)
- a diaphragm (with spermicide).

Your doctor will make sure to test you for pregnancy:

- at least 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, and
- 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) even after a vasectomy, when you have sex with a female partner. Do this during treatment and for 6 months after your final dose of Erivedge. You should not donate semen at any time during treatment and for 6 months after your final dose of Erivedge.

Driving and using machinery

Erivedge may cause fatigue and muscle pain that may influence the ability to drive and use machines.

Important information about some of the ingredients of Erivedge

Erivedge capsules contain a type of sugar called lactose. If you have been told by your doctor that you cannot tolerate or digest some sugars, talk to your doctor before taking Erivedge.

Erivedge contains less than 1 mmol sodium (23 mg) per capsule, i.e. it is essentially 'sodium free'.

Taking other medicines with Erivedge

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional 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:

- ketoconazole (except in shampoo), fluconazole, itraconazole, miconazole, posaconazole, voriconazole – used for fungal infections,
- clarithromycin, telithromycin, rifampicin, erythromycin, azithromycin – used for bacterial infections,

- amiodarone, verapamil – used for certain heart disorders,
- ciclosporin – used in organ transplantation to prevent rejection,
- carbamazepine, phenytoin – used for epilepsy,
- indinavir, lopinavir, nelfinavir, ritonavir, saquinavir, telaprevir, boceprevir – used for viral infections,
- atorvastatin, rosuvastatin, simvastatin – used for high cholesterol,
- topotecan – used for certain types of cancer,
- sulfasalazine – used for certain inflammatory disorders.
- St. John's wort (*Hypericum perforatum*) – a herbal medicine used for depression, since you must not use it at the same time as Erivedge.

HOW TO TAKE ERIVEDGE

Do not share medicines prescribed for you with any other person. Always take Erivedge exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

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.

POSSIBLE SIDE EFFECTS

Erivedge can cause side effects.

Not all side effects reported for Erivedge are included in this leaflet. Should your general health worsen while taking Erivedge, consult your doctor, pharmacist or other healthcare professional for advice.

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 sections “Do not take Erivedge” and “Pregnancy, breastfeeding and fertility”).

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

Frequent:

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

Less frequent:

- pain (in general) or pain in your arms, legs, chest, back or side,
- lack of energy or weakness (asthenia),
- loss of water from the body (dehydration),
- muscle, tendon, ligament, bone pain,
- stomach pain, upset stomach or indigestion,
- rash,
- loss of taste,
- abnormal hair growth,
- eyelashes falling out (madarosis)
- changes in blood tests, which include increased values in liver tests or decreased values in sodium.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

STORING AND DISPOSING OF ERIVEDGE

- Store this medicine out of the 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.
- Store at or below 30 °C. Keep the bottle tightly closed in order to protect from moisture.
- 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 Erivedge.

PRESENTATION OF ERIVEDGE

Each carton contains a white, square HDPE bottle with a white child-resistant screw cap containing 28 hard capsules.

IDENTIFICATION OF ERIVEDGE

The capsules have a pink opaque coloured body marked “150 mg” and a grey cap marked “VISMO” in black edible ink.

REGISTRATION NUMBER

48/32.16/0658

NAME AND ADDRESS OF REGISTRATION HOLDER

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DATE OF PUBLICATION

Registration date: 22 May 2022