Package leaflet: Information for the patient

Verzenios® 50 mg film-coated tablets
Verzenios® 100 mg film-coated tablets
Verzenios® 150 mg film-coated tablets
abemaciclib

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, pharmacist or nurse.
- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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

1. What Verzenios is and what it is used for

Verzenios is a cancer medicine containing the active substance abemaciclib.

Abemaciclib blocks the effects of proteins called cyclin-dependent kinase 4 and 6. These proteins are abnormally active in some cancer cells and make them grow out of control. Blocking the action of these proteins can slow down growth of cancer cells, shrink the tumour and delay progression of the cancer.

Verzenios is used to treat certain types of breast cancer (hormone receptor-positive (HR+), human epidermal growth factor receptor 2-negative (HER2-)) which have:
- spread to the lymph nodes of the armpit, with no detectable spread to other parts of the body, been surgically removed, and have certain characteristics that increase the risk of the cancer returning. Treatment is given in combination with hormonal therapy, such as aromatase inhibitors or tamoxifen, to prevent the cancer from coming back after surgery (treatment after surgery is called adjuvant therapy)
- spread beyond the original tumour and/or to other organs. It is given together with hormonal therapies, such as aromatase inhibitors or fulvestrant.

2. What you need to know before you take Verzenios

Do not take Verzenios:
- if you are allergic to abemaciclib or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions
Verzenios may:
- reduce the number of your white blood cells, and you may be at greater risk of getting an infection. Serious infections such as lung infections can be life-threatening;
- cause blood clots in the veins;
- cause severe or life-threatening inflammation of the lungs;
- affect the way your liver works;
- cause diarrhoea. At the first sign of diarrhoea, start treatment with antidiarrhoeal agents, such as loperamide. Drink plenty of fluids;
- cause blood clots in the arteries in patients also receiving hormone therapies.

See section 4 "Possible side effects", and talk to your doctor if you have any symptoms.

What your doctor will check before and during your treatment
You will have regular blood tests before and during treatment to check whether Verzenios affects your blood (white blood cells, red blood cells, platelets) or the concentration in your blood of enzymes from your liver.

Children and adolescents
Verzenios is not to be used in children and adolescents under 18 years of age.

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

In particular, tell you doctor or pharmacist before taking Verzenios if you are taking the following:
- medicines that may increase the concentration of Verzenios in the blood:
    - **Clarithromycin** (antibiotic used to treat bacterial infections)
    - **Itraconazole, ketoconazole, posaconazole, voriconazole** (used to treat fungal infections)
    - **Lopinavir/ritonavir** (used to treat HIV/AIDS)
- medicines that may reduce the effectiveness of Verzenios:
    - **Carbamazepine** (anti-epileptic used to treat seizures or fits)
    - **Rifampicin**, used to treat tuberculosis (TB)
    - **Phenytoin** (used to treat seizures)
    - **St. John's wort** (a herbal product used to treat mild depression and anxiety)
- medicines whose concentration in the blood might be increased by Verzenios:
    - **Digoxin** (used to treat heart disorders)
    - **Dabigatran etexilate** (used to reduce the risk of stroke and blood clots)

Verzenios with food and drink
Avoid grapefruit or grapefruit juice while you are taking the medicine as they may increase the concentration of Verzenios in the blood.

Pregnancy, breast-feeding and fertility
If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

<u>Pregnancy</u>
You should not use Verzenios if you are pregnant.

You should avoid becoming pregnant while taking Verzenios.

If you are able to have children, you should use adequate contraceptive methods (e.g., double–barrier contraception such as condom and diaphragm) during therapy and for at least 3 weeks after completing therapy. Discuss contraception with your doctor if there is any possibility that you may become pregnant.

You must tell your doctor if you become pregnant.

Breast-feeding
You should not breast-feed while taking Verzenios. It is not known if Verzenios passes into breast milk.

Fertility
Verzenios may decrease fertility in men. Talk to your doctor to seek advice about fertility prior to treatment.

Driving and using machines
Tiredness and dizziness are very common side effects. If you feel unusually tired or dizzy, take special care when driving or using machines.

Verzenios contains lactose
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

Verzenios contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take Verzenios

Recommended dose
Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

When given together with endocrine therapy to treat your breast cancer, the recommended dose of Verzenios is 150 mg taken by mouth twice daily.

If you get certain side effects while you are taking Verzenios your doctor may lower your dose or stop treatment temporarily or permanently.

When and how to take Verzenios
Take Verzenios twice daily, at about the same time every day, preferably in the morning and evening, so there is enough medicine in your body all the time.

You can take the tablets either with or without food, just avoid grapefruit and grapefruit juice (see section 2 "Verzenios with food and drink").

Swallow the tablet whole with a glass of water. Do not chew, crush or split the tablets before swallowing.

How long to take Verzenios
Take Verzenios continuously for as long as your doctor tells you to. If you take Verzenios for early breast cancer treatment, you should take it for up to 2 years.

If you take more Verzenios than you should
If you take too many tablets, or if someone else takes your medicine, contact a doctor or hospital for advice. Show the Verzenios carton and this leaflet. Medical treatment may be necessary.

If you miss a dose of Verzenios
If you vomit after taking the dose or forget a dose, take your next dose at your usual time. Do not take a double dose to make up for the forgotten or vomited dose.

If you stop taking Verzenios
Do not stop taking Verzenios unless your doctor tells you to.

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

4. Possible side effects

Like all medicines, this medicine can cause side-effects, although not everybody gets them. Contact your doctor immediately for any of the following:

- Symptoms such as chills or fever. These could be a sign of low white blood cell counts (which may affect more than 1 in 10 people) and should be treated immediately. If you have cough, fever and difficulty breathing or chest pain, this could be a sign of lung infection. Serious or life-threatening infections are uncommon (may affect up to 1 in 100 people).
- Painful swollen leg, chest pain, shortness of breath, rapid breathing or rapid heart rate as these can be signs of blood clots in the vein (which may affect up to 1 in 10 people).
- Diarrhoea (which may affect more than 1 in 10 people).

Refer to section 2 for more information on any of the possible effects listed above.

Other side effects with Verzenios may include:

Very common side effects (may affect more than 1 in 10 people)

- Infections
- Reduction in white blood cells, red blood cells, and blood platelets
- Nausea (feeling sick), vomiting
- Inflammation or sore mouth
- Decreased appetite
- Headache
- Alteration in sense of taste
- Hair loss
- Tiredness
- Dizziness
- Itching
- Rash
- Abnormalities in liver blood tests

Common side effects (may affect up to 1 in 10 people)

- Watering eyes
- Muscular weakness
- Dry skin
- Inflammation of the lungs which causes breathlessness, cough and raised temperature
- Indigestion or upset stomach
- Nail disorders such as breaking or splitting of nails

Uncommon side effects (may affect up to 1 in 100 people)
- Low levels of white blood cells with fever
- Perception of flashes of light or floaters in your vision
- Keratitis (inflammation of the Cornea)

Rare side effects (may affect up to 1 in 1000 people)
- A skin reaction that causes red spots or patches on the skin that may look like a target or "bullseye" with a dark red centre surrounded by paler red rings (erythema multiforme).

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 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 Verzenios

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 blister and carton after "EXP". The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

Do not use this medicine if you notice that the pack is damaged or shows signs of tampering.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Verzenios contains
- The active substance is abemaciclib. Verzenios film-coated tablets come in different strengths:
  - Verzenios 50 mg film-coated tablet: each tablet contains 50 mg abemaciclib.
  - Verzenios 100 mg film-coated tablet: each tablet contains 100 mg abemaciclib.
  - Verzenios 150 mg film-coated tablet: each tablet contains 150 mg abemaciclib.

- The other ingredients in this medicine are:
  - Tablet core: colloidal hydrated silica, croscarmellose sodium, lactose monohydrate, microcrystalline cellulose, sodium stearyl fumarate (see section 2 under 'Verzenios contains lactose' and 'Verzenios contains sodium' for further information).
  - Film-coating: titanium dioxide (E171), talc (E553b), polyvinyl alcohol (E1203), macrogol 3350 (E1521), iron oxide yellow (E172) [50 mg and 150 mg tablets only], iron oxide red (E172) [50 mg tablets only].

What Verzenios looks like and contents of the pack
- Verzenios 50 mg film-coated tablets are beige, oval tablets debossed with "Lilly" on one side and "50" on the other.
- Verzenios 100 mg film-coated tablets are white, oval tablets debossed with "Lilly" on one side and "100" on the other.
- Verzenios 150 mg film-coated tablets are yellow, oval tablets debossed with "Lilly" on one side and "150" on the other.

Verzenios is available in calendar blister packs of 14, 28, 42, 56, 70 and 168 film-coated tablets and perforated unit dose blisters of 28 x 1 film-coated tablets.

Not all the pack sizes may be marketed.

Marketing Authorisation Holder
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Manufacturer
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For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

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