Package leaflet: Information for the patient

Vitekta 150 mg film-coated tablets
Elvitegravir

▼This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

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 Vitekta is and what it is used for

Vitekta contains the active substance elvitegravir.

Vitekta is a **treatment for human immunodeficiency virus (HIV) infection** in adults aged 18 years and over.

Vitekta must always be taken with certain other HIV medicines. See section 3, *How to take Vitekta*.

The HIV virus produces an enzyme called HIV integrase. This enzyme helps the virus to multiply in the cells in your body. Vitekta stops this enzyme working and reduces the amount of HIV in your body. This will improve your immune system and reduce the risk of developing illnesses linked to HIV infection.

This medicine is not a cure for HIV infection. While taking Vitekta you may still develop infections or other illnesses associated with HIV infection.

2. What you need to know before you take Vitekta

Do not take Vitekta

- **if you are allergic to elvitegravir** or any of the other ingredients of this medicine (listed in section 6 of this leaflet).

- **if you are taking one of these medicines:**
  - **carbamazepine, phenobarbital, phenytoin,** used to treat epilepsy and prevent seizures
  - **rifampicin,** used to prevent and treat tuberculosis and other infections
  - **St. John's wort** (*Hypericum perforatum*), a herbal remedy used for depression and anxiety, or products that contain it

→ If any of these applies to you, do not take Vitekta and tell your doctor immediately.

Warnings and precautions

Your treatment with Vitekta should only be started by a doctor who is experienced in treating HIV infection.

You can still pass on HIV when taking this medicine, although the risk is lowered by effective antiretroviral therapy. Discuss with your doctor the precautions needed to avoid infecting other people. This medicine is not a cure for HIV infection. While taking Vitekta you may still develop infections or other illnesses associated with HIV infection.

Talk to your doctor before taking Vitekta:

- **If you have liver problems or a history of liver disease, including hepatitis.** Patients with liver disease including chronic hepatitis B or C, who are treated with antiretrovirals, have a higher risk of severe and potentially fatal liver complications. If you have hepatitis B infection, your doctor will carefully consider the best treatment for you.

→ If any of these applies to you, talk to your doctor before taking Vitekta.

While you are taking Vitekta

Look out for the following:

- **any signs of inflammation or infection**

- **bone problems**

→ If you notice any of these symptoms, tell your doctor immediately. For more information see section 4 of this leaflet.

Children and adolescents

- **Do not give this medicine to children** and adolescents under 18 years of age. The use of Vitekta in children and adolescents has not yet been studied.

Other medicines and Vitekta

Tell your doctor or pharmacist if you are taking, plan to take, or have recently taken any other medicines. This includes medicines and herbal products obtained without a prescription. Vitekta may interact with other medicines which can affect the amounts of Vitekta or other medicines in your blood. This may stop your medicines from working properly, or may make any side effects worse.

Medicines that should never be taken with Vitekta:
- **carbamazepine, phenobarbital, phenytoin,** used to treat epilepsy and prevent seizures
- **rifampicin,** used to prevent and treat tuberculosis and other infections
- **St. John's wort** (*Hypericum perforatum*), a herbal remedy used for depression and anxiety, or products that contain it

Other medicines used in treating HIV infection:
You should not take Vitekta with other medicines containing:
- **cobicistat**
- **elvitegravir**

Talk to your doctor if you are taking:
- **efavirenz**
- **nevirapine**
- **didanosine** (see also section 3 of this leaflet)

→ **Tell your doctor** if you are taking any of these HIV medicines.

Other types of medicine:
Talk to your doctor if you are taking:
- **rifabutin,** used to treat bacterial infections including tuberculosis
- **warfarin,** used to thin the blood
- **contraceptive pill,** used to prevent pregnancy
- **bosentan,** used to treat pulmonary arterial hypertension
- **antacids,** used to treat heartburn or acid reflux, such as aluminium/magnesium hydroxide or calcium carbonate (see also section 3 of this leaflet)
- **multivitamins,** used to supplement your diet (see also section 3 of this leaflet).

→ **Tell your doctor** if any of these apply to you.

→ **Tell your doctor if you are taking these or any other medicines.** Do not stop your treatment without contacting your doctor.

Pregnancy and breast-feeding

Ask your doctor or pharmacist for advice before taking any medicine.

- **Women must not get pregnant** while taking Vitekta.
- Use effective contraception while taking Vitekta.
- **Tell your doctor immediately if you become pregnant.** If you are pregnant, you should not take Vitekta unless you and your doctor decide it is clearly needed. Your doctor will discuss the potential benefits and risks of taking Vitekta to you and your child.

Do not breast-feed during treatment with Vitekta: It is not known if the active substance in this medicine can pass into human breast milk. If you are a woman with HIV it is recommended that you do not breast-feed to avoid passing the virus to the baby in breast milk.

Vitekta contains lactose

Tell your doctor if you are lactose intolerant or intolerant to other sugars. Vitekta contains lactose. If you are lactose-intolerant, or if you have been told that you have an intolerance to other sugars, talk to your doctor before taking this medicine.

3. How to take Vitekta

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure. This is to make sure that your medicine is fully effective, and to reduce the risk of developing resistance to the treatment. Do not change the dose unless your doctor tells you to.

You must always take Vitekta with one of the following combinations of medicines:

- atazanavir and ritonavir
- darunavir and ritonavir

- fosamprenavir and ritonavir
- lopinavir/ritonavir

A dose of 150 mg is recommended:
If you are taking Vitekta with:
- darunavir and ritonavir
- fosamprenavir and ritonavir

In these combinations the dose is one 150 mg tablet each day, with food. Do not chew, crush or split the tablet. Take the 150 mg tablet at the same time as the first dose of darunavir or fosamprenavir and ritonavir.

A dose of 85 mg is recommended:
If you are taking Vitekta with:
- atazanavir and ritonavir
- lopinavir/ritonavir

In these combinations the dose is one 85 mg tablet each day, with food. Do not chew, crush or split the tablet. Take the 85 mg tablet at the same time as atazanavir and ritonavir or at the same time as the first dose of lopinavir/ritonavir. Refer to the package leaflet for Vitekta 85 mg tablets.

If you are also taking other medicines:

If you are also taking didanosine, take it at least 1 hour before or at least 2 hours after Vitekta.

If you are also taking an antacid such as aluminium/magnesium hydroxide or calcium carbonate, or a **multivitamin supplement,** take it at least 4 hours before or at least 4 hours after Vitekta.

If you take more Vitekta than you should

If you accidentally take more than the recommended dose of Vitekta you may be at increased risk of experiencing possible side effects with this medicine (see section 4 of this leaflet).

Contact your doctor or nearest emergency department immediately for advice. Keep the tablet bottle with you so that you can easily describe what you have taken.

If you forget to take Vitekta

It is important not to miss a dose of Vitekta.

If you do miss a dose:
- **If you notice within 18 hours** of the time you usually take Vitekta, you must take the tablet as soon as possible. Always take the tablet with food. Then take the next dose as usual.
- **If you notice 18 hours or more** after the time you usually take Vitekta, then do not take the missed dose. Wait and take the next dose, with food, at your usual time.

If you vomit less than 1 hour after taking Vitekta, take another tablet with food.

Do not stop taking Vitekta

Do not stop taking Vitekta without talking to your doctor. Stopping Vitekta can seriously affect your response to future treatment. If Vitekta is stopped for any reason, speak to your doctor before you restart taking Vitekta tablets.

When your supply of Vitekta starts to run low, get more from your doctor or pharmacist. This is very important because the amount of virus may start to increase if the medicine is stopped for even a short time. The disease may then become harder to treat.

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

4. Possible side effects

During HIV therapy there may be an increase in weight and in levels of blood lipids and glucose. This is partly linked to restored health and life style, and in the case of blood lipids sometimes to the HIV medicines themselves. Your doctor will test for these changes.

Like all medicines, this medicine can cause side effects, although not everybody gets them. When treating HIV infection, it is not always possible to tell whether some of the unwanted effects are caused by Vitekta or by other medicines that you are taking at the same time, or by the HIV infection itself.

Common side effects
(may affect 1 to 10 in every 100 patients treated)
- stomach pain
- vomiting
- rashes
- headache
- diarrhoea
- feeling sick *(nausea)*
- tiredness.

Uncommon side effects
(may affect up to 1 in every 100 patients treated)
- suicidal thoughts and suicide attempts (in patients who have had depression or mental health problems before)
- depression
- difficulty sleeping *(insomnia)*
- problems with digestion resulting in discomfort after meals *(dyspepsia)*
- feeling bloated
- wind *(flatulence)*
- dizziness
- tingling
- sleepiness
- abnormal taste.

→ If you think that you may have any of these side effects, talk to your doctor.

Other effects that may be seen during HIV treatment
The frequency of the following side effects is not known (frequency cannot be estimated from the available data):

Any signs of inflammation or infection. If you have advanced HIV infection (AIDS) and have an infection, you may develop symptoms of infection and inflammation or worsening of the symptoms of an existing infection once treatment with Vitekta is started. These symptoms may indicate that your body's improved immune system is fighting infection. Look out for signs of inflammation or infection soon after you start taking Vitekta. If you notice signs of inflammation or infection, **tell your doctor at once.** In addition to the opportunistic infections, autoimmune disorders (a condition that occurs when the immune system attacks healthy body tissue) may also occur after you start taking medicines for the treatment of your HIV infection. Autoimmune disorders may occur many months after the start of treatment. If you notice any symptoms of infection or other symptoms such as muscle weakness, weakness beginning in the

hands and feet and moving up towards the trunk of the body, palpitations, tremor or hyperactivity, please inform your doctor immediately to seek necessary treatment.

- **Bone problems.** Some patients taking combination antiretroviral therapy may develop a bone disease called osteonecrosis (death of bone tissue caused by loss of blood supply to the bone). The length of combination antiretroviral therapy, corticosteroid use, alcohol consumption, severe immunosuppression, higher body mass index, among others, may be some of the many risk factors for developing this disease. Signs of osteonecrosis are:
  - joint stiffness
  - joint aches and pains (especially of the hip, knee and shoulder)
  - difficulty with movement.

  If you notice any of these symptoms, **tell your doctor.**

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 national reporting system listed in Appendix V. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Vitekta

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.

This medicine does not require any special storage conditions.

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 Vitekta contains

The active substance is elvitegravir. Each film-coated tablet contains 150 mg elvitegravir.

The other ingredients are

Tablet core:
Croscarmellose sodium, hydroxypropyl cellulose, lactose (as monohydrate), magnesium stearate, microcrystalline cellulose, sodium lauryl sulfate.

Film coating:
Indigo carmine aluminium lake (E132), macrogol 3350 (E1521), polyvinyl alcohol (partially hydrolysed) (E1203), talc (E553B), titanium dioxide (E171), iron oxide yellow (E172).

What Vitekta looks like and contents of the pack

Vitekta film-coated tablets are green, triangle-shaped tablets, debossed on one side with "GSI" and "150" on the other side of the tablet.

The following pack size is available: outer cartons containing 1 bottle of 30 film-coated tablets.

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Detailed information on this medicine is available on the European Medicines Agency web site: http://www.ema.europa.eu.