Patient Information Leaflet

SCHEDULING STATUS:

S4

KIVEXA Film-coated tablets

Abacavir 600 mg/Lamivudine 300 mg

Sugar-free

IMPORTANT - HYPERSENSITIVITY REACTION

KIVEXA contains abacavir. Patients taking KIVEXA may develop a hypersensitivity reaction (serious allergic reaction). It is essential you read the information on this reaction in the "Take special care with KIVEXA" section of this leaflet. There is also **an Alert Card** included in the KIVEXA pack, to remind you and medical staff about KIVEXA hypersensitivity. This card should be removed from the pack and kept with you at all times. The text on this card is shown below.

Patients taking KIVEXA may develop a hypersensitivity reaction (serious allergic reaction) which **can be life-threatening** if treatment with KIVEXA is continued.

CONTACT YOUR DOCTOR IMMEDIATELY for advice on whether you should stop taking KIVEXA if:

1) **you get a skin rash OR**
2) **you get one or more symptoms from at least TWO of the following groups**:
   - fever
   - shortness of breath, sore throat or cough
   - nausea or vomiting or diarrhoea or abdominal pain
   - severe tiredness or achiness or generally ill feeling.

If you have discontinued KIVEXA due to a hypersensitivity reaction, **YOU MUST NEVER TAKE** KIVEXA, or any other medicine containing abacavir again, as **within hours** you may experience a life-threatening lowering of your blood pressure or death.

Read all of this leaflet carefully before you start taking KIVEXA.

- Keep this leaflet, you may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- **KIVEXA** 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.

What is in this leaflet:

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

1. WHAT KIVEXA IS AND WHAT IT IS USED FOR:

KIVEXA contains both abacavir and lamivudine. KIVEXA belongs to a group of antiretroviral medicines called nucleoside analogue reverse transcriptase inhibitors (NRTIs) and is used

in combination with other antiretrovirals to treat Human Immunodeficiency Virus (HIV) infection in adults and adolescents from 12 years of age, weighing at least 40 kg.
KIVEXA reduces HIV viral load and keeps it at a low level. Response to treatment with KIVEXA varies between patients. Your doctor will be monitoring the effectiveness of your treatment.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE KIVEXA:

Do not take KIVEXA:

- if you are allergic to the active substances abacavir, lamivudine or any of the other ingredients in KIVEXA.
- if you have serious liver disease, KIVEXA may not be suitable for you
- if you are pregnant, intend to become pregnant or if you are breastfeeding your baby.

If you are not sure whether you should be taking KIVEXA, please discuss with your doctor before taking this medicine.

Warnings and precautions:

Take special care with KIVEXA:

***Hypersensitivity reaction (serious allergic reaction)*:**

KIVEXA contains abacavir.

Abacavir can cause a serious allergic reaction known as a hypersensitivity reaction, which can be life-threatening if treatment with abacavir containing products is not stopped.

Who gets these reactions?

Anyone taking KIVEXA could develop a hypersensitivity reaction to abacavir, which could be life-threatening if they continue to take KIVEXA.

Research has found that people with a gene called HLA-B (type 5701) are more likely to have a hypersensitivity reaction to abacavir. However, even if you do not have this gene

type it is still possible for you to get this reaction. **If you know you have this gene type, be sure to tell your doctor before you take abacavir.**

What are the symptoms?

The most common symptoms of this reaction are:

- high temperature (fever) and a skin rash.

Other frequently observed signs or symptoms include:

- nausea (feeling sick), vomiting (being sick), diarrhoea, abdominal (stomach) pain, shortness of breath, cough, headache and severe tiredness.

Other symptoms may include:

- joint or muscle pain, discomfort, swelling of the neck, serious breathing problems and sore throat. Occasionally inflammation of the eye (conjunctivitis), ulcers in the mouth, low blood pressure or tingling or numbness of the hands or feet may occur.

When do these reactions happen?

The symptoms of this allergic reaction can occur at any time during treatment with KIVEXA. However, they usually occur in the first six weeks of treatment and get worse with continued treatment.

If you are caring for a child who is being treated with KIVEXA, it is important that you understand the information about this hypersensitivity reaction. If your child gets the symptoms described below **it is essential** that you follow the instructions given.

The hypersensitivity reaction can be life-threatening or fatal if treatment with KIVEXA is continued. You should contact your doctor immediately for advice on whether you should stop taking KIVEXA if:

1) you get a skin rash OR

2) you get one or more symptoms from at least TWO of the following groups:

- fever
- shortness of breath, sore throat or cough
- nausea or vomiting or diarrhoea or abdominal(stomach) pain

- severe tiredness or achiness or generally ill feeling.

Your doctor may advise you to stop taking KIVEXA.

Always carry your Alert Card while you are taking KIVEXA.

If you have stopped taking KIVEXA:

If you have discontinued KIVEXA due to a hypersensitivity reaction, **YOU MUST NEVER TAKE KIVEXA**, **or any other medicine containing abacavir** again as **within hours** you may experience a life-threatening lowering of your blood pressure or death.

If you have stopped taking KIVEXA for any reason, particularly because you think you are having side effects or for other illness:

It is important that you inform your doctor before restarting. Your doctor will check whether any symptoms you had before stopping may be related to this hypersensitivity reaction. If your doctor thinks there is a possibility that they were related, **you may be told never to take KIVEXA or any other medicine containing abacavir again.** It is important that you follow this advice.

Reactions have developed in people who start taking abacavir again and had **only one** symptom on the Alert Card before they stopped taking it.

Reactions have developed in people who start taking abacavir again, but who had no symptoms before they stopped taking it.

If your doctor advises that you can start taking KIVEXA again, you may be asked to take your first doses in a place where you will have ready access to medical care if you need it.

If you are hypersensitive to KIVEXA you should return all of your unused KIVEXA to your doctor or pharmacist for proper disposal.

The KIVEXA pack includes an Alert Card, to remind you and medical staff about hypersensitivity reactions. **Detach this card and keep it with you at all times.**

Before you take KIVEXA your doctor needs to know:

- if you have ever had **liver disease,** including hepatitis B or C.

Talk to your doctor if any of the above applies to you. You may need extra check-ups, including blood tests, while you're taking your medication. **See section 4 for more information**.

Conditions you need to look out for:

Heart Disease:

There may be an increased risk for heart attacks in patients using KIVEXA.

Tell your doctor if you have heart problems, if you smoke, or have other illnesses that may increase your risk of heart disease such as high blood pressure, or diabetes. Don't stop taking KIVEXA unless your doctor advises you to do so.

Symptoms of infection and inflammation:

People with advanced HIV infection (AIDS) have weak immune systems and are more likely to develop serious infections (*opportunistic infections*). When they start treatment, the immune system becomes stronger, so the body starts to fight infections.

Symptoms of infection and inflammation may develop, caused by either:

- old, hidden infections flaring up again as the body fights them
- the immune system attacking healthy body tissue (*auto-immune disorders*).

The symptoms of auto-immune disorders may develop many months after you start taking medicine to treat your HIV infection.

See '*Conditions you need to look out for*' in section 4.

Change in body shape:

People taking combination therapy for HIV may find that their body shape changes, because of changes in fat distribution.

See '*Conditions you need to look out for'* in section 4.

Lactic acidosis:

A condition that is caused by build-up of lactic acid in the body. It is more likely to develop in people who have liver disease, especially in women.

See '*Conditions you need to look out for'* in section 4.

Protect other people:

HIV infection is spread by sexual contact with someone who has the infection, or by transfer of infected blood (for example, by sharing injection needles). KIVEXA will not stop you passing HIV infection on to other people. To protect other people from becoming infected with HIV:

- **Use a condom** when you have oral or penetrative sex.
- **Do not risk blood transfer** - for example, don't share needles.

Other medicines and KIVEXA:

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines.) Abacavir or lamivudine in KIVEXA may interact with certain other medicines.

KIVEXA should not be taken with zalcitabine or emtricitabine, high doses of co-trimoxazole, injections of ganciclovir or foscarnet.

If you are taking methadone, your doctor may need to adjust your methadone dose, as abacavir (one of the active substances in KIVEXA) increases the rate at which methadone is cleared from your body. This is unlikely to affect most methadone users.

KIVEXA with food and drink and alcohol:

KIVEXA can be taken with or without food.

Pregnancy, breastfeeding and fertility:

KIVEXA is not recommended for use in pregnant women.

You should not breastfeed your baby while taking KIVEXA. Additionally, it is recommended that HIV infected women do not breastfeed their infants under any circumstances in order to avoid transmission of HIV from mother to child.

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking KIVEXA.

Driving and using machinery:

KIVEXA is unlikely to affect your ability to drive or operate machinery. If you have any concerns consult your doctor.

3. HOW TO TAKE KIVEXA:

Do not share medicines prescribed for you with any other person.

Always take KIVEXA exactly as your doctor has instructed. You should check with your doctor or pharmacist if you are unsure. Take KIVEXA for as long as your doctor recommends. Don't stop unless your doctor advises you to. Take great care not to miss any doses if at all possible. Swallow the tablet whole with water.

The usual dose in adults and adolescents from 12 years of age, who weigh at least 40 kg, is one tablet daily.

If you take more KIVEXA than you should:

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you forget to take KIVEXA:

It is important to take KIVEXA as prescribed to ensure you get maximum benefit. If you forget to take a dose, take it as soon as you remember and then continue as before. Do not take a double dose to make up for forgotten individual doses. It is important to take KIVEXA regularly because irregular intake may increase the risk of hypersensitivity reactions.

If you stop taking KIVEXA:

If you have stopped taking KIVEXA for any reason, particularly because you think you are having side effects or for other illness, it is important that you contact your doctor before restarting. In some cases, your doctor will ask you to restart KIVEXA under direct medical supervision. If your doctor thinks that there is a possibility that your symptoms were related to a hypersensitivity reaction, you may be told never to take KIVEXA or any other medicine containing abacavir again.

4. POSSIBLE SIDE EFFECTS:

KIVEXA can have side effects.

Not all side effects reported for KIVEXA are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking this medicine, please consult your doctor, pharmacist or other healthcare professional for advice.

Conditions you need to look out for:

KIVEXA may cause other conditions to develop during HIV treatment.

Hypersensitivity reaction:

KIVEXA can cause a serious allergic reaction known as a hypersensitivity reaction, see 'Hypersensitivity reaction' in 'Take special care with KIVEXA'. **It is important that you read and understand the information about this serious reaction**.

Symptoms of infection and inflammation:

Symptoms of infection and inflammation may develop and include:

- **muscle weakness** and/or **muscle pain**
- **joint pain** or **swelling**
- **weakness** beginning in the hands and feet and moving up towards the trunk of the body
- **palpitations** or **tremor**
- **hyperactivity** (excessive restlessness and movement).

If you get any symptoms of infection while you're taking KIVEXA:

➔ **Tell your doctor immediately.** Don't take other medicines for the infection without your doctor's advice.

Your body shape may change:

People taking combination therapy for HIV may find that their body shape changes, because of changes in fat distribution:

- fat may be lost from the legs, arms or face.
- extra fat may build up around the stomach, or on the breasts or internal organs.
- fatty lumps (sometimes called buffalo hump) may appear on the back of the neck.

If you notice changes in your body shape, tell your doctor.

Lactic acidosis is serious side effect:

Some people taking KIVEXA or other medicines like it (NRTIs), develop a condition called lactic acidosis, together with an enlarged liver.

Signs of lactic acidosis include:

- **deep, rapid, difficult breathing**
- **drowsiness**
- **numbness** or **weakness** in the limbs
- **feeling sick** (nausea), **being sick** (vomiting)
- **stomach pain**.

During your treatment, your doctor will monitor you for signs of lactic acidosis. If you have any of the symptoms listed above or any other symptoms that worry you:

➔ **See your doctor as soon as possible**.

Other effects may show up in blood tests:

Combination therapy for HIV can also cause:

- **increased levels of lactic acid** in the blood, which on rare occasions can lead to lactic acidosis
- **increased levels of sugar and fats** (triglycerides and cholesterol) in the blood.

As KIVEXA contains both abacavir and lamivudine, the side effects reported for each of these have been combined.

Frequent side effects:

- headache
- feeling sick (*nausea*)
- hypersensitivity reaction (*see 'Hypersensitivity reactions' section above*)
- being sick (*vomiting*)
- diarrhoea
- stomach pains
- loss of appetite
- tiredness, lack of energy
- high temperature (*fever*)

- general feeling of being unwell
- muscle pain and discomfort
- joint pain
- skin rash
- hair loss.

Less frequent side effects:

Side effects that may show up in blood tests are:

- a low red blood cell count *(anaemia)* or low white blood cell count *(neutropenia or leucopenia)*
- an increase in the level of liver enzymes
- a decrease in the number of cells involved in blood clotting (*thrombocytopenia*)
- lactic acidosis (see '*Conditions you need to look out for*')
- inflammation of the pancreas (*pancreatitis*)
- breakdown of muscle tissue
- increase in an enzyme called amylase.

Frequency unknown:

- tingling or numbness of the skin, arms or legs
- skin rash, which may form blisters and looks like small targets (central dark spots surrounded by a paler area, with a dark ring around the edge) *(erythema multiforme)*
- a widespread rash with blisters and peeling skin, particularly around the mouth, nose, eyes and genitals *(Stevens-Johnson syndrome)* and a more severe form causing skin peeling on large parts of your body surface *(toxic epidermal necrolysis)*.
- **If you notice any of these symptoms contact a doctor urgently**.

Side effects that may show up in blood tests are:

- a failure of the bone marrow to produce new red blood cells *(pure red cell aplasia)*. Symptoms include fatigue, shortness of breath with exertion, rapid or irregular heart rate, pale skin, frequent or prolonged infections, unexplained or easy bruising, nosebleeds and bleeding gums, prolonged bleeding from cuts, skin rash, dizziness and headache.

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

Reporting of side effects:

If you get side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects to SAHPRA via the '6.04 Adverse Drug Reaction Reporting Form', found on-line under SAHPRA'S publications: htpp://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of KIVEXA.

5. HOW TO STORE KIVEXA:

Store at or below 30 °C. Keep the blisters in the carton until required for use.

Do not take the medicine after the expiry date stated on the blister and carton.

Store all medicines out of the reach of children.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. CONTENTS OF THE PACK AND OTHER INFORMATION:

What KIVEXA contains:

The active substances are abacavir and lamivudine. Each KIVEXA film-coated tablet contains 600 mg of abacavir as abacavir sulphate and 300 mg lamivudine.

The other ingredients are magnesium stearate, microcrystalline cellulose, sodium starch glycollate in the core of the tablet. The tablet is coated with Opadry Orange YS-1-13065-A containing: hypromellose (E464), titanium dioxide (E171), macrogol 400, polysorbate 80 (E433), and sunset yellow aluminium lake (E110).

Sugar-free

What KIVEXA looks like and contents of the pack:

Orange, film-coated, modified capsule-shaped tablets, debossed with 'GS FC2' on one side and plain on the other side.

KIVEXA tablets are available in opaque white, polyvinyl chloride (PVC)/polyvinylidene chloride (PVdC) blister packs or in opaque white, PVC/PVdC child-resistant blister packs each containing 30 tablets. The blister strips are packed in a cardboard carton.

Registration Number:

A39/20.2.8/0030

Holder of Certificate of Registration:

GlaxoSmithKline South Africa (Pty) Ltd

39 Hawkins Avenue

Epping Industria 1, 7460

The leaflet was last revised in 5 August 2019.

GDS-19

Trademarks are owned by or licensed to the ViiV Healthcare group of companies.

© 2022 ViiV Healthcare group of companies or its licensor.

