

KIVEXA TABLETS

Abacavir sulfate/lamivudine (600 mg/300 mg)

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What Kivexa is used for

Kivexa is used to treat HIV (human immunodeficiency virus) infection in adults, adolescents and in children weighing at least 25 kg. Kivexa contains two active ingredients that are used to treat HIV infection: abacavir and lamivudine. These belong to a group of anti-retroviral medicines called *nucleoside analogue reverse transcriptase inhibitors (NRTIs)*.

How Kivexa works

Kivexa does not completely cure HIV infection; it reduces the amount of virus in your body and keeps it at a low level. It also increases the CD4 cell count in your blood. CD4 cells are a type of white blood cells that are important in helping your body to fight infection. Not everyone responds to treatment with Kivexa in the same way. Your doctor will monitor the effectiveness of your treatment.

Before you use Kivexa

- When you must not use it

Do not take Kivexa:

- If you are allergic (hypersensitive) to abacavir (or any other medicine containing abacavir – (e.g. Ziagen), lamivudine or any of

the other ingredients of this medicine.

You are more likely to develop this reaction if you have a gene called HLA-B*5701 (but you can get a reaction even if you do not have this gene). You should have been tested for this gene before Kivexa was prescribed for you. If you know you have this gene, tell your doctor before you take Kivexa.

Carefully read all the information about hypersensitivity reactions in section “Side Effect”. Check with your doctor if you think this applies to you. Do not take Kivexa.

Pregnancy

Kivexa is not recommended for use during pregnancy. Kivexa and similar medicines may cause side effects in unborn babies.

If you have taken Kivexa during your pregnancy, your doctor may request regular blood tests and other diagnostic tests to monitor the development of your child.

Breast-feeding

Women who are HIV-positive must not breast-feed, because HIV infection can be passed on to the baby in breast milk. A small amount of the ingredients in Kivexa can also pass into your breast milk.

If you are breast-feeding, or thinking about breast-feeding: Talk to your doctor immediately.

- Before you start to use it

Some people taking Kivexa or other combination treatments for HIV are more at risk of serious

side effects. You need to be aware of the extra risks:

- If you have moderate or severe liver disease
 - If you have ever had liver disease, including hepatitis B or C (if you have hepatitis B infection, do not stop taking Kivexa without your doctor’s advice, as your hepatitis may come back)
 - If you are seriously overweight (especially if you are a woman)
 - If you have a kidney problem
- Talk to your doctor if any of these apply to you before using Kivexa. You may need extra check-ups, including blood tests, while you are taking your medicine.

- Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, if you have taken any recently or if you start taking new medicine. This includes herbal medicines or other medicines you bought without a prescription.

These medicines should not be used with Kivexa:

- Emtricitabine, to treat HIV infection
- other medicinal products containing lamivudine, used to treat HIV infection or hepatitis B infection
- high doses of trimethoprim/sulfamethoxazole, an antibiotic
- cladribine, used to treat hairy cell leukaemia

Tell your doctor if you are being treated with any of these.

Some medicines interact with Kivexa. These include:

- phenytoin, for treating epilepsy. Tell your doctor if

you are taking phenytoin. Your doctor may need to monitor you while you are taking Kivexa.

- Methadone, used as a heroin substitute. If you are taking methadone, you will be checked for any withdrawal symptoms. Your methadone dose may need to be changed. Tell your doctor if you are taking methadone.
- Riociguat, a medicine used to treat high blood pressure in the blood vessels (the pulmonary arteries) that carry blood from the heart to the lungs). If you are taking riociguat, your doctor may need to reduce your riociguat dose, as abacavir (one of the active substances in Kivexa) may increase riociguat blood levels.

How to use Kivexa

- How much to use

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

The recommended dose of Kivexa for adults, adolescents and children weighing 25 kg or more is one tablet once a day. Swallow the tablets whole, with some water. Kivexa can be taken with or without food.

- When to use it

It is important to take Kivexa regularly, because if you take it at irregular intervals, you may be more likely to have a hypersensitivity reaction.

- How long to use it

Stay in regular contact with your doctor. Kivexa helps to control your condition. You need to keep taking it every day to stop your illness getting worse. You may still develop other infections and illnesses linked to HIV infection.

Do not stop taking Kivexa without your doctor's advice.

- If you forget to use it

If you forget to take a dose, take it as soon as you remember.

Then continue your treatment as before.

Do not take a double dose to make up for a forgotten dose.

- If you use too much (overdose)

If you accidentally take too much Kivexa, tell your doctor or your pharmacist, or contact your nearest hospital emergency department for further advice.

While you are using it

- Things you must do *Abacavir hypersensitivity reactions*

Carefully read all the information about hypersensitivity reactions in Section "Side Effect" of this leaflet.

If you have stopped taking Kivexa for any reason — especially because you think you are having side effects, or because you have other illness: Talk to your doctor before you start taking it again. Your doctor will check whether your symptoms were related to a hypersensitivity reaction. If the doctor thinks they may have been related, you will be told never again to take Kivexa, or any other medicine containing abacavir (e.g. Ziagen). It is important that you follow this advice.

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.

- Things you must not do

Kivexa may cause side effects which could affect your ability to drive or use machines.

- Things to be careful of *Risk of heart attack*

It cannot be excluded that abacavir may increase the risk of having a heart attack.

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. Do not stop taking Kivexa unless your doctor advises you to do so.

Kivexa contains a colouring called sunset yellow (E110), this may cause allergic reactions in some people.

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). 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.

Side Effects

During HIV therapy there may be an increase in weight and in levels of blood lipids and glucose. Your doctor will test for these changes.

Like all medicines, this medicine can cause side effects, although not everyone gets them.

When you are being treated for HIV, it can be hard to tell whether a symptom is a side effect of Kivexa or other medicines you are taking, or an effect of the HIV disease itself. So it is very important to talk to

your doctor about any changes in your health.

Hypersensitivity reactions

The most common symptoms are:

- fever and skin rash.

Other common symptoms are:

- nausea, vomiting, diarrhoea, stomach pain, severe tiredness.

Other symptoms include:

- pains in the joints or muscles, swelling of the neck, shortness of breath, sore throat, cough, occasionally headache, inflammation of the eye, mouth ulcers, low blood pressure, tingling or numbness of the hands or feet.

Contact your doctor immediately:

1 if you get a skin rash, OR
2 if you get symptoms from at least 2 of the following groups:

- fever
- shortness of breath, sore throat or cough
- nausea or vomiting, diarrhoea or stomach pain
- severe tiredness or achiness, or generally feeling ill.

Common side effects

- hypersensitivity reaction
- headache
- being sick (*vomiting*)
- feeling sick (*nausea*)
- diarrhoea
- stomach pains
- loss of appetite
- tiredness, lack of energy
- fever
- general feeling of being unwell
- difficulty in sleeping (*insomnia*)
- muscle pain and discomfort
- joint pain
- cough
- irritated or runny nose
- skin rash
- hair loss.

Uncommon side effects

- a low red blood cell count (*anaemia*) or low white blood cell count (*neutropenia*)
- an increase in the level of liver enzymes
- a decrease in the number of cells involved in blood clotting (*thrombocytopenia*).

Rare side effects

- liver disorders, such as jaundice, enlarged liver or fatty liver, inflammation (hepatitis)
 - inflammation of the pancreas (pancreatitis)
 - breakdown of muscle tissue.
- Rare side effects that may show up in blood tests are:
- increase in an enzyme called amylase.

Very rare side effects

- numbness, tingly feelings in the skin (pins and needles)
- sensation of weakness in the limbs
- 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 in more than 30% of the body surface (toxic epidermal necrolysis).
- lactic acidosis (excess lactic acid in the blood)

If you notice any of these symptoms contact a doctor urgently.

Very rare side effects that may show up in blood tests are:

- a failure of the bone marrow to produce new red blood cells

Other possible side effects of combination therapy for HIV

Combination therapy such as Kivexa may cause other conditions to develop during HIV treatment.

Symptoms of infection and inflammation

Old infections may flare up. After starting treatment, you may experience symptoms of infection or inflammation. Symptoms usually include fever, plus some of the following:

- headache
- stomach ache
- difficulty breathing

In rare cases, as the immune system becomes stronger, it can also attack healthy body tissue (autoimmune disorders). The symptoms of autoimmune disorders may develop many months after you start taking medicine to treat your HIV infection. Symptoms may include:

- palpitations (rapid or irregular heartbeat) or tremor
- hyperactivity (excessive restlessness and movement)
- weakness beginning in the hands and feet and moving up towards the trunk of the body

If you get any symptoms of infection and inflammation or if you notice any of the symptoms above:

Tell your doctor immediately. Do not take other medicines for the infection without your doctor's advice.

You may have problems with your bones

Some people taking combination therapy for HIV develop a condition called *osteonecrosis*. With this condition, parts of the bone tissue die because of reduced blood supply to the

bone. People may be more likely to get this condition:

- if they have been taking combination therapy for a long time
- if they are also taking anti-inflammatory medicines called corticosteroids
- if they drink alcohol
- if their immune systems are very weak
- if they are overweight.

Signs of osteonecrosis include:

- stiffness in the joints
- aches and pains (especially in the hip, knee or shoulder)
- difficulty moving.

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

You may report any side effects of adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website nptra.gov.my (Consumer → Reporting Side Effects to Medicine (ConSERF) or Vaccines (AEFI))

Storage and Disposal of Kivexa

- Storage

- Keep this medicine out of the sight and reach of children.
- Do not store above 30°C.
- Do not take this medicine after the expiry date shown on the carton. The expiry date refers to the last day of that month.

- Disposal

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

Product Description

- What it looks like

Orange, film-coated, modified capsule shaped tablets, debossed with GS FC2 on one side.

- Ingredients

- Active ingredient(s)

Abacavir as sulfate (600 mg)

Lamivudine (300 mg)

- Inactive ingredient(s)

Tablet core:

Magnesium stearate

Microcrystalline cellulose

Sodium starch glucolate

Tablet coat:

Opadry orange YS-1-13065-A containing: Hypromellose, Titanium dioxide, Macrogol 400, Polysorbate 80, Sunset yellow FCF (E110)

- MAL number

MAL20071699ACRZ

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Product Registration Holder

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