PACKAGE LEAFLET

Package leaflet: Information for the patient

Abacavir Hexal® 300 mg, filmomhulde tabletten

abacavir

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.

IMPORTANT - Hypersensitivity reactions

[Nationally completed name] contains abacavir (which is also an active substance in medicines such as **Kivexa, Triumeq** and **Trizivir**). Some people who take abacavir may develop a **hypersensitivity reaction** (a serious allergic reaction), which can be life-threatening if they continue to take abacavir containing products.

You must carefully read all the information under 'Hypersensitivity reactions' in the panel in Section 4.

The [Nationally completed name] pack includes an **Alert Card**, to remind you and medical staff about abacavir hypersensitivity. **Detach this card and keep it with you at all times**.

What is in this leaflet

1. What [Nationally completed name] is and what it is used for

[Nationally completed name] is used to treat HIV (human immunodeficiency virus) infection.

[Nationally completed name] contains the active ingredient abacavir. Abacavir belongs to a group of anti-retroviral medicines called *nucleoside analogue reverse transcriptase inhibitors (NRTIs)*.

[Nationally completed name] 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 cell that are important in helping your body to fight infection.

Not everyone responds to treatment with [Nationally completed name] in the same way. Your doctor will monitor the effectiveness of your treatment.

2. What you need to know before you take [Nationally completed name]

Do not take [Nationally completed name]:
- if you are **allergic** *(hypersensitive)* to abacavir (or any other medicine containing abacavir - such as **Trizivir, Triumeq** or **Kivexa**) or any of the other ingredients of this medicine (listed in Section 6)
  Carefully read all the information about hypersensitivity reactions in Section 4.

  Check with your doctor if you think any of these apply to you.

Take special care with [Nationally completed name]
Some people taking [Nationally completed name] 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 are seriously **overweight** (especially if you are a woman)
- if you have **severe kidney disease**

Talk to your doctor if any of these apply to you. You may need extra check-ups, including blood tests, while you are taking your medicine. **See Section 4 for more information**.

Abacavir hypersensitivity reactions
Even patients who don't have the HLA-B*5701 gene may still develop a **hypersensitivity reaction** (a serious allergic reaction).

Carefully read all the information about hypersensitivity reactions in Section 4 of this leaflet.

Risk of cardiovascular events
It cannot be excluded that abacavir may increase the risk of having cardiovascular events.
Tell your doctor if you have cardiovascular problems, if you smoke, or have other illnesses that may increase your risk of cardiovascular diseases such as high blood pressure, or diabetes. Do not stop taking [Nationally completed name] unless your doctor advises you to do so.

Look out for important symptoms
Some people taking medicines for HIV infection develop other conditions, which can be serious. You need to know about important signs and symptoms to look out for while you are taking [Nationally completed name].
Read the information 'Other possible side effects of combination therapy for HIV' in Section 4 of this leaflet.

Other medicines and [Nationally completed name]
Tell your doctor or pharmacist if you are taking any other medicines, or if you have taken any recently, including herbal medicines or other medicines you bought without a prescription. Remember to tell your doctor or pharmacist if you begin taking a new medicine while you are taking [Nationally completed name].

Some medicines interact with [Nationally completed name]
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 **[Nationally completed name]**.

- **methadone** used as a **heroin substitute**. Abacavir increases the rate at which methadone is removed from the body. 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,** for treating **high blood pressure in the blood vessels** (the pulmonary arteries) that carry blood from the heart to the lungs. Your doctor may need to reduce your riociguat dose, as abacavir may increase riociguat blood levels.

Pregnancy
[Nationally completed name] is not recommended for use during pregnancy. [Nationally completed name] and similar medicines may cause side effects in unborn babies. If you have taken [Nationally completed name] during your pregnancy, your doctor may request regular blood tests and other diagnostic tests to monitor the development of your child. In children whose mothers took NRTIs during pregnancy, the benefit from the protection against HIV outweighed the risk of side effects.

Breast-feeding
Breast-feeding is **not recommended** in women living with HIV because HIV infection can be passed on to the baby in breast milk. A small amount of the ingredients in [Nationally completed name] can also pass into your breast milk.

If you are breast-feeding, or thinking about breast-feeding, you should **discuss it with your doctor as soon as possible**.

Driving and using machines
Do not drive or operate machines unless you are feeling well.

[Nationally completed name] contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per film-coated tablet, that is to say essentially ‘sodium-free’.

3. How to take [Nationally completed name]

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

Swallow the tablets with some water. [Nationally completed name] can be taken with or without food.

If you cannot swallow the tablet(s), you may crush and combine them with a small amount of food or drink, and take all the dose immediately.

Stay in regular contact with your doctor
[Nationally completed name] 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.
Keep in touch with your doctor, and do not stop taking [Nationally completed name] without your doctor's advice.

How much to take

Adults, adolescents and children weighing at least 25 kg
The usual dose of [Nationally completed name] is 600 mg a day. This can be taken either as one 300 mg tablet twice a day or two 300 mg tablets once a day.

Children from one year of age weighing less than 25 kg

The dose given depends on the body weight of your child. The recommended dose is:

- **Children weighing at least 20 kg and less than 25 kg:** The usual dose of [Nationally completed name] is 450 mg a day. This can be given as 150 mg (half of a tablet) taken in the morning and 300 mg (one whole tablet) taken in the evening, or 450 mg (one and a half tablets) once a day as advised by your doctor.

- **Children weighing at least 14 kg and less than 20 kg**: The usual dose of [Nationally completed name] is 300 mg a day. This can be given as 150 mg (half of a tablet) twice daily, or 300 mg (one whole tablet) once a day as advised by your doctor.

The tablet can be divided into equal doses.

Abacavir oral solution may be available for the treatment of children over three months of age and weighing less than 14 kg, or for people who need a lower than usual dose, or who cannot take tablets.

If you take more [Nationally completed name] than you should
If you accidentally take too much [Nationally completed name], tell your doctor or your pharmacist, or contact your nearest hospital emergency department for further advice.

If you forget to take [Nationally completed name]

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.

It is important to take [Nationally completed name] regularly, because if you take it at irregular intervals, you may be more likely to have a hypersensitivity reaction.

If you have stopped taking [Nationally completed name]
If you have stopped taking [Nationally completed name] 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 [Nationally completed name], or any other medicine containing abacavir (e.g. Triumeq, Trizivir or Kivexa)**. It is important that you follow this advice.

If your doctor advises that you can start taking **[Nationally completed name]** 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.

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 everyone gets them.

When you are being treated for HIV, it can be hard to tell whether a symptom is a side effect of [Nationally completed name] 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**.

Even patients who don't have the HLA-B*5701 gene may still develop a **hypersensitivity reaction** (a serious allergic reaction), described in this leaflet in the panel headed 'Hypersensitivity reactions'.

It is very important that you read and understand the information about this serious reaction.

As well as the side effects listed below for [Nationally completed name], other conditions can develop during combination therapy for HIV.
It is important to read the information later in this section under 'Other possible side effects of combination therapy for HIV'.

Hypersensitivity reactions

[Nationally completed name] contains **abacavir** (which is also an active ingredient in **Trizivir, Triumeq** and **Kivexa**). Abacavir can cause a serious allergic reaction known as a hypersensitivity reaction.
These hypersensitivity reactions have been seen more frequently in people taking medicines that

contain abacavir.

Who gets these reactions?
Anyone taking [Nationally completed name] could develop a hypersensitivity reaction to abacavir, which could be life threatening if they continue to take [Nationally completed name].

You are more likely to develop such a reaction if you have the **HLA-B*5701** gene (but you can get a reaction even if you do not have this gene). You should have been tested for this gene before [Nationally completed name] was prescribed for you. **If you know you have this gene, tell your doctor before you take [Nationally completed name]**. About 3 to 4 in every 100 patients treated with abacavir in a clinical trial who did not have the HLA-B*5701 gene developed a hypersensitivity reaction.

What are the symptoms?
The most common symptoms are:
- **fever** (high temperature) and **skin rash**.

Other common symptoms are:
- nausea (feeling sick), vomiting (being sick), diarrhoea, abdominal (stomach) pain, severe tiredness

Other symptoms include:

Pains in the joints or muscles, swelling of the neck, shortness of breath, sore throat, cough, occasional headaches, inflammation of the eye (conjunctivitis), mouth ulcers, low blood pressure, tingling or numbness of the hands or feet.

When do these reactions happen?
Hypersensitivity reactions can start at any time during treatment with [Nationally completed name], but are more likely during the first 6 weeks of treatment.

If you are caring for a child who is being treated with [Nationally completed name], 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.

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 abdominal pain
- severe tiredness or achiness, or generally feeling ill.

Your doctor may advise you to stop taking [Nationally completed name].

If you have stopped taking [Nationally completed name]

If you have stopped taking [Nationally completed name] because of a hypersensitivity reaction, **you**

must NEVER AGAIN take [Nationally completed name], or any other medicine containing abacavir (e.g. Trizivir, Triumeq or Kivexa). If you do, within hours, your blood pressure could fall dangerously low, which could result in death.

If you have stopped taking **[Nationally completed name]** 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 again. Your doctor will check whether your symptoms were related to a hypersensitivity reaction. If the doctor thinks they may have been, **you will then be told never again to take [Nationally completed name], or any other medicine containing abacavir (e.g. Trizivir, Triumeq or Kivexa)**. It is important that you follow this advice.

Occasionally, hypersensitivity reactions have developed in people who start taking abacavir containing products again, but who had only one symptom on the Alert Card before they stopped taking it.

Very rarely, patients who have taken medicines containing abacavir in the past without any symptoms of hypersensitivity have developed a hypersensitivity reaction when they start taking these medicines again.

If your doctor advises that you can start taking [Nationally completed name] 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 [Nationally completed name], return all your unused [Nationally completed name] tablets for safe disposal. Ask your doctor or pharmacist for advice.

The [Nationally completed name] 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**.

Common side effects
These may affect **up to 1 in 10** people:
- hypersensitivity reaction
- feeling sick *(nausea)*
- headache
- being sick *(vomiting)*
- diarrhoea
- loss of appetite
- tiredness, lack of energy
- fever (high temperature)
- skin rash

Rare side effects
These may affect **up to 1 in 1,000** people:
- inflammation of the pancreas *(pancreatitis)*

Very rare side effects
These may affect **up to 1 in 10,000** people:

- 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.

If you get side effects

Tell your doctor or pharmacist if any of the side effects get severe or troublesome, or if you notice any side effects not listed in this leaflet.

Other possible side effects of combination therapy for HIV

Combination therapy including [Nationally completed name] may cause other conditions to develop during HIV treatment.

Symptoms of infection and inflammation

Old infections may flare up

People with advanced HIV infection (AIDS) have weak immune systems, and are more likely to develop serious infections (opportunistic infections). When these people start treatment, they may find that old, hidden infections flare up, causing signs and symptoms of inflammation. These symptoms are probably caused by the body's immune system becoming stronger, so that the body starts to fight these infections. 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 while you are taking [Nationally completed name]:
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.

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 [Nationally completed name]

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 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 [Nationally completed name] contains

- The active substance is abacavir. Each film-coated tablet contains 300 mg of abacavir.
- The other excipients are:

Tablet content: Microcrystalline cellulose (PH 102), sodium starch glycolate (Type A)**,** colloidal anhydrous silica, magnesium stearate.
Tablet coat (OPADRY yellow85F520373)**:**
Poly vinyl alcohol-part hydrolyzed, titanium dioxide (E 171), talc, yellow iron oxide (E 172), macrogol/PEG.

What [Nationally completed name] looks like and contents of the pack

[Nationally completed name] film-coated tablets are yellow, capsule shaped, film-coated, biconvex tablets de bossed with 'H' on one side with score line and 'A and 26' separated by score line on other side (18.50 mm x 7.30 mm).

[Nationally completed name] is packed in PVC/Alu blisters or Alu/Alu blisters with pack sizes of 60 and 180 film-coated tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Houder van de vergunning voor het in de handel brengen
Hexal AG
Industriestrasse 25
83607 Holzkirchen
Duitsland

Fabrikant
Salutas Pharma GmbH
Otto-von-Guericke Allee 1
39179 Barleben
Duitsland

Lek Pharmaceuticals, d.d.
Verovskova Ulica 57,
Ljubljana, 1526
Slovenië

In het register ingeschreven onder:
RVG 117143

Dit geneesmiddel is geregistreerd in lidstaten van de EEA onder de volgende namen:
Nederland: Abacavir Hexal 300 mg, filmomhulde tabletten
Duitsland: Abacavir Hexal 300 mg Filmtabletten

Deze bijsluiter is voor het laatst goedgekeurd in december 2024