The format of this leaflet was determined by the Ministry of Health and its content was checked and approved by it

PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986

The medicine is dispensed with a doctor's prescription only

Lamicavir Teva®
Film-coated Tablets

Composition
Each film-coated tablet contains:
Abacavir 600 mg
Lamivudine 300 mg
For the list of inactive ingredients in the preparation, see section 6 – "Further information".

Read this leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.
This medicine has been prescribed to treat your ailment. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar.

IMPORTANT – Hypersensitivity reactions
Lamicavir Teva® contains abacavir. 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 preparations.
You should carefully read all the information under the 'Hypersensitivity reactions' heading, that appears in the panel in Section 4. The Lamicavir Teva® pack includes an **Alert Card**, to remind you and the medical staff about abacavir hypersensitivity. **Detach this card and keep it with you at all times.**

1. WHAT IS THE MEDICINE INTENDED FOR?
Lamicavir Teva® is used to treat HIV (acquired immunodeficiency syndrome) infection in adults and in children over the age of 12 years.

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

2. BEFORE USING THE MEDICINE

☒ Do not use the medicine if:
you are **sensitive** (allergic) to abacavir or to any other medicine containing abacavir, to lamivudine or to any of the other ingredients contained in the medicine (see list 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.

Special warnings regarding use of the medicine
Some people taking Lamicavir Teva® or other combination treatments for HIV, are at higher risk of serious side effects. You need to be aware of the extra risks:
- if you have **moderate or severe liver disease**
- if you suffered from **liver disease** in the past, including hepatitis B or C (if you have hepatitis B infection, do not stop taking Lamicavir Teva® without consulting your doctor, as your hepatitis may come back)
- if you are seriously **overweight** (especially if you are a woman)
- if you have a **kidney disease**

! If any of these apply to you, refer to your doctor before using Lamicavir Teva®. You may need extra tests, including blood tests, while you are taking your medicine. **See Section 4 for more information.**
Abacavir hypersensitivity reactions
Even patients who do not have the HLA-B*5701 gene can 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 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 Lamicavir Teva® unless your doctor recommends that you do so.
Look out for important symptoms
Some people taking medicines for HIV infection develop other medical conditions, which can be serious.
You need to know about important signs and symptoms so you can look out for them while you are taking Lamicavir Teva®.
Read the information 'Other possible side effects of combination therapy for HIV' - in Section 4 of this leaflet.

Protect other people
HIV infection is spread by sexual contact with someone who carries the infection, or by transmission of contaminated blood (for example, by sharing injection needles). You can still transmit HIV when taking this medicine, although the risk is lowered by effective antiretroviral therapy. Discuss with your doctor the necessary precautions to avoid infecting other people.

! Other medicines and Lamicavir Teva®
If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist.
Remember to inform your doctor or pharmacist if you begin taking a new medicine while you are taking Lamicavir Teva®.
Avoid taking these medicines with Lamicavir Teva®:
- Emtricitabine, to treat **HIV infection**
- other medicinal preparations containing lamivudine, used to treat **HIV infection** or **hepatitis B infection**
- high dosages of **trimethoprim/sulfamethoxazole** (an antibiotic)
- cladribine, used to treat **hairy cell leukemia**

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

Some medicines interact with Lamicavir Teva®
These include:
phenytoin, for treating **epilepsy**.
Tell your doctor if you are taking phenytoin. Your doctor may need to monitor your condition while you are taking Lamicavir Teva®.
- **methadone**, used as a **heroin substitute**. Abacavir increases the rate at which methadone is cleared 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.

! Pregnancy
Lamicavir Teva® is not recommended for use during pregnancy. Lamicavir Teva® and similar medicines may cause side effects in unborn babies. If you have taken Lamicavir Teva® during your pregnancy, your doctor may request regular blood tests and additional 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.

! Breastfeeding
Women who are HIV carriers must not breastfeed, because HIV infection can be passed on to the baby in breast milk. A small amount of the ingredients in Lamicavir Teva® can also pass into your breast milk.
If you are breastfeeding, or thinking about breastfeeding, **refer to your doctor immediately**.

! Driving and using machines
It is not known whether Lamicavir Teva® can affect your ability to drive or use machines. Pay attention to the side effects of the preparation that may sometimes affect your ability to drive or use machines.
Talk to your doctor about your ability to drive or operate machines while taking Lamicavir Teva®.

3. HOW SHOULD YOU USE THE MEDICINE?
Always use according to the doctor's instructions. Check with the doctor or pharmacist if you are not sure.
Swallow the tablets whole, with a little water. Lamicavir Teva® can be taken with or without food.
Stay in regular contact with your doctor
Lamicavir Teva® helps control your condition. Continue taking it every day to prevent your illness from getting worse. Other illnesses and infections linked to HIV infection may still develop.
Keep in touch with your doctor, and do not stop taking Lamicavir Teva® without consulting him.
The dosage and treatment regimen will be determined by the doctor only.
The recommended dosage of Lamicavir Teva® for adults and children over the age of 12 weighing at least 40 kg, is one tablet, once a day.

Do not exceed the recommended dose.

If you accidentally took a higher dosage
If you took an overdose or if a child accidentally swallowed the medicine, immediately refer to a doctor or proceed to a hospital emergency room and bring the package of the medicine with you.

If you forget to take the medicine
If you forget to take a dose, take it as soon as you remember. Then, continue treatment as before.
Do not take a double dose to compensate for a forgotten dose.
Adhere to the treatment regimen as recommended by the doctor.
It is important that you continue taking Lamicavir Teva® regularly, since if you take it at irregular intervals, there is a higher chance that you will experience a hypersensitivity reaction.

If you stop taking the medicine
If you stopped taking Lamicavir Teva® for any reason — especially because you think you are having side effects, or because you have another illness:
Refer 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 that they may be related, **you will be told to never again take Lamicavir Teva®, or any other medicine containing abacavir.** It is important that you follow this advice.
If your doctor instructs you that you can start taking Lamicavir Teva® again, you may be instructed to take your first doses in a place where you will have ready access to medical care if you need it.
Do not take medicines in the dark! Check the label and the dose each time you take medicine. Wear glasses if you need them.
If you have further questions regarding use of this medicine, consult the doctor or pharmacist.

4. SIDE EFFECTS
During HIV therapy there may be an increase in weight and in levels of blood lipids and sugar. These effects are partly linked to restored health and lifestyle, and in the case of blood lipids, there is sometimes a link to the HIV medicines themselves. Your doctor will test for these changes.
As with any medicine, use of Lamicavir Teva® can cause side effects in some users. Do not be alarmed by the list of side effects. You may not suffer from any of them.
When you are being treated for HIV infection, it may be difficult to distinguish whether a symptom is a side effect of Lamicavir Teva® or of other medicines you are taking, or is an effect of the HIV disease itself. **Therefore, it is very important to tell your doctor about any changes in your health.**
Even patients who do not have the HLA-B*5701 gene can 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.
In addition to the side effects listed below for Lamicavir Teva®, other medical conditions can develop during combination therapy for HIV.
It is important to read the information presented later in this section under 'Other possible side effects of combination therapy for HIV'.

Hypersensitivity reactions
Lamicavir Teva® contains **abacavir**.
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 develops these reactions?
Anyone taking Lamicavir Teva® could develop a hypersensitivity reaction to abacavir, which could be life-threatening if they continue taking Lamicavir Teva®.
You are more likely to develop this reaction if you have a gene called **HLA-B*5701** (but you may develop a reaction even if you do not have this gene). You should have been tested for this gene before Lamicavir Teva® was prescribed for you. **If you know you have this gene, tell your doctor about it before you take Lamicavir Teva®.**
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 and skin rash.**

Other common symptoms are:
- nausea, vomiting, diarrhea, abdominal pain, severe fatigue.

Other symptoms include:
Pains in the joint or muscles, swelling of the neck, shortness of breath, sore throat, cough, transient headaches, inflammation of the eye (conjunctivitis), mouth ulcers, low blood pressure, tingling or numbness of the hands or feet.
When do these symptoms occur?
Hypersensitivity reactions can start at any time during treatment with Lamicavir Teva®, but are more likely during the first 6 weeks of treatment.
Contact your doctor immediately:
1. if you develop a skin rash, OR
2. if you develop symptoms from at least 2 of the following groups:
- fever
- shortness of breath, sore throat or cough
- nausea or vomiting, diarrhea or abdominal pain
- severe tiredness or pain, or malaise.

Your doctor may advise you to stop taking Lamicavir Teva®.
If you have stopped taking Lamicavir Teva®
If you have stopped taking Lamicavir Teva® because of a hypersensitivity reaction, **you must NEVER AGAIN take Lamicavir Teva®, or any other medicine containing abacavir.** If you take it, within hours, your blood pressure could drop dangerously low, which could result in death.
If you have stopped taking Lamicavir Teva® for any reason — especially because you think you are having side effects, or because you have another illness:
Refer 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 be related, **you will be told to never again take Lamicavir Teva® or any other medicine containing abacavir.** It is important that you follow this advice.
Occasionally, hypersensitivity reactions have developed in people who started taking abacavir-containing preparations 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 started taking these medicines again.
If your doctor tells that you can start taking Lamicavir Teva® 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 Lamicavir Teva®, return all your remaining Lamicavir Teva® tablets for safe disposal. Consult with your doctor or pharmacist.
The Lamicavir Teva® pack includes an **Alert Card**, to remind you and the medical staff about hypersensitivity reactions. **Detach this card and keep it with you at all times.**

Common side effects
These may occur **in up to 1 in 10** people:
- hypersensitivity reaction
- headache
- vomiting
- nausea
- diarrhea
- stomach pains
- loss of appetite
- tiredness, lack of energy
- fever
- general unwell feeling
- difficulty in sleeping (*insomnia*)
- muscle pain and discomfort
- joint pain
- cough
- irritated or runny nose
- skin rash
- hair loss

Uncommon side effects
These may occur **in up to 1 in 100** people and may show up in blood tests:
- a low red blood cell count (*anemia*) 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
These may occur **in up to 1 in 1,000** people:
- liver disorders, such as jaundice, enlarged liver or fatty liver, inflammation (*hepatitis*)
- inflammation of the pancreas (*pancreatitis*)
- breakdown of muscle tissue.

A rare side effect that may show up in blood tests is:
- increase in the *amylase* enzyme.

Very rare side effects
These may occur **in up to 1 in 10,000** people:
- numbness, tingling sensation in the skin (pins and needles)
- sensation of weakness in the limbs
- skin rash, which may form blisters and look 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.
A very rare side effect that may show up in blood tests is:
- failure of the bone marrow to produce new red blood cells (*pure red cell aplasia*).

Other possible side effects of combination therapy for HIV
Combination therapy such as Lamicavir Teva® may cause development of other medical conditions during HIV treatment.
Flare ups of old infections
People with advanced HIV infection (AIDS) have a weak immune system, and are more likely to develop serious infections (*opportunistic infections*). Such infections may have been "dormant" and not detected by the weak immune system before treatment was initiated. After starting treatment, the immune system becomes stronger, and may attack the infections, which can cause symptoms of infection and 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. The symptoms may include:
- palpitations (rapid or irregular heartbeat) or tremor
- hyperactivity (excessive restlessness and movement)
- weakness beginning in the feet or hands and moving up towards the trunk of the body

If you develop 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 instructions from your doctor.
Bone necrosis
Some people taking combination therapy for HIV develop a condition called osteonecrosis (bone decay). In 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 system is very weak
- if they are overweight.

Signs of osteonecrosis include:
- stiffness in the joint
- aches and pains (especially in the hip, knee or shoulder)
- difficulty moving.

If you notice any of these symptoms, **tell your doctor.**
If a side effect occurs, if any of the side effects worsen, or if you are suffering from a side effect not mentioned in the leaflet, consult the doctor.
Reporting side effects
Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link:
https://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffectMedic@moh.gov.il

5. HOW SHOULD THE MEDICINE BE STORED?
Avoid poisoning! This medicine and any other medicine must be kept in a safe place out of the reach of children and/or infants in order to avoid poisoning. Do not induce vomiting without explicit instruction from the doctor.
Do not use the medicine after the expiry date (Expiry date) that appears on the package. The expiry date refers to the last day of that month.
Store the medicine below 25°C.
Do not discard medicines in the wastewater or waste bin. Ask the pharmacist how to dispose of medicines no longer in use. These measures will help to protect the environment.

6. FURTHER INFORMATION
In addition to the active ingredients, the medicine also contains:
Microcrystalline cellulose, Sodium starch glycolate type A, Hydroxypropyl cellulose, Hypromellose, Magnesium stearate, Titanium dioxide (E171), Macrogol/PEG 4000, Iron oxide yellow (E172), Polysorbate 80, Iron oxide red (E172)
Each film-coated tablet contains approximately 3.3 mg sodium

What the medicine looks like and the contents of the package:
Orange, oblong biconvex film coated tablet, with 300 debossed on one side and 600 on the other side. The pack contains 30 film-coated tablets in blisters (trays).

License Holder and its address
Abic Marketing Ltd., P.O.B. 8077, Netanya

Manufacturer and address
Teva Pharmaceutical Industries, Ltd., P.O.B. 3190, Petach Tikva

This leaflet was checked and approved by the Ministry of Health in 09.2017

Registration number of the medicine in the National Drug Registry of the Ministry of Health:
Lamicavir Teva® 159243462100