

## **WHO-PQ RECOMMENDED PATIENT INFORMATION LEAFLET**

*This patient information leaflet focuses on uses of the medicine covered by WHO's Prequalification Team - Medicines. The recommendations for use are based on WHO guidelines and on information from stringent regulatory authorities.\**

*The medicine may be authorised for additional or different uses by national medicines regulatory authorities.*

---

\* [https://extranet.who.int/prequal/sites/default/files/document\\_files/75%20SRA%20clarification\\_Feb2017\\_newtempl.pdf](https://extranet.who.int/prequal/sites/default/files/document_files/75%20SRA%20clarification_Feb2017_newtempl.pdf)

## Information for the patient

### [HA483 product name]<sup>†</sup> Zidovudine

*The warnings and instructions in this leaflet are intended for the person taking the medicine.  
If you are a parent or carer responsible for giving the medicine to someone else such as a child,  
you will need to apply the instructions accordingly.*

### **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 questions about the medicine, ask your health care provider.
- This medicine is for you only. Do not pass it on to others. It may harm them, even if their illness seems to be the same as yours.
- If you are concerned about any side effects, talk to your health care provider. This includes unwanted effects not listed in this leaflet. See section 4.

### **What is in this leaflet**

1. What [HA483 product name] is and what it is used for
2. What you need to know before you take [HA483 product name]
3. How to take [HA483 product name]
4. Possible side effects
5. How to store [HA483 product name]
6. Contents of the pack and other information

#### **1. What [HA483 product name] is and what it is used for**

[HA483 product name] is used in combination with other HIV medicines to treat HIV infection in patients weighing at least 25 kg.

The medicine reduces the amount of virus in your body and keeps it at a very low level. It is not a cure for HIV infection but if taken correctly, the combination will improve your immune system and reduce the risk of developing illnesses linked to HIV infection.

[HA483 product name] contains the active substance zidovudine. Zidovudine belongs to a group of medicines called nucleoside reverse transcriptase inhibitors (NRTIs).

#### **2. What you need to know before you take [HA483 product name]**

##### **Do not take [HA483 product name]:**

- if you are allergic (hypersensitive) to zidovudine or to any of the other ingredients of [HA483 product name] (see section 6, 'What [HA483 product name] contains').
- if you have a very low red blood cell count (severe anaemia) or a very low white blood cell count (neutropenia or leucopenia).

Check with your health care provider if you think any of these apply to you.

##### **Do not use [HA483 product name] if a newborn baby has certain liver problems:**

- Some cases of increased amount of bilirubin in the blood (hyperbilirubinaemia), a condition which might make the baby's skin look yellow;

---

<sup>†</sup> Trade names are not prequalified by WHO. This is the national medicines regulatory agency's responsibility.

- Blood tests showing excessive amount of certain liver enzymes in the blood.

### **Take special care with [HA483 product name]**

It is important to tell your health care provider about all your symptoms even when you think they are not related to HIV infection.

Some people taking [HA483 product name] or other combination treatments for HIV have a higher risk of side effects. You are more likely to have side effects if you:

- have or ever had liver disease, including hepatitis B or C. If you have hepatitis B, do not stop taking [HA483 product name] without checking with your health care provider, as the hepatitis may come back
- are seriously overweight (especially if you are a woman)

Talk to your health care provider if any of these apply to you before you start [HA483 product name]. You may need extra check-ups, including blood tests, while you are taking this medicine.

### *Look out for certain illnesses*

Contact your health care provider at once if you get the conditions described below.

If your immunity is weak when you start [HA483 product name], you might develop infections or inflammation. With continuing treatment your immunity will recover. When your immune system has improved enough, you will no longer be at risk. An infection usually causes fever, as well as any of the following:

- headache
- stomach pain
- difficulty breathing

Do not take other medicines for the infection without checking with your health care provider first.

Rarely, as the immune system becomes stronger, it can attack healthy body tissue (autoimmune disorders). The symptoms of autoimmune disorders may occur many months after you start taking HIV medicines. Autoimmune disorders can cause:

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

Some people taking medicines for HIV infection develop bone damage that can be serious. It causes joint pain, stiffness and bone problems.

A condition in which lactic acid builds up in your body (lactic acidosis) can occur rarely. It usually starts a few months after treatment with [HA483 product name]. People who have liver disease and very overweight people are most likely to get lactic acidosis. It is a serious condition and can cause:

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

### *Other medicines and [HA483 product name]*

Tell your health care provider if you are taking or have recently taken any other medicines, including herbal medicines or medicines obtained without a prescription. Also check with your health care provider if you begin taking a new medicine while you are taking [HA483 product name].

- stavudine, used to treat HIV infection
- high doses of trimethoprim/sulfamethoxazole, an antibiotic
- doxorubicin, used to treat certain types of cancers

- ribavirin to treat viral infections

Some medicines can make it more likely that you will have side effects, or make side effects worse.

Tell your health care provider if you are being treated with any of these:

- albendazole, used to treat infection with certain types of parasitic worms
- sodium valproate, used to treat epilepsy
- amodiaquine, primaquine or atovaquone, used to treat malaria
- dapsone, to prevent pneumonia and treat skin infections
- amphotericin, fluconazole or flucytosine, to treat fungal infections
- sulfadiazine or trimethoprim/sulfamethoxazole, to treat infections
- fluphenazine or quetiapine, used to treat certain mental disorders
- probenecid, to treat gout and similar conditions.
- methadone, used as a substitute for opioids such as morphine and heroin
- methyldopa, used to treat high blood pressure
- medicines to treat cancer.

Other medicines that can interact with [HA483 product name] include:

- clarithromycin, used as an antibiotic, if you are taking clarithromycin, take your dose at least 2 hours before or after you take [HA483 product name].
- phenytoin, used for treating epilepsy. Tell your health care provider if you are taking phenytoin. Your health care provider may need to monitor you while you are taking [HA483 product name].

### **Pregnancy and breast-feeding**

If you become pregnant, or are planning to become pregnant, you must contact your health care provider to discuss the potential benefits and risks of your HIV medicines to you and your child.

In children whose mothers took medicines like zidovudine during pregnancy, the reduced chance of getting HIV outweighs the risk of any side effects of the medicines.

If you want to breast-feed your baby, you should discuss the risks and benefits with your health care provider.

### **Driving and using machines**

[HA483 product name] may cause side effects such as dizziness, fatigue or headache, which can affect your ability to drive and to use machines. You should consider how you feel and the possible side effects of [HA483 product name] before deciding to drive or use machines.

### **3. How to take [HA483 product name]**

You should take [HA483 product name] exactly as described by your health care provider. Check with your health care provider if you are not sure.

#### **Taking [HA483 product name]**

*Adults, adolescents and children weighing at least 25 kg*

The recommended dose of [HA483 product name] is one tablet twice a day, about every 12 hours. Swallow the tablet with some water. You can take the tablet either with food or between meals.

It is important to take [HA483 product name] regularly. This helps to stop your infection becoming resistant to this medicine and reduces the chances of getting allergic (hypersensitivity) reactions.

*Children weighing less than 25 kg*

For patients who weigh less than 25 kg, medicines containing lower amounts of zidovudine should be used.

### **If you take more [HA483 product name] than you should**

If you accidentally take too much medicine, tell your health care provider or contact your nearest hospital emergency department for advice.

You may need medical attention. Remember to take the medicine container with you to show to the health care provider.

### **If you forget to take [HA483 product name]**

If you forget to take a dose and:

- it is more than 2 hours to the next dose, take the dose immediately and take the next dose at the usual time
- it is less than 2 hours to the next dose, skip the dose and take the next dose at the usual time

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

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

### **If you stop taking [HA483 product name]**

You should continue taking the medicine to keep the infection in control. Talk with your health care provider if you are thinking of stopping treatment and don't stop it unless the health care provider says you can.

If you have any questions about the use of this medicine, ask your health care provider.

## **4. Possible side effects**

Like all medicines, [HA483 product name] can cause side effects, although not everybody gets them.

During HIV therapy your weight may increase and levels of blood lipids and glucose may rise. This is partly linked to improvement in your health and lifestyle and, for blood lipids, sometimes to the HIV medicines. Your health care provider will look out for these changes.

Treatment with [HA483 product name] often causes a loss of fat from legs, arms and face (lipoatrophy). Tell your health care provider if you notice any loss of fat from your legs, arms, and face.

The most serious adverse reactions include anaemia (low red blood cell count), low white blood cell count and lactic acidosis (a build-up of lactic acid in the body that can cause dehydration and coma). These are more common in patients with advanced HIV infection.

Anaemia has not been serious during [HA483 product name] use for prevention of mother-to-child transmission.

Unwanted effects during treatment may be caused by [HA483 product name], by other medicines you take, or by the HIV disease. Tell your health care provider about changes in your health in case the health care provider needs to change your treatment in any way.

### **Very common side effects** (these may affect more than 1 in 10 patients treated):

- headache
- feeling sick (nausea).

### **Common side effects** (these may affect up to 1 in 10 patients treated):

- being sick (vomiting)
- diarrhoea
- abdominal (belly) pain
- feeling dizzy
- generally feeling unwell
- muscle pain and discomfort

- joint pain

Common side effects that might 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 sign of liver problems)
- an increased amount in the blood of bilirubin (a substance produced in the liver) which may make your skin appear yellow.

**Uncommon side effects** (these can affect up to 1 in every 100 patients treated):

- feeling breathless
- wind or gas (flatulence)
- itching
- rash
- muscle weakness
- feeling weak
- lack of energy
- pain
- fever (high temperature)

An uncommon side effect that may show up in blood test is:

- a decrease in the number of cells involved in blood clotting (thrombocytopenia) or in all blood cells (pancytopenia).

**Rare side effects** (these can affect up to 1 in 1000 patients treated):

- liver disorders, such as jaundice, enlarged liver or fatty liver, inflammation (hepatitis)
- lactic acidosis (excess lactic acid in the blood; see section 2, under ‘Look out for certain illnesses’)
- weight loss
- inflammation of the pancreas (pancreatitis)
- chest pain; heart muscle damage (cardiomyopathy)
- fits (convulsions)
- feeling depressed or anxious, loss of mental alertness feeling drowsy or difficulty sleeping (insomnia)
- indigestion, taste disturbance
- itchy rash (urticaria)
- changes in the colour of your nails, your skin or the inside of your mouth
- a flu-like feeling – chills and sweating
- cough
- tingly feelings in the skin (pins and needles)
- sensation of weakness in the limbs
- breakdown of muscle tissue which may lead to kidney damage
- numbness
- passing urine more often
- enlarged breasts in men.

Rare side effects that may show up in blood tests are:

- an increase in an enzyme called amylase (sign of problems with the pancreas)
- a failure of the bone marrow to produce new red blood cells (pure red cell aplasia).

**Very rare side effects** (these can affect less than 1 in every 10,000 patients treated):

A very rare side effect that may show up in blood tests is:

- a failure of the bone marrow to produce new red or white blood cells (aplastic anaemia).

**Other side effects** (not known how frequently they occur)

The following side effects are serious but it is not known how frequently they occur. Contact your health care provider if any of them occur. See section 2, under ‘Look out for certain illnesses’ for more information.

- bone damage (osteonecrosis)
- changes in your immune system which may lead to signs of infection or damage to body tissue

### **Reporting of side effects**

If you get a side effect, talk to your health care provider. This includes side effects not listed in this leaflet. You may also be able to report such effects directly to your national reporting system if one is available. By reporting side effects, you can help to improve the available information on this medicine.

### **5. How to store [HA483 product name]**

Keep this medicine out of the sight and reach of children.

Do not store above 30°C. Protect from high humidity.

Do not use this medicine after the expiry date stated on the carton after 'EXP'. The expiry date refers to the last day of that month.

Do not use this medicine if you notice the description of the visible signs of deterioration that it is different from the description below.

Do not throw away any medicines in wastewater <or household waste>. Ask your health care provider 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 [HA483 product name] contains**

- The active ingredient is Zidovudine 300 mg.
- The other ingredients of [HA483 product name] are;  
Tablet core: Hypromellose, magnesium stearate, microcrystalline cellulose and sodium starch glycolate.  
Film coating (Opadry white): Hypromellose, polyethylene glycol 400, polysorbate 80 and titanium dioxide.

There is too little sodium in this medicine to have any effect, even if you are on a low-sodium diet.

#### **What [HA483 product name] looks like and contents of the pack**

White, round biconvex, film-coated tablet plain on both the sides.

The tablets should not be divided.

The primary packs are:

- PVDC/PVC–Aluminium blisters; 10 tablets per blister card and 10 blister cards per carton (pack size: 100 tablets).
- Round, white opaque HDPE bottle 40cc/33 MM SP 400 Neck Style M (heavy weight) sealed with induction seal and white round, polypropylene cap (pack size: 30 tablets).
- Round, white opaque HDPE bottle 50cc/33 MM SP 400 Neck Style M (heavy weight) sealed with induction seal and white round, polypropylene cap (pack size: 60 tablets)
- Round, white opaque HDPE bottle 75cc/38 MM SP 400 Neck Style M (heavy weight) sealed with induction seal and white round, polypropylene cap; (pack size: 90 tablets).

## Supplier and Manufacturer

### *Supplier*

Micro Labs Limited  
31, Race Course Road  
Bengaluru-560001  
Karnataka  
India  
Tel : +91-80-22370451-57  
Fax : +91-80-22370463  
Email: info@microlabs.in

### *Manufacturer*

Micro Labs Limited  
Plot No S-155 to S-159 & N1 ,  
Phase III & Phase IV,  
Verna Industrial Estate,  
Verna, Goa – 403722, India  
Tel: +91-832- 6686262  
Fax No. +91-832- 6686203

*“For any information about this medicinal product, please contact the supplier”.*

**This leaflet was last revised in April 2024**

*Detailed information on this medicine is available on the World Health Organization (WHO) website:  
<https://extranet.who.int/prequal/medicines/prequalified/finished-pharmaceutical-products>*