

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

Information for the patient

[HA526 trade name][†]
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 [HA526 trade name] is and what it is used for
2. What you need to know before you take [HA526 trade name]
3. How to take [HA526 trade name]
4. Possible side effects
5. How to store [HA526 trade name]
6. Contents of the pack and other information

1. What [HA526 trade name] is and what it is used for

[HA526 trade name] is used in combination with other HIV medicines to treat HIV infection in babies and children who weigh between 2 and 14 kg.

[HA526 trade name] can also be used to prevent HIV from being passed on from a mother to her newborn baby.

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.

[HA526 trade 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 [HA526 trade name]

Do not take [HA526 trade name]:

- if you are allergic (hypersensitive) to zidovudine or to any of the other ingredients of [HA526 trade name] (see section 6, 'What [HA526 trade 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.

[†] Trade names are not prequalified by WHO. This is the national medicines regulatory agency's responsibility.

Do not use [HA526 trade 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;
- Blood tests showing excessive amount of certain liver enzymes in the blood.

Take special care with [HA526 trade 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 [HA526 trade 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 [HA526 trade 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 [HA526 trade 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 [HA526 trade 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 [HA526 trade 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 [HA526 trade 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 [HA526 trade 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
- methyl dopa, used to treat high blood pressure
- medicines to treat cancer.

Other medicines that can interact with [HA526 trade name] include:

- clarithromycin, used as an antibiotic, if you are taking clarithromycin, take your dose at least 2 hours before or after you take [HA526 trade 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 [HA526 trade 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

[HA526 trade 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 [HA526 trade name] before deciding to drive or use machines.

Important information about some of the ingredients of [HA526 trade name]

[HA526 trade name] contains sucrose. Contact your health care provider before taking this medicinal product if you have intolerance to some sugars or a disease called diabetes mellitus

Because this medicine contains sucrose, it may be harmful to the teeth.

[HA526 trade name] also contains 2 mg sodium benzoate in each ml. Sodium benzoate may increase jaundice (yellowing of the skin and eyes) in newborn babies (up to 4 weeks old).

3. How to take [HA526 trade name]

Take [HA526 trade name] exactly as described by your health care provider. Check with your health care provider if you are not sure.

It is important to take [HA526 trade name] regularly. This helps to stop your infection becoming resistant to this medicine and reduces the chances of getting allergic (hypersensitivity) reactions.

Take this medicine twice a day – morning and evening. The tables below show the usual recommended

doses for babies younger than 4 weeks and for older infants and children.

Infants younger than 4 weeks and weighing between 2 kg and 5 kg

Child's weight	Morning dose	Evening dose
2 to less than 3 kg	1 mL	1 mL
3 to less than 4 kg	1.5 mL	1.5 mL
4 to less than 5 kg	2 mL	2 mL

Infants and children aged over 4 weeks and weighing from 3 kg to 14 kg

Child's weight	Morning dose	Evening dose
3 to less than 6 kg	6 mL	6 mL
6 to less than 10 kg	9 mL	9 mL
10 to less than 14 kg	12 mL	12 mL
14 kg or more	Other zidovudine medicines are more suitable	

Preventing HIV passing from mother to her child

To prevent HIV being passed from mother to her child, the newborn baby should start taking [HA526 trade name] within 12 hours of birth and treatment may continue for up to 6 weeks. The baby may also be treated with another HIV medicine in combination with [HA526 trade name].

If you take more [HA526 trade name]

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 [HA526 trade name]

It is important not to miss doses of [HA526 trade 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.

If you stop taking [HA526 trade 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.

How to take [HA526 trade name]

Your child can be given [HA526 trade name] with food or between meals.

Use the oral dosing syringe supplied with the pack to measure your child's dose accurately:

1. Remove the bottle cap. Keep it safely
2. Hold the bottle firmly. Push the plastic adapter into the neck of the bottle.
3. Insert the syringe firmly into the adapter.
4. Turn the bottle upside down.

5. Pull out syringe plunger until the syringe contains the right dose for the child.
6. Turn the bottle the correct way up. Remove the syringe from the adapter.
7. Put the syringe into your child's mouth, placing the tip of the syringe against the inside of your child's cheek. Slowly push the plunger in, allowing time to swallow. Do not push too hard and squirt the liquid into the back of your child's throat or your child may choke.
8. Take the syringe out of the bottle and wash it thoroughly in clean water. Let it dry completely before you use it again.
9. Close the bottle tightly with the cap, leaving the adaptor in place.

4. Possible side effects

Like all medicines, [HA526 trade 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 [HA526 trade 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 [HA526 trade name] use for prevention of mother-to-child transmission.

Unwanted effects during treatment may be caused by [HA526 trade 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
- tingling 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 [HA526 trade name]

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

Store tightly closed in the original bottle. Do not store above 30°C.

Discard the solution 28 days after first opening.

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

Do not use this medicine if you notice signs of deterioration or if the medicine looks 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 [HA526 trade name] contains

- The active ingredient is zidovudine. Each 5 mL of [HA526 trade name] contains 50 mg of zidovudine.
- The other ingredients of [HA526 trade name] are anhydrous citric acid, glycerol, purified water, sodium benzoate, strawberry flavour and sucrose.

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

What [HA526 trade name] looks like and contents of the pack

[HA526 trade name] is clear, colourless to pale-yellow, strawberry-flavoured oral solution.

[HA526 trade name] is provided in 250 mL or 100 mL round, opaque white plastic (HDPE) bottle closed with plastic (polypropylene) cap having induction sealing wad inside.

Each bottle contains 240 mL or 100 mL solution. A 3-mL and 10-mL oral-dosing syringe is included in the packs which are used with an adaptor for low doses and higher doses, respectively. The syringes are calibrated (have markings to measure the volume of solution).

Supplier and Manufacturer

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For any information about this medicine, contact the local representative of the supplier.

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

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