ATRIPLA® Tablets

300 mg tenofovir disoproxil fumarate / 200 mg emtricitabine/ 600 mg efavirenz

Consumer Medicine Information

What is in this leaflet

This leaflet answers some of the common questions about ATRIPLA tablets. It does not contain all of the available information.

It does not take the place of talking to your doctor or pharmacist about your medical condition or treatment. If you have further questions, please ask your doctor or your pharmacist.

Keep this leaflet with your ATRIPLA medicine. You may need to read it again.

This medicine has been prescribed for you personally and you should not pass it on to others. It may harm them, even if their symptoms are the same as yours

What is ATRIPLA

ATRIPLA is used to treat Human Immunodeficiency Virus (HIV-1) infection in adults. This medicine can be taken alone or in combination with other anti-HIV medicines.

ATRIPLA consists of three medicines:

- VIREAD® (tenofovir disoproxil fumarate, also called tenofovir DF)
- EMTRIVA® (emtricitabine or FTC)
- STOCRIN® (efavirenz)

These are combined in one tablet to help control Human Immunodeficiency Virus (HIV-1) infection.

VIREAD and EMTRIVA belong to a group of antiviral medicines known as nucleoside and nucleotide reverse transcriptase inhibitors (NRTI).

STOCRIN belongs to a group of antiviral medicines known as non-nucleoside reverse transcriptase inhibitors (NNRTI).

Tenofovir DF and emtricitabine are components of TRUVADA® and ATRIPLA® tablets.

How ATRIPLA works

HIV-1 infection destroys CD4 T cells, which are important to the immune system. The immune system helps fight infection. After a large number of T cells are destroyed, acquired immune deficiency syndrome (AIDS) may develop.

ATRIPLA helps block HIV-1 reverse transcriptase, a viral chemical in your body (enzyme) that is needed for HIV-1 to multiply. ATRIPLA lowers the amount of HIV-1 in the blood (viral load). ATRIPLA may also help to increase the number of T cells ($CD4^+$ cells), allowing your immune system to improve. Lowering the amount of HIV-1 in the blood lowers the chance of death or infections that happen when your immune system is weak (opportunistic infections).

Use in Children and Elderly

ATRIPLA is for adults. Do not take ATRIPLA if you are under the age of 18 years. Do not take ATRIPLA if you are over the age of 65 before discussing with your doctor.

Does ATRIPLA cure HIV OR AIDS

ATRIPLA does not cure HIV-1 infection or AIDS.

The long-term effects of ATRIPLA are not known at this time. People taking ATRIPLA may still get opportunistic infections or other conditions that happen with HIV-1 infection. Opportunistic infections are infections that develop because the immune system is weak.

Some of these conditions are:

- pneumonia,
- herpes virus infections, and
- *Mycobacterium avium complex* (MAC) infection.

This medicine is only available from a pharmacist after it has been prescribed by a doctor who specialises in the treatment of HIV-1 infection.

If you wish to continue receiving treatment with ATRIPLA it is important you remain under the care of a hospital or doctor who specialises in the treatment of HIV-1 infection.

Does ATRIPLA reduce the risk of passing HIV to others

ATRIPLA has not been shown to lower your chance of passing HIV to others through sexual contact, sharing needles, or being exposed to your blood.

Do not share needles or other injection equipment.

Do not share personal items that can have blood or body fluids on them, like toothbrushes or razor blades.

Do not have any kind of sex without protection.

Before you take ATRIPLA

Who must not take it

Together with your doctor, you need to decide whether ATRIPLA is right for you. If you are not sure whether you should be taking ATRIPLA, talk to your doctor.

Do not take ATRIPLA if you are allergic to:

- tenofovir
- tenofovir DF
- emtricitabine,
- efavirenz or
- any of the other ingredients of ATRIPLA

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- rash, itching or hives on the skin
- swelling of the face, lips, tongue or other parts of the body.

The ingredients of ATRIPLA are listed in the product description section of this leaflet.

If you are not sure whether you should be taking ATRIPLA, talk to your doctor.

Before you start to take it

Tell your doctor if you are allergic to foods, dyes, preservatives or any other medicines.

Tell your doctor if you are pregnant, or planning to become pregnant during your course of medication.
Women taking ATRIPLA should not become pregnant. Serious birth defects have been seen in the babies of animals and women treated with efavirenz (a component of ATRIPLA) during pregnancy. It is not known whether efavirenz caused these defects.

Tell your doctor immediately if you become pregnant while taking ATRIPLA
Also, talk to your doctor if you want to become pregnant.

Do not breast-feed if you are taking ATRIPLA.
Do not breast-feed if you are taking ATRIPLA. The active substances in this medicine (tenofovir and emtricitabine and efavirenz) have been found in breast milk at low concentrations.

It is recommended that nursing mothers do not breast-feed during treatment with ATRIPLA. In general, women infected with HIV should not breast-feed their infants in order to avoid transmission of HIV to their newborn infant.

Tell your doctor if you have kidney problems or are undergoing kidney dialysis treatment.

Tell your doctor if you have bone problems.

Tell your doctor if you have liver problems, including Hepatitis B Virus (HBV) infection.
Your doctor may want to do tests to check your liver while you take ATRIPLA.

Tell your doctor if you have ever had mental illness or are using recreational drugs or alcohol.

Tell your doctor if you have ever had seizures or are taking medicine for seizures.

Tell your doctor if you have ever had a serious allergic drug reaction involving the skin (e.g. Stevens-Johnson syndrome).

Taking other medicines

ATRIPLA may change the effect of other medicines, including the ones for HIV-1 and may cause serious side effects.

Your doctor may change your other medicines or change their doses. Other medicines, including herbal products may affect ATRIPLA.

For this reason, it is very important to let your doctor or pharmacist know what medications, herbal supplements, or vitamins you are taking.

Medicines you should not take with ATRIPLA

The following medicines may cause serious or life-threatening side effects when taken with ATRIPLA.

Do not take St. Johns wort (*Hypericum perforatum*) or products containing St. Johns wort with ATRIPLA.
St. John's wort is a herbal product sold as a dietary supplement. Talk to your doctor or pharmacist if you are taking or are planning to take St. John's wort. Taking St. John's wort may decrease ATRIPLA levels and lead to increased viral load and possible

resistance to ATRIPLA or cross-resistance to other anti-HIV drugs.

Voriconazole (e.g. Vfend) should not be taken with ATRIPLA.
It may lose its effect or may increase the chance of having side effects from ATRIPLA.

Do not take ATRIPLA if you are already taking any other medicines that contain the same active ingredients.

The ingredients of ATRIPLA are listed in the product description section of this leaflet.

Do not take ATRIPLA if you are taking other medicines that contain:

- efavirenz (e.g. STOCRIN)
- lamivudine (e.g. Combivir, Zeffix, Kivexa, Trizivir)

Do not take ATRIPLA to treat your HIV infection if you are also taking adefovir dipivoxil.

It is also important to tell your doctor if you are taking any of the following:

- Bepridil, cisapride (e.g. Prepulsid), midazolam (e.g. Hypnovel), pimozide (e.g. Orap), triazolam (e.g. Halcion), ergot medications (e.g. Cafergot).
- Saquinavir (e.g. Invirase), clarithromycin (e.g. Klacid); these medicines may need to be replaced with another medicine when taken with ATRIPLA.
- Calcium channel blockers such as diltiazem (e.g. Vasocardol) and others; indinavir (e.g. Crixivan); methadone, rifabutin (e.g. Mycobutin), rifampin (e.g. Rifadin).
- Lipid-lowering medicines such as atorvastatin (e.g. Lipitor), pravastatin (e.g. Pravachol) or simvastatin (e.g. Zocor).
- Antidepressant medicines such as sertraline (e.g. Zoloft) or bupropion (e.g. Zyban); immunosuppressant medicines cyclosporine (e.g. Neoral), tacrolimus (e.g. Prograf) or sirolimus (e.g. Rapamune); these medicines may need to have their dose changed when taken with ATRIPLA.
- Didanosine (also known as ddI or Videx); tenofovir DF (a component of ATRIPLA) may increase the amount of didanosine in your blood, which could result in more side effects. You may need to be monitored more carefully if you are taking didanosine and ATRIPLA together. Also, the dose of didanosine may need to be changed.
- Atazanavir sulphate (e.g. Reyataz) or lopinavir/ritonavir (e.g. Kaletra); these medicines may increase the amount of tenofovir DF (a component of ATRIPLA) in your blood which could result in more side effects. Atazanavir sulphate is not recommended with ATRIPLA. You may need to be monitored more carefully if you are taking ATRIPLA and lopinavir/ritonavir together. Also, the dose of lopinavir/ritonavir may need to be changed.
- Other HIV medications including amprenavir (e.g. Agenerase), ritonavir (e.g. Norvir), fosamprenavir calcium (e.g. Telzir), raltegravir (e.g. Isentress), ritonavir or maraviroc (e.g. Celsentri), Also, the dose of maraviroc may need to be changed.
- Medicine for seizures such as phenytoin (e.g. Dilantin), carbamazepine (e.g. Tegretol) or phenobarbitone; your doctor may want to switch you to another medicine or check drug levels in your blood from time to time.
- Antifungal medications such as itraconazole (e.g. Sporanox) and posaconazole (e.g. Noxafil); these medicines may need to be replaced with another medicine when taken with ATRIPLA.
- Hepatitis C antiviral agents such as ledipasvir/sofosbuvir (e.g. HARVONI) or sofosbuvir/velpatasvir (e.g. EPCLUSA), simeprevir, (e.g Olysio), bocepravir (e.g. Victrelis) and telaprevir (e.g. Incivek).
- Antimalarial Agents such as artemether/lumefantrine (Coartem/Riamet).

These are not all the medicines that may cause problems if you take ATRIPLA. Be sure to tell your healthcare provider about all medicines that you take.

How to take ATRIPLA

Take the exact amount of ATRIPLA your doctor has prescribed for you.

Never change the dose on your own.

Do not stop this medicine unless your healthcare provider tells you to stop.

How much to take

The usual dose is one ATRIPLA tablet orally, once daily.

How to take it

Always take ATRIPLA on an empty stomach.

Swallow ATRIPLA with water.

Taking ATRIPLA at bedtime may make some side effects less bothersome.

If you forget to take ATRIPLA

Do not miss a dose of ATRIPLA.

Take the missed dose right away, unless it is almost time for your next dose.

Carry on with your regular dosing schedule.

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

If you take too much (overdose)

Immediately telephone your doctor or Poisons Information Centre: 131126 (Australia) and 0800 764 766 (New Zealand) or go to the Accident and Emergency department at your nearest hospital if you think you or anyone else may have taken too many ATRIPLA tablets. Do this even if there are no signs of discomfort or poisoning. This may need urgent medical attention.

While you are taking ATRIPLA

Things you must do

Tell your doctor or pharmacist that you are taking ATRIPLA if you are about to be started on any other medicines.
Your doses may need adjustment.

When your ATRIPLA supply starts to run low, get more from your doctor or pharmacy.
This is very important because the amount of virus in your blood may increase if the medicine is stopped for even a short time. The virus may develop resistance to ATRIPLA and become harder to treat.

Things you must not do

Do not breast-feed. See "Before you start to take it".

Women taking ATRIPLA should not become pregnant. See "Before you start to take it".

Women of child-bearing age receiving treatment with ATRIPLA should not rely only on hormone-based birth control, such as pills, injections or implants.
ATRIPLA may make these contraceptives ineffective. Women must use a reliable form or barrier contraception (such as a condom or diaphragm), even if they also use other methods of birth control.

Taking ATRIPLA with alcohol or other medicines causing similar side effects as ATRIPLA, such as drowsiness, may increase those side effects.

Do not take any other medicines, including prescription or non-prescription medicines and herbal products, without checking with your doctor.

Avoid doing things that can spread HIV infection since ATRIPLA does not stop you from passing the HIV infection to others.

Do not take ATRIPLA after the expiry or "use by" date (EXP) printed on the bottle.
If you take it after the expiry date has passed, it may not work as well.

Do not take ATRIPLA if the packaging is torn or shows signs of tampering.

Things to be careful of

Be careful driving or operating machinery until you know how ATRIPLA affects you.
If you are dizzy, have trouble concentrating, or are drowsy, avoid activities that may be dangerous, such as driving or operating machinery.

SIDE EFFECTS

Like all medicines, ATRIPLA can have side effects, although not everybody gets them. Some may be serious and need medical attention.

Check with your doctor as soon as possible if you have any problems while taking ATRIPLA, even if you do not think the problems are connected with the medicine or are not listed in this leaflet.

ATRIPLA may cause the following serious side effects:

Lactic Acidosis

If you have any of the following symptoms after taking your medication, tell your doctor IMMEDIATELY or go to the accident and emergency department at your nearest hospital:

- You feel very weak or tired
- You have unusual (not normal) muscle pain
- You have trouble breathing
- You have stomach pain with nausea and vomiting

- You feel cold, especially in your arms and legs
- You feel dizzy or light headed
- You have a fast or irregular heartbeat

These side effects may be due to a condition called lactic acidosis (build-up of an acid in the blood).

Lactic acidosis can be a medical emergency and may need to be treated in the hospital.

Serious Liver Problems (hepatotoxicity)

If you have any of the following symptoms while taking your medication, tell your doctor IMMEDIATELY or go to the accident and emergency department at your nearest hospital:

- Your skin or the white part of your eyes turns yellow (jaundice)
- Your urine turns dark
- Your bowel movements (stools) turn light in colour
- You don't feel like eating food for several days or longer
- You feel sick to your stomach (nausea)
- You have lower stomach area (abdominal) pain

These side effects may be due to a condition called hepatotoxicity with liver enlargement (hepatomegaly) and fat deposits in the liver (steatosis) which sometimes occurs in patients taking anti-HIV-1 medicines.

You may be more likely to get lactic acidosis or liver problems if you are female, very overweight (obese), or have been taking similar nucleoside analog-containing medicines, like ATRIPLA, for a long time.

Hepatic Flares

If you have HIV-1 infection and hepatitis B virus (HBV) infection you should not stop your ATRIPLA treatment without first discussing this with your doctor, as some patients have had blood tests or symptoms indicating a worsening of their hepatitis ("hepatic flare") after stopping individual components (tenofovir DF, and emtricitabine) of ATRIPLA.

You may require medical exams and blood tests for several months after stopping treatment. ATRIPLA is not approved for the treatment of HBV, so you must discuss your HBV therapy with your doctor.

Serious Psychiatric Problems

A small number of patients may experience severe depression, strange thoughts, or angry behaviour while taking ATRIPLA.

Some patients have thoughts of suicide and a few have actually committed suicide.

These problems may occur more often in patients who have had mental illness.

Contact your doctor right away if you think you are having these psychiatric problems, so your doctor can decide if you should continue to take ATRIPLA.

Kidney Problems

If you have had kidney problems in the past or take other medicines that can cause kidney problems, your doctor should do regular blood tests to check your kidneys.

Changes in Bone Mineral Density (thinning bones)

It is not known whether long-term use of ATRIPLA will cause damage to your bones.

If you have had bone problems in the past, your doctor may need to do tests to check your bone mineral density or may prescribe medicines to help your bone mineral density.

Allergy

Some people are allergic to medicines.

If you have any of the following symptoms soon after taking your medicine, DO NOT TAKE ANY MORE ATRIPLA and tell your doctor IMMEDIATELY or go to the accident and emergency department at your nearest hospital.

- Skin troubles such as lumpy skin rash or "hives"
- Swelling of the face, lips, mouth or throat which may cause difficulty in swallowing or breathing
- Wheezing, chest pain or tightness
- Fainting

These are very serious effects. If you have them, you may have a serious allergic reaction. You may need urgent medical attention or hospitalisation. Hypersensitivity reactions are very rare.

Pancreatitis

If you have any of the following symptoms after starting your medication, tell your doctor IMMEDIATELY or go to the Accident and Emergency department at your nearest hospital:

- Severe stomach pain or cramps
- Nausea
- Vomiting

These side effects may be due to a condition called pancreatitis which sometimes occurs in patients taking anti-HIV-1 medicines.

Common Side Effects:

Patients may have the following during treatment with ATRIPLA:

- dizziness
- headache
- trouble sleeping
- drowsiness
- trouble concentrating
- dizziness
- unusual dreams

These side effects may be reduced if you take ATRIPLA at bedtime on an empty stomach. They also tend to go away after you have taken the medicine for a few weeks. If you have these common side effects, such as dizziness, it does not mean that you will also have serious psychiatric problems, such as severe depression, strange thoughts or angry behaviour.

Tell your doctor right away if any of these side effects continue or if they bother you.

It is possible that these symptoms may be more severe if ATRIPLA is used with alcohol or mood altering (recreational) drugs.

Other common side effects may include:

- Rash.

Rashes usually go away without any change in treatment. In a small number of patients, rash may be serious. If you develop a rash, call your doctor immediately.

- Tiredness
- Upset stomach
- Vomiting
- Gas and diarrhoea

Other possible side effects:

- Changes in body fat. Changes in body fat develop in some people receiving anti HIV-1 therapy. These changes may include an increased amount of fat in the upper back and neck ('buffalo hump'), in the breasts and around the trunk. Loss of fat from the legs, arms and face may also happen. The cause and long-term health effects of these fat changes are not known.sleeping problems (including difficulty to fall asleep or sleepiness)
- Skin discolouration (small spots or freckles) may also occur with ATRIPLA.

Tell your doctor or pharmacist if you notice any side effects while taking ATRIPLA.

Contact your doctor before stopping ATRIPLA because of side effects or for any other reason.

Ask your doctor or pharmacist if you don't understand anything in this list.

This is not a complete list of side effects possible with ATRIPLA.

Ask your doctor or pharmacist for a more complete list of side effects of ATRIPLA and all the medicines you will take.

After taking ATRIPLA

Storage

Keep ATRIPLA tablets where children cannot reach them.
A locked cupboard at least one-and-a half metres above the ground is a good place to store them.

Keep ATRIPLA tablets in a cool, dry place where it stays below 30°C.

Do not store ATRIPLA or any other medicine in a bathroom or near a sink.

Do not leave ATRIPLA in the car or on a window sill.
Heat and dampness can destroy some medicines.

Keep your ATRIPLA tablets in the bottle with the cap tightly closed until you take them.
If you take ATRIPLA tablets out of their pack they may not keep well.

GENERAL ADVICE

Talk to your doctor or pharmacist if you have any questions about this medicine or your condition.

Medicines are sometimes prescribed for conditions that are not mentioned in this leaflet.

Do not use ATRIPLA for a condition for which it was not prescribed.

Do not give ATRIPLA to other people, even if they have the same symptoms that you have. It may harm them.

This leaflet summarises the most important information about ATRIPLA. If you would like more information, ask your doctor or pharmacist. Your doctor or pharmacist can give you information about this medicine that was written for doctors or pharmacists (Product Information/Data Sheet).

PRODUCT DESCRIPTION

What the tablets look like

ATRIPLA tablets are capsule-shaped and pink in colour.

Each tablet is debossed with "123" on one side and plain on the other side.

ATRIPLA tablets are supplied in bottles containing 30 tablets.

Ingredients

Each ATRIPLA tablet contains the following active ingredients:

- tenofovir disoproxil fumarate
- emtricitabine
- efavirenz

Each ATRIPLA tablet also contains the following inactive ingredients:

- croscarmellose sodium
- hyprolose
- magnesium stearate
- microcrystalline cellulose
- sodium lauryl sulphate
- iron oxide black
- iron oxide red
- macrogol
- poly(vinyl alcohol)
- talc
- titanium dioxide

SPONSOR

ATRIPLA tablets are supplied in Australia by:

Gilead Sciences Pty Ltd
Level 6, 417 St Kilda Road
Melbourne, Victoria 3004

In New Zealand:

Gilead Sciences (NZ)
c/- PricewaterhouseCoopers
Level 8 Pricewaterhousecoopers Tower
188 Quay Street
Auckland 1010

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