

Fact Sheet: ATRIPLA

Australians living with human immunodeficiency virus (HIV) can now access ATRIPLA[®], the first medication to combine three preferred HIV treatments into a once-daily single tablet regimen, for the cost of a single PBS script.

ATRIPLA: an effective HIV treatment

- ATRIPLA contains three medications (300mg tenofovir disoproxil fumarate/ 200mg emtricitabine/ 600mg efavirenz) in one tablet to treat HIV infection in adults and is available only on prescription. The combination works by stopping the virus from multiplying, therefore lowering the amount of HIV in the blood (called viral load).^{1,2}
- Australian and international treatment guidelines recommend treating HIV with a combination of at least three drugs, referred to as highly active antiretroviral therapy treatment (HAART).² ATRIPLA is a complete once-daily HAART regimen.
- No medication can cure HIV; however ATRIPLA is effective in helping control the virus, improving the management of the disease for people living with HIV.³

ATRIPLA: supported by clinical trials

- People living with HIV who switch to ATRIPLA are able to simplify their treatment and maintain effective control of their infection. In a randomised, controlled open-label multicentre study undertaken overseas, ATRIPLA was shown to control HIV infection by stopping the virus multiplying.³
- This is supported by several studies which have shown it is possible to change HIV treatments while maintaining control of the virus.⁴⁻⁵

ATRIPLA: a simplified HIV treatment

- People living with HIV currently require multiple medications. Leading clinicians acknowledge that complicated medication schedules (incl. the need for multiple tablets taken daily) can lead to some patients not taking their treatments as prescribed.³
- International HIV specialists recognise the need for simplified treatment options which reduce the number of tablets required for people living with HIV, while maintaining safety and efficacy.^{3,6}
- People living with HIV who switch to ATRIPLA are able to simplify their treatment to one pill once a day.

ATRIPLA: a well tolerated HIV treatment

- Clinical studies have found ATRIPLA to be generally well tolerated.³
- Like all medicines ATRIPLA can have side effects, although not everybody gets them.¹ Common side effects include dizziness, headache, trouble sleeping, drowsiness, trouble concentrating, unusual dreams, rash, tiredness, upset stomach, vomiting, gas and/or diarrhea, nausea and flatulence.¹ This is not a complete list and the Full Product Information should be reviewed (please also note the Minimum Product Information is on the following page).

ATRIPLA: available on the PBS from 1 January 2010 for people living with HIV

- From 1 January 2010 ATRIPLA will be available on the Pharmaceutical Benefits Scheme (PBS Section 100 prescription) for the treatment of HIV infection in patients with: a) CD4 cell counts of less than 500 per cubic millimetre; b) viral load of greater than 10,000 copies per mL.⁷
- People living with HIV will be able to access ATRIPLA for the cost of a single PBS script (\$32.90 for a general patient or \$5.30 for concession card holders), which is an important monthly saving for those who were previously using multiple medications.

PBS information prior to the new PBS listing on 1 January 2010:

PBS Information: ATRIPLA is not PBS listed for treatment of HIV.

Minimum product information

ATRIPLA (300 mg tenofovir disoproxil fumarate/200 mg emtricitabine/600 mg efavirenz) tablets. INDICATIONS: HIV infection in adults (>18 years). **DOSAGE AND ADMINISTRATION:** One tablet, daily, orally on an empty stomach at bedtime. Dosing adjustment required in moderate or severe renal impairment (creatinine clearance <50 mL/min) and cannot be achieved with ATRIPLA; individual agents are available. **CONTRAINDICATIONS:** Hypersensitivity to active substances or excipients. Concurrent use: terfenadine, astemizole, cisapride, midazolam, triazolam, bepridil, pimozide, ergot derivatives, voriconazole. **PRECAUTIONS:** Concurrent use with other drugs containing tenofovir DF, emtricitabine, efavirenz, lamivudine, adefovir dipivoxil. Lactic Acidosis/Severe Hepatomegaly with Steatosis. Renal Impairment (calculate CrCl). Bone Effects. Hepatic Impairment. Post treatment exacerbations of hepatitis in co-infected patients (HIV/HBV). Psychiatric Symptoms. Nervous System Symptoms (generally resolve after 2-4 weeks). Convulsions (patients with history of seizures). Skin Rash. Lipodystrophy. Immune Reconstitution Syndrome. Monitoring virological failure and/or emergence of resistance. Children. Pregnancy (category D) and lactation. Effects on ability to drive and use machines. **DRUG INTERACTIONS:** Not recommended with atazanavir, atazanavir/ritonavir, drugs that decrease or compete for renal clearance or compete with active tubular secretion, nephrotoxic agents, St. John's wort or St. John's wort-containing products. Dosage adjustments may be required: lopinavir/ritonavir, rifampicin, diltiazem, drugs that induce CYP3A4 activity, methadone (monitor withdrawal signs). Potential drug interactions to take into consideration: amprenavir, fosamprenavir calcium, ritonavir (monitor liver enzymes), saquinavir (do not use as sole protease inhibitor), didanosine (closely monitor for didanosine-associated adverse events), clarithromycin, rifabutin, itraconazole, anticonvulsants (periodic monitoring of plasma levels), sertraline, oral contraceptives (barrier contraception should also be used), cannabinoid test interaction. **ADVERSE EFFECTS:** *tenofovir DF* - nausea, diarrhoea, vomiting, flatulence, dizziness, increased creatinine, renal failure, Fanconi syndrome. *emtricitabine* - headache, diarrhoea, nausea, rash (including skin discolouration), increased liver enzymes (AST, ALT), hyperbilirubinaemia, increased creatine kinase, hypertriglyceridaemia, neutropaenia, increased amylase (including pancreatic), hyperglycaemia, increased serum lipase, anaemia. *efavirenz* - rash, dizziness, nausea, headache, fatigue, paranoid reaction, suicide, psychosis, delusion, convulsions, cerebellar coordination and balance disturbances, blurred vision, pancreatitis, hepatic failure, impaired concentration, insomnia, anxiety, abnormal dreams/thinking, depression, hallucination. **This is not a full list for more details/complete list of adverse events refer to full Product Information. Full Product Information is available from Gilead Sciences Pty Ltd and should be reviewed before prescribing ATRIPLA.** Date of Preparation: 12 November 2009

For a full copy of the Product Information please call Gilead Customer Service on 1800 806 112 or email AU.NZ.Medicalinformation@gilead.com.

For full Consumer Medicine Information please visit:

<https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/pdf?OpenAgent&id=CP-2009-CMI-01079-3>

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