

FACT SHEET - PrEP: Access Options



What is PrEP?

“PrEP” stands for Pre-Exposure Prophylaxis, with “prophylaxis” meaning “to prevent or control the spread of an infection or disease.” PrEP is a new HIV prevention method in which people who do not have HIV take a pill daily to reduce their risk of contracting HIV. The pill is called Truvada and it contains two antiviral medicines. These are the same drugs used to suppress the virus in people living with HIV.

Who should take PrEP?

The effectiveness of using HIV antiretroviral drugs as PrEP has been established by clinical trials conducted in gay men, heterosexual adults and people who inject drugs. PrEP can be considered for people in these populations who are at high risk of acquiring HIV, such as gay and other men who have sex with men who are having multiple events of condomless sex.

How does Truvada work?

If you take Truvada and you are exposed to HIV through sex or injecting drug use, this medicine can work to prevent HIV infection by interfering with the HIV’s ability to establish itself permanently in the body. Along with other prevention methods like condoms, PrEP can offer effective protection against HIV if taken every day.

Truvada (a dual combination of the antiviral drugs tenofovir and emtricitabine) has been investigated in several major clinical trials and has shown to be highly effective as HIV pre-exposure prophylaxis, provided the medication is taken as prescribed.

Is Truvada available in Australia?

Truvada has been licensed for use as PrEP in the USA, but it is not yet licensed for PrEP in Australia by the Therapeutic Goods Administration (TGA) and is not therefore available at a subsidised price through Australia’s Pharmaceutical Benefits Scheme (PBS). Community and medical organisations are urging Gilead Pharmaceuticals, who manufacture Truvada, to apply for TGA licensing and PBS listing as soon as possible. However, a decision on any such applications would be unlikely until at least 12 months after lodgement.

What are the options for obtaining PrEP?

If you are considering PrEP, you should discuss this with a doctor with experience in HIV or sexual health to help decide if PrEP is right for you. This fact sheet explains your options for obtaining PrEP through the Australian health system, and how to go about obtaining generic Truvada via the internet if you and your doctor decide that this is your best access option.

Ask your doctor about the possibility of getting Truvada through access programs operating in NSW, Victoria and Queensland. HIV and sexual health clinics and general practices are listed on <http://www.endhiv.org.au/services>. Places in these programs are limited and only available for residents of these three states. Truvada is free in these access programs – although a dispensing fee may be charged as for most other PBS medicines.

Your doctor can also prescribe Truvada “off label”, even though it is not yet licensed in Australia. This would involve asking the local supplier, Gilead Sciences Australia, to supply the drug via your doctor’s “off label” prescription. The cost is approximately \$10,000 - \$13,500 for a year’s supply of Truvada, which will be too expensive for many people.

Another option is to purchase a generic version of Truvada from a reliable overseas supplier and import it to Australia. Generics are copies of brand-name drugs. The cost of generic Truvada is much less than the brand-name and would be approximately \$1300 per year, which may be a more affordable option.

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Australia's Personal Importation Scheme for Medicines (IPU)

You can legally import most medicines for your personal use under Australia's personal importation scheme. This involves arranging from within Australia for a medicine to be sent to you from an overseas supplier or family/friend. The medicines are only to be used by you (or a member of your immediate family) and must not be supplied to any other person. It is important to note that such medicines may not be approved for supply in Australia by the TGA; and the TGA warns there are no guarantees about their safety or quality. Subject to satisfying various conditions you may import a 3 month supply (at the maximum dose recommended by the manufacturer) of an unapproved medicine without any prior approval required by the TGA.

Medicines ordered over the internet require an Australian-issued prescription from your doctor. To purchase or import a generic version of Truvada into Australia, you must first get a valid Australian-issued prescription to accompany the medicine being imported.

Buying medicines online

The internet can offer consumers a convenient and less expensive way to access medicines. However, online purchases of medicines must be approached with caution. Medicines available on international websites are not regulated by the TGA. You need to ensure that the website is legitimate, otherwise consumers face risks, including that medicines are fake, past their use-by date or not manufactured to appropriate standards.

Medical guidance from the Internet should never replace consultation with your doctor and should be interpreted with caution.

Obtaining generic Truvada online for PrEP?

If you and your doctor decide that obtaining generic Truvada via online is an option for you, then your local HIV clinic or organisation can provide additional information to assist you and your doctor. A step by step guide to ordering generic Truvada for PrEP online is attached. The site used in this information sheet is *AIDS Drugs Online* (<https://www.aidsdrugsonline.net>), which a number of Australian's and their doctors are using to obtain generic versions of HIV medicines from various overseas manufacturers.

Where can I find out more?

For more information on importing medicines for personal use see the Australian Government's Therapeutic Goods Administration (TGA) website:

<http://www.tga.gov.au/consumers/import.htm#.VBe7B-kcTq4>

For more information on Truvada for PrEP, talk to your local HIV organisation, your doctor or sexual health clinic. In Queensland, the community based organisations who can assist with information about PrEP, eligibility and steps to access PrEP are:

- HIV Foundation Queensland <http://hivfoundation.org.au/>
- Queensland Positive People <http://www.qpp.net.au/> and free call 1800 636241
- Community HIV Education and Prevention <http://www.chep.hiv/contacts>
- Queensland AIDS Council <http://www.qahc.org.au/>
- Queensland Injectors Health Network <http://www.quihn.org/>

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The information in this fact sheet is for general health care information purposes only, and anyone considering PrEP should talk to a doctor with HIV or sexual health experience about whether PrEP is right for them.

For people taking PrEP, regular follow up with their doctor is essential to monitor for any medication side effects or other issues, including that the medication is being taken correctly.

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How to order Generic Truvada for PrEP online

The online supplier used for the purposes of this information sheet is *AIDS Drugs Online* (<https://www.aidsdrugsonline.net>), which sources low-cost generic versions of HIV medications from various overseas manufacturers.

Please be aware the brand names used on AIDS Drugs Online are not the same as the brands in Australia:

- a. Australian brand name: **Truvada**
- b. AIDS Drugs Online (ADO) brand name: **Tenvir EM**

Once you have obtained your prescription for Truvada (Tenvir EM) from your doctor, take the following steps to order Tenvir EM online.

1. Go to <https://www.aidsdrugsonline.net>
2. Type in the **Tenvir EM** into the **product search** area (in the orange box on the right side) and click on the **search** button.
3. Two options will then appear for selection (Tenvir EM 30 tabs @ \$104.98 & Tenvir EM 90 tabs @ \$313.36).
4. Select which option of Tenvir EM you would like to purchase.
5. As it can take some time for your order to reach Australia (up to 8 weeks) it is worthwhile to order at least 3 months so that medication is never running out.
6. Put your quantity (e.g. **1**) into the field next to **'add to cart'**. Then click **'add to cart'** button. An orange bar will appear at the top of the page showing what is in your cart.
7. Now click on the **'Show Cart'** button (in the orange bar). If this is your first time to ADO you will not have a username or password and this will be organised for you at this stage.
8. If you are happy with what is in your cart then scroll down to the bottom of the page to the payment section. You will be asked to **'select a payment method'** and most people will choose the **'Invoice me'** option. Once chosen an option select the **'Check out now'** button.
9. You will now be asked to fill out all your billing and personal information. Once this has been completed then select the **'Register and Checkout'** button on the top of the page. Please note some people may not want the medications to arrive at home and instead may use another address (consult with your doctor and pharmacist about the best address option. Some HIV clinics may agree to receive the drugs for you).
10. Once you complete the checkout process, you will receive a receipt for your order. You will also need to print the **patient release form** and sign it indicating that you accept.
11. Once this is complete you can either:
 - a. **Scan/Email** your prescription and release form by replying to the receipt that you receive for your order. Or send to admin@aidsdrugsonline.net quoting your order number in the subject line.
 - b. **Fax to this USA number:** 1-866-795-9461

If you have any problems with the above instructions, please contact your doctor, local sexual health clinic or local HIV organisation for assistance.