



HIV PrEP in Ireland

Information booklet for
people who are accessing
PrEP themselves or are
considering accessing PrEP

The HSE Sexual Health and Crisis Pregnancy Programme (SHCPP) and the HIV PrEP working group strongly encourages people who are accessing PrEP themselves, to attend a health care provider for regular monitoring while taking PrEP.

The HSE SHCPP and the HIV PrEP working group strongly encourage people who are accessing medicines online to be aware of the potential risks associated with this.

PrEP refers to a combination pill containing tenofovir DF and emtricitabine. When taken correctly in combination with other HIV prevention measures, PrEP dramatically reduces the risk of HIV sexual transmission.

This booklet was produced with kind permission from i-Base to adopt their resource for use in Ireland. The original i-Base resource is available at <http://i-base.info/uk-guide-to-prep/>.

The legal situation in Ireland regarding prescription medications is different to other countries and information provided in this document is based on legal advice obtained by the HSE SHCPP on behalf of the HIV PrEP working group.

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HIV PrEP: Some background

What is HIV PrEP?

PrEP stands for Pre-Exposure Prophylaxis. HIV PrEP is taken before sex to prevent HIV infection. PrEP is used by HIV negative people to prevent them from becoming HIV positive.

Currently licensed PrEP is in tablet form. It is a combination tablet containing two drugs: tenofovir DF and emtricitabine. Both tenofovir DF and emtricitabine are medicines used to treat HIV. The brand name for this is “Truvada”. The combined tablet was approved for HIV treatment in 2004 and for use as PrEP in the United States in 2012. In August 2016, Truvada® was licensed for use as PrEP in Europe, including Ireland. Small surveys carried out in Ireland have shown that some people are accessing generic PrEP online. As of 4th December 2017, generic PrEP is available on a private prescription through community pharmacies.

PrEP is not currently available in Ireland through the HSE.

Who might benefit from taking PrEP?

If you are HIV negative and don't always use condoms, then PrEP could reduce your risk of HIV.

You may have a higher risk of HIV if you:

- Are having sex with HIV positive partners who are not on treatment or whose treatment may not be working properly
- had a recent sexually transmitted infection (STI), especially a rectal infection or syphilis
- have previously used PEP (post-exposure prophylaxis)
- are using recreational drugs for sex (crystal meth, mephedrone or GHB), also known as ChemSex.

Discuss this with your doctor or nurse if you are not sure.

Is there anyone who should not take PrEP?

PrEP should not be used:

- If you are HIV positive.

PrEP is usually not necessary:

- If you are only having sex with HIV positive partners who are on treatment and have an undetectable viral load.
- If you are using condoms consistently and happy to continue doing so.

How well does PrEP work?

PrEP has been shown in many studies to be highly effective at reducing the risk of HIV infection and works extremely well if taken correctly.

The PROUD study carried out in several sexual health clinics in England, enrolled more than 500 gay and other men who have sex with men (MSM) and included some trans women. One group took daily PrEP as soon as they enrolled in the study (immediate group). The other group started PrEP after a year (delayed group).

In October 2014, PROUD reported that PrEP dramatically reduced the risk of HIV infection (by 86%). Nearly all new HIV infections happened in people in the delayed PrEP group. The few infections that happened in the immediate PrEP group were in people who had not taken PrEP properly.

The IPERGAY study, from France and Canada, also reported an 86% reduction in a similar high risk group of gay men and trans women. IPERGAY used event based dosing (EBD) rather than daily PrEP. There is more information on event based dosing later in the leaflet.

There are also good results from heterosexual studies. The Partners PrEP study in Africa reported a 96% reduction in new HIV infections in people taking PrEP correctly.

In PrEP studies where HIV infections have happened, not taking the medication properly was the biggest factor for those who became HIV positive.

PrEP and side effects

The majority of people taking PrEP do not report side effects.

However, like all other medicines, PrEP has the potential to cause side effects. Mild nausea, diarrhoea, bloating and headache were reported in the first month by less than 1 in 10 people. These side effects then usually stop.

PrEP can also affect your kidneys, which is why monitoring is important. In the small proportion of people taking PrEP who developed reduced kidney function, these changes reversed on stopping PrEP. This risk is higher if you are aged 40 and over or if you already have reduced kidney function when you start PrEP.

PrEP can also reduce bone density by between 1% and 2%, causing slight thinning of the bones. This loss reverses after PrEP is stopped. This side effect might be more important if you already have low bone density related to other factors. It might also be important if you are younger than 30 as your bones are still developing.

PrEP and drug resistance

If PrEP is taken correctly, there is very little chance of developing resistance.

If you become HIV positive while taking PrEP, there is a small risk of developing drug resistance to one or both drugs. This means that these drugs may not work as well in future treatment for HIV.

In PrEP studies, very few people became HIV positive whilst taking PrEP. In those who did, less than 1 in 20 developed drug resistance.

The possibility of drug resistance increases if:

- you start PrEP and you are already HIV positive

- you take a break from PrEP and don't check your HIV status before re-starting
- you don't take enough doses for protection and become HIV positive.

In February 2016, a case was reported of someone who became HIV positive even though he was taking his PrEP correctly. This was because he caught HIV from a partner who was already resistant to the drugs in PrEP. This is a rare event as drug resistance in people living with HIV, to tenofovir DF and emtricitabine is not very common.

PrEP and other sexually transmitted infections (STIs)

PrEP will not protect against other STIs. Using condoms at the same time as PrEP will reduce the risk of getting other STIs and condom use is recommended for people taking PrEP. Regular STI testing, at least every three months, is recommended for people taking PrEP.

Does PrEP interact with any other medications?

Tenofovir DF and emtricitabine don't interact with many other medicines. (Interaction means that two or more drugs combined together can cause problems or side effects).

You should always tell your doctor (including your GP) if you are prescribed other medicines. You can also ask a pharmacist. Say you are taking PrEP so that they can check for any interactions, including with over-the-counter meds.

One important interaction is between tenofovir DF and non-steroidal anti-inflammatory drugs (NSAIDs), especially diclofenac. Together these can cause kidney problems. Other medicines from within this class include ibuprofen and naproxen. Avoid using these medicines if you are taking PrEP, or let your doctor know if you need to take them.

For trans people taking PrEP, there is no reason to expect PrEP will change the effectiveness of hormone therapy.

Sourcing PrEP

Getting PrEP on prescription

The branded PrEP product, Truvada®, is available on private prescription following licensing for the PrEP indication in August 2016.

As of 4th December 2017, generic PrEP is available on a private prescription through community pharmacies in Ireland.

Before getting a prescription for PrEP from your doctor, you should discuss the routine care and monitoring that will be necessary while you are taking PrEP, and where you will go for this.

Buying PrEP online

The following is not a recommendation but information to help you with any decision you make:

It is possible to buy generic PrEP products over the internet.

In Ireland, it is illegal for a person to source prescription medication without a prescription.

This means that if you want any prescription medication you must have a prescription.

Doctors can (but are not obliged to) provide a prescription to patients who may want to source medication over the internet.

In Ireland, it is illegal to supply medication by mail order, including over the internet.

The Health Products Regulation Authority (HPRA) provides information for the public in relation to sourcing medication over the internet. This is available at <http://www.hpra.ie/docs/default-source/publications-forms/information-leaflets>.

These laws are in place to protect the public from bogus suppliers and there is always a possible risk if you choose to buy PrEP (or any other medication) online that you are not receiving genuine product.

Before you start PrEP

1. Speak with your healthcare provider about your intention to start PrEP

It is recommended that you talk to a health care professional if you are planning to take, or are already taking PrEP.

2. Get a 4th generation HIV test

It is really important to have an HIV test before or as you start PrEP, and to have regular tests when you are taking PrEP.

PrEP can only be used if you are HIV negative. If you are already HIV positive and don't realise it, you could develop resistance to drugs that you may need for treatment.

Most laboratory based HIV testing is '4th generation' HIV blood testing. This is also called a 'combined antigen/antibody' test. This test has a window period of approximately four weeks. It is the usual type of blood sample, taken from your arm, which is done at your GP or sexual health clinic.

The majority of current finger-prick HIV tests, are '3rd generation' HIV blood testing. This checks for HIV antibodies only. This test has a window period of approximately three months. Please do not rely on a finger-prick test result alone before you start PrEP.

Don't start PrEP if you have flu-like symptoms and if you had a recent HIV risk. Flu-like symptoms may be related to recent HIV infection (HIV seroconversion). If you experience these it is really important to have a HIV test before starting or if you are already taking PrEP.

If you do start PrEP and had a risk in the last four weeks, you should have another 4th generation HIV blood test four weeks after starting; just to be sure an early infection was not missed.

If you are starting PrEP after PEP, it is best to start immediately if you have ongoing risks. Ideally you should have an HIV blood test around the time you finish PEP/start PrEP plus another HIV blood test four weeks into PrEP.

3. Test for hepatitis B

It is essential to test for hepatitis B because PrEP medicines are active against both HIV and hepatitis B.

You can still use PrEP if you have hepatitis B, but it needs to be used more carefully.

People with hepatitis B need to take PrEP every day with medical advice and monitoring, especially if you want to stop.

Event based dosing (EBD) is not suitable for people who have hepatitis B (or who don't know their hepatitis B status).

4. Get vaccinated against hepatitis A and B

Hepatitis A and B vaccination is recommended for men who have sex with men (MSM) and people who inject drugs (PWID).

This is a good time to be vaccinated, or to boost a previous vaccine.

5. Check your kidneys

Kidney monitoring just involves a blood test for creatinine, and a urine test for protein. These should ideally be done just before or on the day you start PrEP with your health care provider.

6. Check for other sexually transmitted infections (STIs)

This is always a good idea! This includes testing for syphilis, chlamydia, gonorrhoea and Hepatitis C.

How to take HIV PrEP

For PrEP to be most effective, the medicine needs to be at protective levels at the time that HIV exposure may happen. As the body takes a while to absorb medicines, this means PrEP needs to be taken both **before** sex and for several days **afterwards**.

1. Daily PrEP: for anal and vaginal sex

> Taking one pill per day, every day.

The European Medicines Authority has licensed **daily** use of PrEP to prevent sexual acquisition of HIV.

Anal sex

For anal sex daily, PrEP has the most evidence. You need to take at least two tablets of PrEP between 2 and 24 hours before anal sex to make sure that the drug levels are high enough to be protected. You need to take PrEP every day, and continue daily.

Vaginal sex

For vaginal sex, you need to take daily PrEP. You also need to take PrEP daily for 7 days before sex to reach drug levels that give the highest protection. This is because PrEP does not get into the vaginal tissues as well as it gets into rectal tissues.

2. Event Based Dosing (EBD): only for anal sex

> Taking two pills before sex as a double dose and a single pill 24 and 48 hours after.

Although there is less data on using event based dosing (EBD), it was shown to be effective in the iPERGAY study.

Anal sex

You need to take at least two tablets of PrEP (double dose) between 2 and 24 hours before anal sex. The before-sex dose is very

important to make sure that there is enough medicine in the body when you have sex.

You need to continue taking one pill every 24 hours for the days you are having condomless anal sex.

After your last condomless anal sex, you need to take a single pill 24 and 48 hours later.

Further information and examples on EBD can be found at <http://i-base.info/uk-guide-to-prep/>. It is best to have a conversation with your doctor before considering EBD for PrEP.

EBD is NOT suitable for any form of vaginal sex.

EBD is NOT suitable if you have hepatitis B and it is really important to know your hepatitis B status before taking PrEP.

3. What to do if you miss a pill?

If you miss one, or even two pills occasionally, don't stop PrEP, just carry on once you remember. There is still likely to be enough drug in your body to protect against HIV.

If you are missing several doses each week, you are not going to be protected against HIV if you are having condomless sex. Remember that you may need to consider PEP in a situation where you have missed several doses of PrEP and haven't used a condom or had a condom accident.

Pick a regular time to take your PrEP and try to stick to this each day. Link it to a routine task like brushing your teeth. It doesn't have to be the exact same time but it will help get you into a routine.

If you have a break from PrEP and have risks during this time, it is important to consider PEP and have another HIV test. If you are not sure of anything, please discuss further with your doctor or nurse.

Routine care if you are taking HIV PrEP

Once you have started PrEP, monitoring is important. If you are currently using PrEP and have not been monitored, talk to your health care professional about doing this now.

Every 3 months:

- have a '4th generation' (antigen/antibody) HIV blood test
- have a full screen for other STIs
- have a urine dipstick test for protein when you have your STI check-up; if there is more than a trace, an additional blood or urine test can be done to check your kidney function.

Every 12 months:

- have a blood test to check your kidney function
 - sometimes this needs to be done more frequently
- have a hepatitis C test
 - sometimes this needs to be done more frequently.

Stopping HIV PrEP

There may come a time when you might decide that you want to stop PrEP altogether. Discuss your decision to stop with your healthcare provider.

If possible, discuss any plans to stop PrEP with any regular sex partner(s) and get tested for HIV and other STIs at the same time. Make sure you both have a 4th generation HIV test four weeks after the last risk.

Anal sex

If you've been taking PrEP to prevent HIV through anal sex don't stop taking it until 48 hours after the last risk for HIV. During this time, take PrEP at your regular time.

Vaginal sex

If you've been taking PrEP to prevent HIV through vaginal sex don't stop taking it until 7 days after the last risk for HIV. During this time, take the PrEP at your regular time.

Injecting/slamming drugs

If you're at risk of HIV through injecting drugs or slamming Chems, you should continue taking it until 7 days after the last risk for HIV. During this time, take the PrEP at your regular time.

If your circumstances change in the future, you can restart PrEP.

Remember if you have stopped PrEP and have a sexual exposure risk, you should consider PEP (post exposure prophylaxis). Ideally this should be as soon as possible but no later than 72 hours after the risk.

Other considerations

Although PrEP is very effective at stopping HIV, it can also change how you feel about your sex life, including risks for HIV. Your clinic can provide a chance to talk about this in confidence.

Talk to your nurse, doctor or health advisor about how you feel about PrEP, and how PrEP affects the risks you sometimes take.

Other things affect taking risks, including how you feel about yourself, pressure from other people, and using alcohol and recreational drugs. Extra support is also available that can help with many of these issues.

Tell the nurse or doctor if your health has changed, or if you start new medications.

Other STIs are important. This is a reason to still carry and use condoms.

**Shláinte Gnéis agus
Clár Thoirchis Ghéarchéime**
**Sexual Health &
Crisis Pregnancy Programme**

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