



HIV PrEP in Ireland

**Information booklet
for people who are
taking PrEP or are
considering
taking PrEP to
prevent HIV**



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The information in this booklet is to be used in discussion with your healthcare provider.



What is HIV PrEP?

PrEP stands for Pre-Exposure Prophylaxis. This booklet is about taking PrEP to prevent HIV (HIV PrEP).

HIV PrEP is taken by HIV negative people before having sex (pre-exposure) and after sex, to prevent HIV (this is called prophylaxis).

Currently available HIV PrEP is a combination tablet containing two drugs: tenofovir and emtricitabine. These medicines are widely used to treat HIV. They have been licensed for use as PrEP in Europe since August 2016.

For the remainder of this booklet, HIV PrEP is referred to as 'PrEP' and is the combination of tenofovir and emtricitabine. In the context of this booklet 'PrEP' relates to PrEP for HIV prevention only.

How well does PrEP work?

PrEP has been shown in many studies to be safe, and when taken correctly, highly effective at preventing HIV.

In PrEP studies where HIV infections have happened, most of those who became HIV positive were not taking the medication properly at the time they contracted HIV.

If you decide to use PrEP, it is important that you do so with support from a healthcare provider and that you understand how to take PrEP correctly.

PrEP and other sexually transmitted infections (STIs)

PrEP does not protect against other STIs, such as syphilis, chlamydia, gonorrhoea and hepatitis C. PrEP users can combine condoms and PrEP to reduce the risk of contracting other STIs.

Regular STI testing, usually every three months is recommended for people taking PrEP.

Vaccination against hepatitis A and B is recommended for all gay, bisexual and men who have sex with men (gbMSM), people who inject drugs, and high-risk heterosexual men and women. HPV vaccination is recommended for gbMSM up to and including 45 years of age to protect against genital warts and HPV-associated cancers. These vaccines are available for free through public STI clinics.



Getting PrEP in Ireland

If you are HIV negative and don't always use condoms for anal or vaginal/frontal sex, then you may be at risk of HIV.

PrEP is available through the HSE free of charge to those who are considered to be at substantial risk of contracting HIV through sex.

PrEP is available in some public sexual health services and through some general practice (GP) and private providers. For further information on where PrEP is available, see www.sexualwellbeing.ie/getprep

PrEP is dispensed through community pharmacies and you will need a drug payment scheme (DPS), medical card or long term illness card to access free PrEP through the HSE. Anyone with a PPS number can apply for a DPS card. Please see www.myDPS.ie or ask your pharmacist.

If you don't have a PPS number, visit https://www.citizensinformation.ie/en/social_welfare/irish_social_welfare_system/personal_public_service_number.html

Who is eligible for free PrEP through the HSE?

To avail of free PrEP through the HSE you need to:

- test negative for HIV
- be able to attend for follow up appointments, usually every 3 months.

You also need to meet **at least one** of the following criteria:

- you are having sex without condoms with HIV-positive partners who
 - ◆ are not on HIV treatment OR
 - ◆ are on treatment but not virally suppressed (do not have an “undetectable” viral load)
- you are a man who has sex with men (includes transgender men who have sex with men) or a transgender woman who has sex with men, who meets any **one of** the following:
 - ◆ had anal sex without condoms with more than one partner in the last 6 months
 - ◆ likely to have anal sex without a condom in the coming 3 months
 - ◆ had a sexually transmitted infection (STI) in the last year
 - ◆ used HIV post-exposure prophylaxis (PEP) in the last year

- ◆ used recreational drugs for sex (also known as chemsex) in the last 6 months
- you are considered to be at substantial risk of contracting HIV through sex, by a consultant in Genitourinary Medicine or Infectious Diseases.

What if I am not eligible for free PrEP?

If you do not meet the criteria for free PrEP and decide to pay for PrEP yourself, this can be purchased through community pharmacies with a prescription. You should be aware of the situations where PrEP is NOT recommended, see below.

Regardless of how you are getting PrEP, we recommend that, for your safety, you should follow the same assessment and monitoring guidance that is recommended in the later sections of this booklet.

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 for at least 6 months.
- If you are using condoms consistently and intend to continue doing so.

If you are buying PrEP online

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 and it is illegal for medication to be supplied by mail order, including over the internet. The Health Products Regulation Authority (HPRA) provide information for the public on the risks of buying medicines online.

<http://www.hpra.ie/homepage/medicines/safety-information>



Side effects, drug interactions and resistance

Does PrEP have side effects?

Most people taking PrEP do not report any major side effects.

However, like all medicines, PrEP has the potential to cause side effects. Less than 1 in 10 people taking PrEP report mild nausea, diarrhoea, bloating or headache. These side effects usually stop within the first month.

Occasionally PrEP can cause more serious side effects. PrEP can also affect your kidneys, which is why monitoring is important. In the small proportion of people taking PrEP who develop reduced kidney function, these changes are usually reversed on stopping PrEP. This risk is higher if you are aged 40 years 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 years as your bones are still developing.

Does PrEP interact with any other medications?

Tenofovir 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 healthcare provider (including your GP) if you are prescribed other medicines or are taking gym supplements. Taking gym supplements such as creatine may affect your kidney function test results.

One important consideration is taking tenofovir at the same time as 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 healthcare provider know if you need to take them.

You can also ask a pharmacist. Tell them that you are taking PrEP so that they can check for any interactions, including with over-the-counter meds.

For transgender people taking PrEP, there is no reason to expect PrEP will change the effectiveness of hormone therapy. However, some studies have shown slightly lower levels of PrEP in transgender women taking feminising hormones. Therefore it is recommended that transgender women who are taking gender affirming (feminising) hormone therapy either use daily PrEP or only use event-based dosing while under the care and supervision of a consultant in Genitourinary Medicine or Infectious Diseases.

PrEP and drug 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 will not work as well against 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 without knowing that you are already HIV positive. This is why it is very important to have a laboratory HIV blood test before you start PrEP.
- Take a break from PrEP and don't check your HIV status before re-starting.
- Don't take PrEP correctly and become HIV positive.
- Come in contact with drug-resistant HIV. This is very rare: globally, only two cases have been reported of PrEP not working where the person came in contact with drug-resistant HIV.



Testing and monitoring

Before you start PrEP

There are a few tests that you will need before you start PrEP.

HIV

It is essential to have a 4th generation HIV test before or as you start PrEP. A blood sample will be taken, usually from your arm, and sent to a laboratory. This test has a window period* of approximately 45 days.

*The window period is the time between when you may have been exposed to HIV, and the point when the test will give an accurate result. During the window period you could be infected with HIV but still have a negative HIV test.

If there is a chance that you have been exposed to HIV in the last 45 days, tell your healthcare provider. There may be a need to do additional blood tests and have a repeat HIV test 45 days (or ~6 weeks) weeks after starting PrEP. This is to ensure that an early infection is not missed.

If you have had a recent HIV risk and have developed flu-like symptoms, it is important to alert your PrEP team as this may be a sign of HIV seroconversion (this is when the immune system produces antibodies in response to a recent HIV infection). In this situation you should not start PrEP until HIV infection has been ruled out. Your healthcare provider will explain this to you.

If you are starting PrEP after PEP (post-exposure prophylaxis), it is best to start immediately after you finish the course of PEP. There is no need to delay starting PrEP after PEP. You should have a 4th generation HIV blood test around the time you finish PEP/start PrEP, plus another HIV blood test 4 to 6 weeks after starting PrEP.

Sometimes a rapid HIV test is done in addition to the laboratory HIV test.

It may be possible to start PrEP on the day of your first PrEP appointment. This will be discussed with you in greater detail by your healthcare provider.

Hepatitis B

It is essential to test for hepatitis B because PrEP medicines are active against both HIV and hepatitis B. Taking PrEP if you have undiagnosed Hepatitis B could be harmful to you.

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

If you have hepatitis B, you need to take daily PrEP with medical advice and monitoring, especially if you want to stop. Event based dosing (EBD) is not suitable if you have hepatitis B (or if you don't know your hepatitis B status).

Hepatitis A and B vaccination is recommended for gbMSM and people who inject drugs.

Kidney function

Kidney monitoring involves a blood test for creatinine, and sometimes a urine test for protein. These should ideally be done just before or on the day you start PrEP. The frequency of kidney monitoring after that will be determined by a number of things including your age, medical history and medications.

Sexually transmitted infections (STIs)

You should have STI testing, which includes testing for syphilis, chlamydia, gonorrhoea and hepatitis C.

In addition to hepatitis A & B vaccination, HPV vaccination is recommended for gbMSM up to and including 45 years of age. HPV vaccination protects against genital warts and HPV-associated cancers.

Pregnancy

Pregnancy status should be established in people who can become pregnant and may be reviewed again during follow up as required. People who are pregnant can take PrEP following discussion and consultation with a doctor specialising in Genitourinary Medicine or Infectious Diseases.

Once you are taking PrEP

Once you have started PrEP, it is essential to monitor for HIV and STIs and check your kidney function on a regular basis. Although side effects are rare, the clinic monitoring will help to identify any potential problems at an early stage.

For new PrEP users

If it is your first time taking PrEP, you may be offered an appointment after 4 to 6 weeks to make sure you are okay with the medication or if you need any more tests or vaccinations.

For people taking daily PrEP

In general people taking daily PrEP need follow up every 3 months to have:

- a '4th generation' HIV blood test
- tests for other STIs
- a blood test to check kidney function
 - ◆ this may be done less frequently depending on your circumstances

For people taking event based PrEP

- If you are taking event based PrEP, the frequency of follow up will be determined by how often you use PrEP and your potential risk for exposure to HIV and STIs.
- Not all people taking event based PrEP will need HIV and STI testing every 3 months. Your PrEP service will discuss this with you and make a follow up plan.

Home STI and HIV testing

- Some people may be able to have some of their follow up STI and HIV testing via the HSE national home STI testing service. You can discuss this with your PrEP service who will decide if it is suitable for you.

Hepatitis C testing

- Is recommended once a year for sexually active gbMSM
 - ◆ it may need to be done more frequently depending on your circumstances



How to take 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**.

There are two different ways you can take PrEP, depending on your circumstances and how often you have sex:

Daily PrEP (taking PrEP every day)

Event based dosing (taking PrEP around the time of sex)

Daily PrEP: for anal and vaginal/frontal sex

➤ Taking one pill per day, every day.

Taking PrEP every day will make sure that there are protective drug levels in vaginal and anal tissue, 24 hours a day, 7 days a week.

This means you do not have to plan when to have sex. For people who routinely have condomless sex at least once a week, daily PrEP is likely to be a better dosing option.

You should try to take PrEP at the same time every day. It doesn't have to be the exact same time but it will help get you into a routine.

PrEP and anal sex

When you start taking PrEP, you need to **take two tablets of PrEP at least 2 hours but no more than 24 hours before sex**, to make sure that the drug levels are high enough to be protective before condomless anal sex.

Continue taking one tablet of PrEP per day, every day.

What if I miss a dose?

Daily PrEP allows some flexibility for anal sex.

Once you are established on daily PrEP, if you occasionally miss 1 or 2 doses, protection will still be very high. If you miss 1 or 2 doses, don't stop PrEP, continue taking it once you remember.

For anal sex, you must at the **very least** have taken PrEP for 4 days a week to have good protection. If you miss more doses than this, you are not going to be protected against HIV if you are having condomless sex. If you have missed more than 3 doses of PrEP in the week and had condomless sex, you may

need PEP (post exposure prophylaxis) and should discuss with your healthcare provider as soon as possible and within 72 hours of having condomless sex. See 'Missed doses and the need for PEP' section on page 14.

If you are missing doses regularly, please discuss this with your healthcare provider and they will advise you on how to proceed.

PrEP and vaginal/frontal sex

For vaginal/frontal sex, you need to take daily PrEP. Event based dosing is NOT suitable. You need to take PrEP every day because PrEP does not get into the vaginal tissues as quickly as it gets into rectal tissues.

When you start taking PrEP you **need to take PrEP every day for 7 days**, to reach protective drug levels **before having condomless sex**.

What if I miss a dose?

There is less flexibility around missing doses for vaginal/frontal sex so it is important to establish a routine for taking the medication.

For vaginal/frontal sex, you must at the very least have taken PrEP for **6 days a week** to have good protection. If you miss more than one dose a week, you are not going to be protected against HIV if you are having condomless sex.

If you have missed more than 1 dose of PrEP in the week and had condomless sex, you may need PEP and should discuss this with your healthcare provider as soon as possible and within 72 hours of having condomless sex. See 'Missed doses and the need for PEP' section on page 14.

If you are regularly missing doses please discuss this with your healthcare provider.

Other tips on how to take PrEP

Use a pill box – this makes it easy to see whether you have taken or missed a dose.

Set an alarm on your phone or use a pill reminder app to remind you, such as My PrEP, PrEPTIME Pill Reminder or PrEPtrack.

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 condomless sex during this time, it is important to consider PEP and have another HIV test before you re-start PrEP.

Event Based Dosing (EBD): only for anal sex in certain circumstances

Also known as 'PrEP 2-1-1' or 'PrEP on demand'

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

Several studies mainly in gay men (including the IPERGAY study) have shown that event based dosing (EBD) is just as effective as daily PrEP for people having anal sex.

Event based dosing (EBD) is a way of using PrEP only when you are likely to have sex.

EBD may be an option for people who do not want to take PrEP all of the time, who only occasionally have sex without condoms, such as once a week, when on holidays or away for the weekend, and who can plan for enough time to take the double dose before having condomless sex.

EBD is suitable only for anal sex and is NOT suitable for vaginal/frontal sex. People who have a mixture of vaginal/frontal and anal sex should take PrEP daily.

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

EBD may be suitable for trans people who only need protection for anal sex. It is recommended that this is done under the care of a consultant in Genitourinary Medicine or Infectious Diseases.

Event based dosing for sex once in a week

1. Take two tablets of PrEP (double dose) at least 2 hours but no more than 24 hours before sex. The before-sex double dose is very important to make sure that there is enough drug in the body when you have sex.
2. Take a single pill 24 hours after the double dose.
3. Take another single pill the following day, 24 hours later.

Figure 1. Example of an event based dosing schedule if you have sex once in a week

Before Sex

2 PrEP tablets (double dose) at least 2 hours but no more than 24 hours before sex



After Sex

1 PrEP tablet 24 hours* after the double dose
 1 PrEP tablet 48 hours* after the double dose
 = total of 2 tablets after sex
 *2 hours before or after planned time is ok



Event based dosing for sex several times over a period of time

For example, where you are away for the weekend or on holidays where you may have sex several times over a period of time.

1. Take your double dose (two tablets of PrEP) as usual at least 2 hours but no more than 24 hours before sex.
2. If you are continuing to have sex, take one pill 24 hours after the double dose and continue taking one pill every 24 hours for the days you are having sex.
3. Continue taking PrEP until you have taken two doses after your last sex. This means taking one dose on each of the two days after your last sex.

Figure 2. Example of an event based dosing schedule if you have sex several times over a period of time

Before Sex

2 PrEP tablets (double dose) at least 2 hours but no more than 24 hours before sex



After Sex

1 PrEP tablet 24 hours* after the double dose
 Continue PrEP every 24 hours* until 2 doses after your last sex
 *2 hours before or after planned time is ok



It is important to make sure you understand how to take EBD correctly before considering EBD for PrEP. Your healthcare provider can explain this to you and answer any questions you may have.

What if I miss a dose?

It is important not to miss doses if you are taking event based PrEP.

In a situation where you have missed doses of PrEP and haven't used a condom or had a condom accident, you may need PEP.

If you missed the BEFORE dose completely, still take a double dose as soon as possible AFTER sex, and continue daily, but contact your clinic as soon as possible and within 72 hours. Depending on the risk involved, you may need to go on PEP which will include an additional HIV drug.

Missed doses and the need for PEP

If you have missed some PrEP doses you may need to start on PEP to reduce the likelihood of becoming HIV positive.

Oral sex only

If the only exposure has been through oral sex, regardless of the number of missed doses of PrEP, **PEP is not indicated.**

Anal sex

Daily PrEP, where fewer than 4 pills have been taken in the last 7 days - **PEP is indicated and should be commenced as soon as possible and within 72 hours of condomless anal sex.**

Event-based PrEP, where any dose of an event-based schedule has been missed - **PEP is indicated and should be commenced as soon as possible and within 72 hours of condomless anal sex.**

Vaginal/frontal sex

If more than 48 hours have elapsed since last dosing or if fewer than 6 tablets have been taken within the previous 7 days – **PEP should be considered, and if indicated, commenced as soon as possible within 72 hours of condomless vaginal/frontal sex.**

Should you have missed doses, you should discuss with your healthcare provider as soon as possible and within 72 hours of having condomless sex.

All PrEP services are required to either have PEP or have an established referral pathway to a service that has PEP, should you need to access it urgently.

The list of locations where PEP is available in Ireland is available here: <https://www.sexualwellbeing.ie/need-urgent-information-and-care-/post-exposure-prophylaxis/>



Changing how you take PrEP

Your risk of HIV may change over time. You can change how you take PrEP or stop and restart PrEP, as your circumstances change.

Changing dosing schedule

PrEP can be individualised to your needs at different times.

If you are taking daily PrEP and want to switch to EBD, discuss this with your healthcare provider. They will help you decide if EBD is an option for you, and make sure you change between daily and event based dosing safely.

If you are taking EBD and want to switch to daily dosing, start with a double dose, remembering that you need to take the medication at least 2 hours and no more than 24 hours before you have condomless sex. After that, continue taking PrEP daily, see daily PrEP. If you switch from EBD to daily dosing it is important to make sure that you have enough medication to take a dose every day before your next appointment with your PrEP service.

Stopping PrEP

If you decide you want to stop taking PrEP altogether, it is best to discuss your decision to stop with your healthcare provider. They can make sure you stop PrEP safely, organise any tests you may need, and provide advice on future HIV and STI prevention.

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

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

How to stop PrEP

Anal sex

If you've been taking PrEP to prevent HIV through anal sex, continue taking it for **48 hours after the last risk for HIV**. This means taking 2 final doses of PrEP: one dose the day after and one dose two days after your last risk. During this time, take PrEP at your regular time.

Vaginal/frontal sex

If you've been taking PrEP to prevent HIV through vaginal/frontal sex, continue taking it for **7 days after the last risk for HIV**. During this time, take the PrEP at your regular time.

Injecting/slamming drugs

If you are also injecting or slamming drugs, you should continue taking **PrEP for 7 days after the last risk for HIV**. During this time, take the PrEP at your regular time.



Other considerations

Contraception

It is safe to use PrEP with most hormonal contraception (ring, patch, the pill, or an implant). PrEP will not affect your contraception and your contraception will not affect PrEP.

PrEP in Pregnancy

While there is limited information available on the use of PrEP in pregnancy, no PrEP-related pregnancy complications have been identified.

Becoming HIV positive during pregnancy is associated with an increased risk of transmission of HIV to the baby. Therefore, it may be appropriate to use PrEP in pregnancy. If you are taking PrEP and could become pregnant it is important to discuss this with your healthcare provider to help you make an informed decision about what is best for you.

Support services and resources

HSE HIV, Sexual Health, Drugs & Alcohol Helpline

The HSE helpline is a free and confidential service that provides support, information and guidance on anything to do with HIV, sexual health, substance use and alcohol. Freephone **1800 459 459** Monday to Friday between 9:30 am and 5:30 pm or email helpline@hse.ie

Sexualwellbeing.ie - The HSE website provides more information on HIV, STIs and sexual health.

Drugs.ie - For more information on chemsex and support services
<http://drugs.ie/ghb>

Man2Man.ie - Information and support for gay, bisexual and men who have sex with men.

The **man2man.ie** website provides more information on the following support services:

Counselling and helplines - <http://man2man.ie/testing-support/>

Chemsex and safer injecting- <http://man2man.ie/alcohol-drugs-cigarettes/>

MPOWER

The MPOWER Programme is a peer led service that offers services, information and support to gay and bisexual men. The MPOWER team is available to answer your PrEP questions on WhatsApp, Grindr, Email or Phone.

For more details visit: mpower.hivireland.ie

**You can order more copies of this booklet free of charge from
www.healthpromotion.ie**

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**Sláinte Ghnéis &
Clár um Thoirchis Ghéarchéime**

**Sexual Health &
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