

HIV PrEP in Ireland

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







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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 highly effective at preventing HIV. When taken correctly PrEP reduces the risk of getting HIV by about 99%.

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. Vaccination against Mpox is recommended for sex workers and some gbMSM. It is available through some public clinics. Speak to your healthcare provider about how you can access vaccines.

Getting PrEP in Ireland

If you are HIV negative and don't always use condoms for sex, or you share injecting drug equipment, then you may be at risk of HIV.

Since 2019, the HSE has made PrEP medication available free of charge through community pharmacies to individuals who are likely to benefit from the intervention and for whom it is not contraindicated.

At this time, free PrEP care is available through public PrEP services. Individuals attending other HSE approved PrEP providers (such as general practice (GP) or private providers) will have to pay for the consultation, investigations, treatment of STIs and vaccines.

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 would benefit from free PrEP?

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 to 6 months.

You might benefit from PrEP if:

- 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, and 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

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- 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 risk of contracting HIV through sex or sharing injecting drug equipment.

You are not eligible for free PrEP if you are:

- in a mutually monogamous relationship with a partner who is living with HIV who is on treatment and virally suppressed
- in a mutually monogamous relationship with a partner who is known to be HIV negative.

What if I am not eligible for free PrEP?

If you are not eligible 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:

- have HIV
- do not know your HIV status
- are allergic to the medications available for PrEP in Ireland.

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 developed reduced kidney function, these changes are usually reversed on stopping PrEP. This risk is higher if you are aged 40 years and over, if you already have reduced kidney function when you start PrEP or if you are taking other medication that can impact on your kidney function.

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 24 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 making them difficult to interpret.

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 PrEP users who are also taking gender affirming hormones, there is no reason to expect PrEP will change the effectiveness of hormone therapy. However, some studies have shown slightly lower levels of PrEP medication 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 get HIV 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 got HIV 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 already have HIV. 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, get HIV and continue to take some PrEP medication.
- 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 have 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 get you to 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 taking a course of 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. If you are taking creatine supplements, it is important to let your PrEP team know, as these can these can make interpretation of kidney monitoring blood tests difficult. It is recommended that you stop taking creatine supplements at least 2 weeks before having kidney blood tests.

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. Mpox vaccination is also recommended for sex workers and some gbMSM to reduce the chances of getting mpox infection or reduce the severity of the illness if infection occurs.

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, and it is recommended for pregnant people who are at risk of HIV infection.

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 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
- some people may need a blood test to check kidney function

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** exposure and **afterwards**.

Current guidelines recommend that PrEP provides protection against HIV after a double dose (2 tablets) taken between 2 and 24 hours before protection is needed. This applies to different types of sex and where protection is needed from injecting drug use. The duration of PrEP after an episode of sex or injecting drug use varies. In the following sections we will look at different circumstances and how to safely start and stop PrEP.

There are two different ways you can take PrEP, depending on your circumstances:

- **Daily PrEP** (taking PrEP every day)
- Event based dosing (taking PrEP around the time of sex)

Starting and stopping PrEP safely

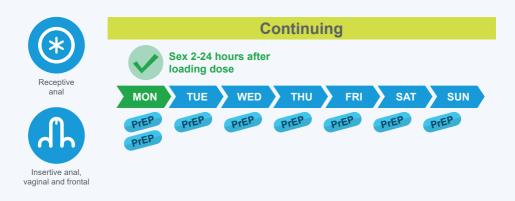
Daily PrEP dosing schedule: for receptive anal, and insertive anal, vaginal* and frontal sex

Starting: 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 sex.



*Throughout this document the term vagina includes neovagina.

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



Stopping: To stop PrEP, you must continue to take 1 tablet every 24 hours until 2 tablets have been taken after your last sexual exposure.

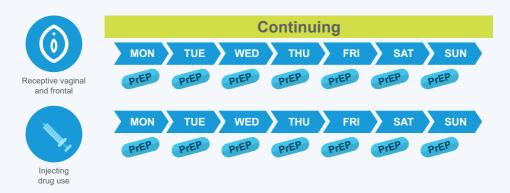


Daily PrEP dosing schedule: for receptive vaginal and frontal sex and sharing injecting drug equipment

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



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



Stopping: To stop PrEP, you must continue to take 1 tablet every 24 hours until **7 tablets** have been taken after your last exposure.



Other tips on how to take daily 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): for receptive anal and insertive anal, vaginal and frontal sex

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

Event based dosing schedule: for sexual episode(s) over one day

- 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 your body when you have sex.
- 2. Take a single tablet 24 hours after the double dose.
- 3. Take a final tablet 24 hours later. This is often referred to as 2 + 1 + 1.



Event based dosing schedule: for sexual episodes over more than one day 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) at least 2 hours but no more than 24 hours before sex.
- 2. If you are continuing to have sex, take one tablet 24 hours after the double dose and continue taking one tablet every 24 hours.
- 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.



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

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 needed.

Daily dosing: condomless anal sex (insertive/receptive) and insertive vaginal and frontal sex

- If it has been more than 7 days since your last oral PrEP dose:
 - you need to restart PrEP with a double dose (2 tablets) as soon as possible, preferably within 24 hours and no later than 72 hours after the sexual exposure. Continue taking one tablet of PrEP daily and seek an urgent PEP assessment as soon as possible within 72 hours.
 - if you do not have any PrEP medication, seek an urgent PEP assessment as soon as possible within 72 hours.
- If it has been **7 days or less**, since your last oral PrEP dose:
 - you need to resume daily PrEP as soon as possible
 - if you do not have any PrEP medication, seek an urgent PEP assessment as soon as possible within 72 hours.

Daily dosing: condomless receptive vaginal and frontal sex

- If it is more than 3 days since your last oral PrEP dose:
 - you need to restart PrEP with a double dose (2 tablets) as soon as possible, preferably within 24 hours and no later than 72 hours after the sexual exposure. Continue taking one tablet of PrEP daily and seek an urgent PEP assessment as soon as possible within 72 hours.
 - if you do not have any PrEP medication, seek an urgent PEP assessment as soon as possible within 72 hours.
- If it has been **3 days or less** since your last oral PrEP dose:
 - you need to resume PrEP with a double dose (2 tablets) as soon as possible. Continue taking one tablet of PrEP daily and make contact with your PrEP service.
 - if you do not have any PrEP medication, seek an urgent PEP assessment as soon as possible within 72 hours.

Risk through sharing injecting drug equipment

- If it is more than 4 days since your last oral PrEP dose:
 - You need to restart PrEP with a double dose (2 tablets) as soon as possible within 24 hours and no later than 72 hours after the exposure. Continue taking one tablet of PrEP daily and seek an urgent PEP assessment as soon as possible within 72 hours.
 - if you do not have any PrEP medication, seek an urgent PEP assessment as soon as possible within 72 hours.
- If it has been **4 days or less** since your last oral PrEP dose:
 - you need to resume PrEP with a double dose (2 tablets) as soon as possible. Continue taking one tablet of PrEP daily and make contact with your PrEP service.
 - if you do not have any PrEP medication, seek an urgent PEP assessment as soon as possible within 72 hours.

Event-based dosing (EBD) for condomless anal sex and insertive anal, vaginal and frontal sex

- If you have missed the after-sex dose for event-based PrEP:
 - if you are late with, or missed, the first after-sex dose, this can still be taken up to 48 hours after sex, provided you took at least one tablet before sex; the second after-sex dose should be taken 24 hours after the first to complete the course.
 - if it is more than 48 hours after your last sexual exposure, the first after-sex dose should be taken and you should seek advice within 24 hours regarding PEP.
 - if you do not have any PrEP medication, seek an urgent PEP assessment as soon as possible within 72 hours.

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 need for PrEP and protection against 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. 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.

In some situations, your PrEP provider may suggest switching from daily to EBD to minimise the impact of the PrEP medication on your kidneys.

Deciding to stop 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). Ideally this should be as soon as possible but no later than 72 hours after the risk.

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 PrEPrelated pregnancy complications have been identified.

Untreated HIV in pregnant people is associated with an increased risk of transmission of HIV to the baby. Therefore, it may be appropriate to use PrEP in pregnancy. PrEP is recommended in pregnancy where there is a risk of HIV. 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 https://www.drugs.ie/drugs_info/about_drugs/chemsex/ Man2Man.ie

Information and support for gay, bisexual and other men who have sex with men (gbMSM).

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

HIV and STI prevention https://man2man.ie/prevention/

Support services and helplines https://man2man.ie/support-services-helplines/

Chemsex and safer injecting https://man2man.ie/chemsex/

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 by Phone. For more details visit https://mpower.hivireland.ie/speak-to-our-team/



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

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