

Buying PrEP online: Safe use and NHS monitoring



This booklet is for people who want to use PrEP that they buy online, or who are thinking about buying PrEP online.

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

PrEP is not currently provided free by the NHS, but some NHS clinics provide free monitoring and advice.

When this booklet went to print, NHS England and NHS Scotland were still considering whether PrEP would be funded.

Contact details:

This booklet was printed in November 2016. As information about PrEP is likely to change based on new research please see the online version on the i-Base website for updates.

Information in this booklet is meant to be used in discussion with your doctor.

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This booklet was written by doctors and community advocates from the following organisations: HIV i-Base (www.i-Base.info), 56 Dean Street, Mortimer Market Centre, BASHH special interest group for men who have sex with men (MSM SIG), www.iwantprepnov.co.uk, www.PrEPster.info and cliniQ.

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PrEP: A bit of background

What is PrEP?

PrEP stands for Pre-Exposure Prophylaxis. PrEP is taken before sex, so it is pre-exposure. Prophylaxis means to prevent infection – in this case HIV. So, PrEP is used by HIV negative people to prevent them from becoming HIV positive.

Currently, PrEP uses oral tablets. For gay men and trans women PrEP needs to be a combination pill containing two drugs: tenofovir DF and emtricitabine. The brand name for this is “Truvada”, but generic versions include Tenvir-EM. More on this later.

Both tenofovir DF and emtricitabine are widely used medicines to treat HIV. The combined pill was approved for HIV treatment in 2004, and for use as PrEP in the United States in 2012.

Tenofovir DF as a single drug is supported by several studies for reducing risk from heterosexual (vaginal) sex.

Who would benefit from taking PrEP?

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

Other factors are related to a higher risk of HIV. These include:

- A recent STI (especially rectal infection or syphilis).
- Use of PEP (post-exposure prophylaxis).
- Using some recreational drugs (crystal meth, mephedrone or GHB) - also known as ChemSex.

Any of these mean you are likely to benefit even more from taking PrEP.

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:

- By people who are HIV positive.

PrEP is usually not necessary if:

- The negative person is only having sex with HIV positive partners who are on treatment with an undetectable viral load. Being undetectable dramatically reduces the risk of transmission.

How well does PrEP work?

PrEP is highly effective at reducing the risk of HIV infection. PrEP works extremely well if taken correctly.

The PROUD study enrolled more than 500 gay and other men who have sex with men (MSM) in several sexual health clinics in England. It included some trans women. Half the group took daily PrEP from the start and half started PrEP after a year.

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

This means that PrEP is likely to be more than 86% effective.

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 report a 96% reduction in new HIV infections in people taking PrEP correctly.

Nearly all infections in PrEP studies have been when people are not taking their meds. However, two cases have been reported of HIV infections on PrEP with drug resistant HIV.

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 older than 40 or if you already have reduced kidney function when you start PrEP.

PrEP can also reduce bone density by 1-5% - 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.

So far there have not been any reports of bone fractures related to PrEP use.

Event based PrEP might reduce the risk of these side effects, though this has not been formally studied yet.

PrEP and drug resistance

If you take PrEP 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 highest risk of drug resistance is if you start PrEP when you are already HIV positive. It can also happen if you have a break from PrEP and don't check your HIV status before restarting. Drug resistance is also possible if you don't take enough doses for protection and become HIV positive.

Two cases have been reported of people who became HIV positive even though they were taking PrEP correctly. These were from partners whose HIV was already resistant to the drugs in PrEP. This is a very rare event but other cases might be reported in the future. Currently, less than 1% of people who are newly diagnosed in the UK have drug resistance to both tenofovir DF and emtricitabine.

PrEP and other STIs

PrEP will not protect against other STIs. This is an advantage of also using condoms.

Other STIs generally are manageable, but sometimes can cause unpleasant symptoms, some of which can be serious. This is why we suggest getting regular checks for STIs when you take PrEP and use condoms when you can.

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. This will hopefully be the focus of future direct studies.

Buying PrEP online

It is legal to buy generic PrEP for personal use, sourced from outside the EU.

Generic PrEP is a version containing the same medicine, but made by a company that does not own the patent in Europe. Personal use is defined as up to three months of daily PrEP.

One of the most widely-used versions of generic PrEP is called Tenvir-EM. This is manufactured by Cipla, a company approved by the US drug regulatory agency. It is important to only use generic versions of PrEP made by manufacturers with this approval. You can find a list here:

<http://www.fda.gov/InternationalPrograms/PEPFAR/ucm119231.htm>

Some clinics can offer a blood test to see whether you have active drug levels.

This is called Therapeutic Drug Monitoring (TDM).

Your clinic might be able to advise you if someone else using the same PrEP medicine or supplier has already been tested. So far, TDM has not shown any problems with PrEP bought online and over 50 samples have been tested.

Sometimes buying PrEP online might take a while for the drugs to arrive. It is best to order at least a month in advance.

Make sure that you order a combination pill that contains BOTH tenofovir DF and emtricitabine. This is especially important for gay men and trans women. For example, you need Tenvir-EM rather than Tenvir.

UK community websites have lots of information about PrEP and how to buy it online:

iwantprepnnow.co.uk

prepster.info

i-base.info/qa/category/prep

We cannot state that there is absolutely no risk if you choose to buy PrEP online because the PrEP is not sourced directly from the manufacturers.

However, a study from 56 Dean Street showed that the online pharmacies listed on the three community websites above, were all selling genuine generic PrEP. [1]

Some clinics will support you and provide advice and monitoring if you buy PrEP online. But currently the NHS will not take responsibility for the pills, because the clinic has not supplied them.

So use the information on the websites above to make sure you are getting the right pills.

Reference

1. Wang X et al. Glasgow HIV Congress 2016, Abstract O315.
<http://i-base.info/htb/30888>

Before you start

Please talk to a health advisor, nurse or doctor at the clinic. They can help you if you are planning to take, or are already taking PrEP.

It is important to have an HIV test before or as you start.

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 will need for treatment.

Ask for a '4th generation' HIV blood test. This is also called a 'combined antigen/antibody' test. This tells you your HIV status approximately 4 weeks ago.

Most finger prick tests are currently '3rd generation'. They tell you your HIV status approximately 3 months ago. So don't rely on a fingerprick test alone before you start PrEP.

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

Don't start PrEP if you have flu-like symptoms and a recent HIV risk. This is to check that these symptoms are not related to a recent HIV infection (ie seroconversion).

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 4 weeks into PrEP.

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.

Check for other sexually transmitted infections (STIs)

This is always a good idea!

Test for hepatitis B (HBV)

This is essential because PrEP medicines are active against both HIV and HBV.

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

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

People with HBV need to take PrEP every day, with medical advice, especially if you want to stop.

Routine care if you have already started PrEP

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

Every 3-4 months

- Have a '4th generation' HIV blood test. This is also called and 'antigen/antibody' HIV blood test.
- Have a full screen for other sexually transmitted infections (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 sent off for kidney function.

Every 12 months

- Have a blood test to check your kidney function.

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.

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

Other sexually transmitted infections are important. This is a reason to still use condoms at least some of the time.

How to take PrEP

This section discusses different ways that you can take PrEP.

It takes a little time for HIV infection to occur. Even if the sex only lasted a few minutes, it takes about 30 minutes after sexual exposure for the virus to get through genital tissue and enter the body. It then takes time for the infection to take hold, although when this happens varies for different people.

For PrEP to be most effective, the medicine needs to be at protective levels throughout this time. As the body takes a while to absorb drugs, this means PrEP needs to be taken both BEFORE sex and for several days AFTERWARDS.

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

For vaginal sex you need to take PrEP every day. You also need to take PrEP daily for two weeks (ideally three) 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.

For anal sex daily PrEP has the most evidence. But other studies have used alternative dosing including event-based dosing (EBD) in IPERGAY. This involved 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 EBD, it is likely to still be very effective.

EBD is NOT suitable if you are a cis woman having vaginal sex. There is limited evidence on PrEP requirements for trans women who only have vaginal sex; daily dosing is considered safer.

There is currently a lack of data about PrEP for trans men taking testosterone and having vaginal sex. Long term testosterone use causes changes in the vaginal tissue; we do not know whether this affects HIV risk or efficacy of PrEP.

Talk to your doctor about what dose and timing is suitable for you and the level of protection that you need.

Daily PrEP: for anal and vaginal sex

Most PrEP studies have used daily PrEP.

Taking PrEP every day will make sure that there are protective drug levels 24 hours a day, 7 days a week. This means you do not have to plan PrEP for when you might have sex.

For people who routinely have sex every week, daily PrEP is likely to be a better dosing option.

Daily PrEP allows some flexibility in that missing an occasional dose is not likely to make much difference.

- If you are just about to start daily dosing but think you may have a risk within the next few days, start with a double dose.
- For anal sex, after two weeks of daily PrEP, four or more doses during the week will give good protection.
- Remember that for vaginal sex you need to take PrEP every day, and continue daily.

Event Based Dosing (EBD): only for anal sex

For people who do not want to take a daily pill there is an option to just use PrEP when you need it. This option is important if you don't have sex without condoms very often, and also if you usually know when you will have sex.

EBD is not recommended if you have hepatitis B.

If you are buying PrEP, event based dosing is also less expensive because you need fewer pills. Taking PrEP in this way may reduce the likelihood of developing kidney or bone problems because you would take fewer pills.

Taking PrEP before and after a risk is still very effective. But the “before-sex” dose is important. You need to make sure that there is enough medicine in the body when you have sex.

Event-based dosing involves:

1. Taking a double dose of PrEP (two pills) before you have sex. Ideally this should be the day before (24 hours before) but between 2 and 24 hours before was used in the IPERGAY study.
2. Taking a single pill 24 hours later.
3. Taking another single pill the following day, 24 hours later.

You should aim to take two single pills after you have sex, roughly 24 hours and 48 hours after the first double-dose.

EBD is also sometimes called “on demand” dosing.

Real-life dosing examples are included on the next three pages.

Real-life examples for Event Based Dosing (EBD)

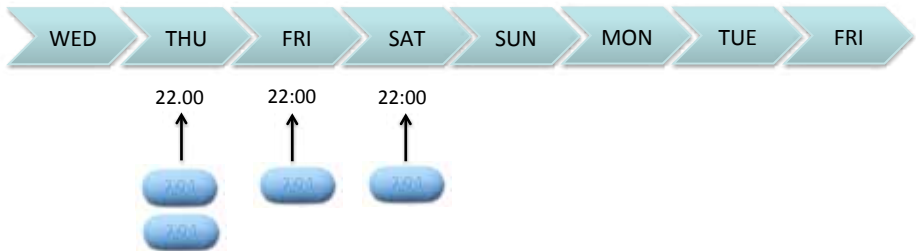
1. EBD: If you have sex once a week

BEFORE SEX

2 PrEP tablets at least 2 hours & ideally 24 hours before sex



19:00



AFTER SEX

1 PrEP 24 hours* after the 1st

2 PrEP 48 hours* after the 1st

= total of 2 tablets after sex

*2 hours before or after planned time is OK

If you think you might have sex on Friday or over the weekend, you would ideally take two pills on Thursday; lets say you took them at 10 pm.

If you have sex on Friday at 7 pm, then you would take a single pill on Friday and Saturday aiming to take the pill at around 10 pm. You have then had two doses after sex.

These times are all approximate - you would still get good protection if you took the Thursday dose at 6 pm and had sex on Friday at 11 pm. Even if the pre-dose is only two hours before sex, or even just before sex, some PrEP is always better than none.

2. EBD: Sex several times over a few days

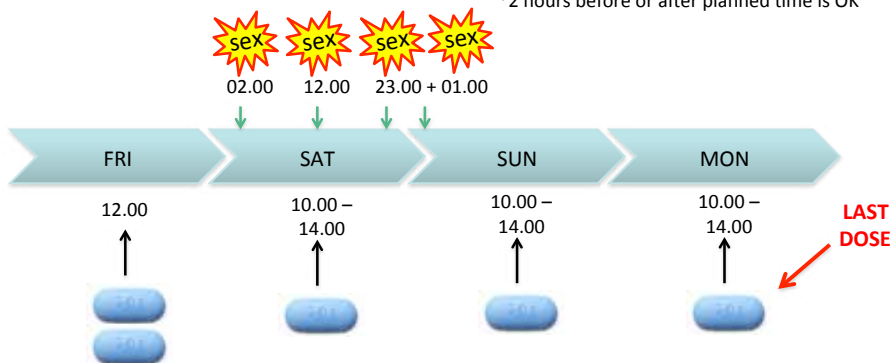
BEFORE SEX

2 PrEP tablets at least 2 hours & not more than 24 hours before sex

AFTER SEX

1 PrEP 24 hours* after the 1st 2
Take Truvada every 24 hours* until 2
doses after your last sex

*2 hours before or after planned time is OK



You take your double dose as usual 2-24 hours before sex.

If you have sex on Saturday, and a few times until Sunday at 1 am, continue to take a single pill every day at around the same time until you have had two doses after sex. Using the example above, your last dose would be on Monday at 12 noon.

If you don't have sex on Saturday or Sunday, but might still have sex on Monday, you only need to continue with a single pill on Sunday and Monday because you already have good levels of PrEP drugs. Continue taking PrEP daily until you have had two doses after the last time you have sex, ie until Wednesday.

If however, you have started PrEP but then don't have sex on Saturday, and have no plans to have sex on Sunday or Monday, then there is no need to take PrEP on any of these days.

3. EBD: Sex several times, then more sex less than 7 days after the last PrEP dose

1st PREP

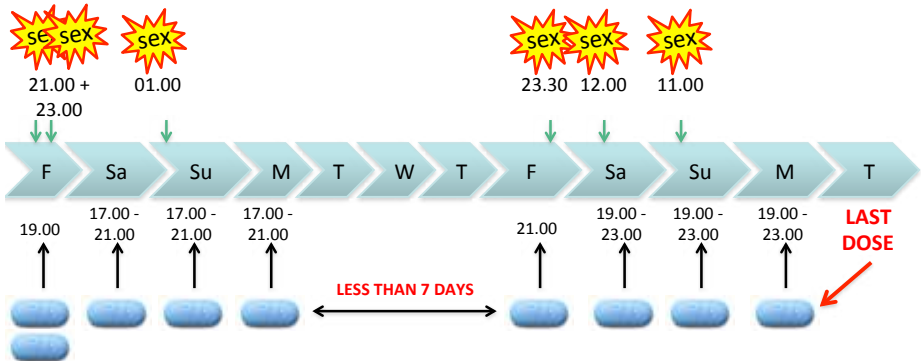
TWO PrEP tablets at least 2 hours & not more than 24 hours before sex. 1 PrEP tablet every 24 hours* until 2 tablets taken since last sex

*2 hours before or after planned time is OK

2nd PREP

ONE PrEP tablet at least 2 hours & not more than 24 hours before sex. 1 PrEP tablet every 24 hours* until 2 tablets taken since last sex

*2 hours before or after planned time is OK



If there are less than seven days between then end of one event based dosing and the beginning of another, you only need to take one PrEP tablet at the beginning of the new dosing schedule.

If there are more than 7 days between the end of one dosing schedule and another, take two pills at the beginning as usual.

Other tips on how to take PrEP

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 then talk to the clinic about support.

If you use daily dosing and miss more than a week of pills take a double dose (2 pills) if you know you are going to have a risk. Then carry on as normal with a daily pill.

Never take more than one double dose when you start PrEP. You only need one double dose at the start. Carrying on double dosing after the first dose is not needed and may do you harm.

Do not take more than a total of seven pills in one week.

A pill box makes it easy to see whether you have taken or missed a dose. They only cost £1 or so - or contact i-Base who can post you one for free. (www.i-Base.org.uk)

Pick a regular time 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 have another HIV test.

If you have a risk in the future when you haven't been taking PrEP, contact a clinic as soon as possible to access PEP. The earlier you do this, the more likely that PEP will work. PEP is still prescribed up to 72 hours after sex.

If you still have some PrEP left, take daily PrEP to provide some protection before you get to the clinic. PEP stands for post-exposure prophylaxis and involves taking a combination of three HIV meds for one month.

Tips on Event Based Dosing (EBD)

If you are having sex over several days, try to take the PrEP approximately at the same time and not to miss any doses. Think of an easy time for you to remember the doses after sex.

If you have sex again and it is 6 days or less since your last PrEP dose, you do not need to repeat the double dose. This is because there will still be some PrEP left in your body from your previous doses.

If you missed the BEFORE dose completely, still take a double dose AFTER sex, and continue daily, but contact your clinic. This is because using an additional HIV drug might be recommended, depending on the risk involved, to make PrEP into PEP.

Missing doses matters more if you are using EBD rather than a daily regimen.

Have an HIV test as soon as possible if you had a break from PrEP and remained at risk.

Can I switch between daily and event-based dosing?

PrEP is a great way of reducing your risk of HIV, but your circumstances can change over time.

If you find your HIV risk changes, you can stop and restart PrEP, or change the way in which you take it. PrEP can be individualised to your needs at different times.

Some people might start by taking daily PrEP and then switch to event-based PrEP if their risks are less frequent.

Others might start with event-based PrEP and find they need this protection every week - and so switch to daily PrEP.

Others might switch between different dosing strategies every few months depending on how much risk they think they have, whether this is acceptable to them, the cost and other factors.

Use your visits to the clinic to talk through the ways of taking PrEP and how to stop or restart when you need to.

EBD is not recommended if you have hepatitis B.

Can I stop PrEP completely?

As with the flexibility for dosing, you might decide that you want to stop PrEP altogether.

Discuss your decision to stop with clinic staff.

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

If you had a recent risk, continue taking PrEP at your regular time for another 48 hours. This means taking two doses, one for each of the two days after your last risk.

If your circumstances change in the future, it is easy to restart PrEP.

If you have stopped PrEP and have a risk in future, you should contact a clinic about PEP. Ideally this should be as soon as possible and no later than 72 hours after the risk.

You can use your PrEP meds immediately to cover the period until you get to the hospital for PEP.

Credits and further information

This leaflet was produced by doctors and community advocates from the following organisations.

BASHH special interest group MSM

www.bashh.org

HIV i-Base

www.i-base.info

iwantprepnov.co.uk

www.iwantprepnov.co.uk

PrEPster.info

www.PrEPster.info

56 Dean Street

www.facebook.com/56DeanStreet

Mortimer Market Centre

www.cnwl.nhs.uk/service/mortimer-market-centre

cliniQ: sexual health and well-being for trans people

www.cliniq.org.uk



Cover graphic: thanks to IwantPrEPnow.co.uk