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GLOSSARY

**SMA:** State Medical Assistance

**AMM**: Marketing authorisation

**CEGIDD:** Free centre for information, screening, and testing for HIV infections, viral hepatitis, and STIs

**UH:** Universal healthcare

CPEF: Family planning and education centre

MSM: Men who have sex with men

HAS: French Public Healthcare Authority

HPV: Human papillomavirus

STI: Sexually transmitted infection

WHO: World Health Organisation

PASS: Permanent access to healthcare

PrEP: Pre-exposure Prophylaxis

PEP: Post-exposure Prophylaxis

HIV: Human immunodeficiency virus





PrEP is a new HIV prevention strategy. It stands for "Pre-Exposure Prophylaxis"

**Prophylaxis** = avoiding infection.

**Pre-exposure** = a treatment taken before (and after) potential exposure to HIV.

rEP is a medicine that individuals who do not have HIV take to avoid infection. This principle of medicinal prevention is not unique to HIV; consider, for example, the drugs people take to avoid contracting malaria, or the statins that people take to reduce the risk of cardiovascular diseases.

Like all medicines, PrEP must be prescribed by a physician and it requires follow-up (see "How do I access PrEP"?).

### PREP ≠ PEP

PrEP should not be confused with post-exposure prophylaxis (PEP), also known as "emergency treatment", which must be taken no later than 48 hours after the risk of transmission, and then every day for one month.

#### PREP ≠ HIV TREATMENT

PrEP should also not be confused with the treatments given to people living with HIV. When a person detected as HIV-positive properly takes his/her medications, the virus levels in his/her body become extremely weak; this is known as an "undetectable viral load". In trials, when viral load remained undetectable for at least six months, no HIV transmission was observed, even during unprotected sex.

#### WHICH MEDICINE?

Currently, the only medicine used for PrEP pairs two anti-retroviral drugs that fight HIV: Emtricitabine and Tenofovir disoproxil. This medicine is sold under the brand name Truvada® and is now available in generic versions (see page 11). Research is on-going in an attempt to identify new molecules and other means of administration.

## AN EFFECTIVE, HIGHLY RECOMMENDED STRATEGY

Several studies have proven the effectiveness of PrEP when taken continuously or on demand: Iprex Ole (USA), Partners Prep (Kenya, Uganda), Proud (UK), and ANRS-Ipergay (France, Canada). These studies were conducted primarily on men who have sex with men (MSM); some of them also included transgender individuals and heterosexual couples.

All these trials demonstrate that the risk of infection is minimal when the medicine is properly taken, according to instructions.

Based on the positive results of these studies, PrEP is now recommended by a number of national and international healthcare authorities, including the World Health Organisation (WHO), the French National Council on AIDS and Viral Hepatitis (CNS), and the Expert Group against HIV at the French Public Healthcare Authority (HAS).

All these trials demonstrate that the risk of infection is minimal when the medicine is properly taken, according to instructions.

#### A COLLECTIVE IMPACT

While is still too soon to say with any certainty, several indicators seem to demonstrate that PrEP has helped reduce infection rates:

- in San Francisco, the number of new cases of HIV fell by 49% between 2012 (the year when PrEP was authorised in the US) and 2016;
- in the UK, the number of new cases of HIV fell by 18% between 2015 and 2016. This drop was even higher among MSMs in London at -29%.

In both cases, the drop in the number of new HIV-positive cases is unprecedented in the history of the disease. It is probably also attributable to better screening and treatment of persons living with HIV that prevent the virus' transmission, and which are prescribed with increasing speed following diagnosis.

In France, the ANRS-Prévenir study, which began in 2017, seeks to assess precisely the effectiveness of PrEP in fighting the epidemic in the Île-de-France region.



### PREP ONLY PROTECTS AGAINST HIV

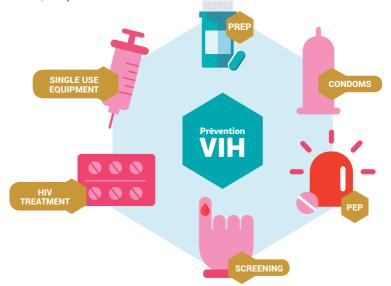
Very importantly, PrEP, like PEP, does not protect against other sexually transmitted infections (STI) such as gonorrhoea, genital warts (tied to the human papilloma virus), chlamydia, hepatitis A, B, or C, and syphilis.

It also does not prevent unwanted pregnancies. This is why PrEP must be accompanied by an extensive, tailored monitoring of one's sexual health, including the use of condoms, vaccinations, regular STI screenings, pregnancy testing, and the use of contraception.

#### A DIVERSIFIED PREVENTION OF HIV

PrEP joins a palette of tools for preventing HIV that can be used on their own or in combination with one another. This is also known as combination prevention:

- the use of internal and external condoms and lubricant gels;
- regular HIV screening (traditional screening, rapid testing, self-testing);
- recourse to PEP in emergency cases;
- recourse to HIV treatment as a prevention tool with an HIV-positive partner: an
  undetectable viral load for at least six months = no cases of transmission to
  the HIV-negative partner;
- the use of single-use equipment when taking drugs (injection, sniff, chemsex, slam, etc.).



Like the decision to use condoms or other prevention tools, the decision to use PrEP is a personal one. The important thing is to find a prevention strategy that works best for you and which contributes to your sexual development.

#### SIDE EFFECTS

Taking Emtricitabine/Tenofovir disoproxil to reduce the risk of contracting HIV is generally well tolerated. However, as with most medicines, it may cause some undesirable side effects.

You may experience light nausea or diarrhoea (1 out of 10 people), headaches, or slight weight loss when you start the treatment. In studies, these effects disappeared in four to eight weeks.

More serious side effects tied to kidney or bone problems are rare. If these occur, they are reversible upon stopping the treatment. This is why kidney functions must be monitored when taking PrEP.

#### **INTERACTIONS**

Emtricitabine/Ténofovir disoproxil do not have any known interactions with alcohol or recreational drugs, nor with most anti-depressants, contraceptive treatments, or other hormonal treatments. Similarly, they have any known effects on one's sex drive or performance.

However, it is inadvisable to take other medicines that are toxic to kidneys, especially on an extended basis, such as non-steroid anti-inflammatory drugs (e.g. lbu-profen, Voltarène®, and Indocid®).



Two hours before and after taking PrEP, one should also avoid ingesting products such as psyllium, active carbon, or antacids.

Please consult the following guide for more information on interactions: actions-traitements.org/reglette



#### AND IN THE LONG TERM?

There is a lot of data on the long-term safety of this medicine, as it has been used for more than ten years in combination therapies prescribed to people living with HIV. As PrEP is a relatively new prevention tool, we don't yet have such data on HIV-negative individuals.

For all these reasons it is essential to see your physician regularly when you are taking PrEP. Healthcare providers are fully able to assess your proper tolerance of the medication through routine tests.



# The regulatory overview: Marketing Authorisation

Truvada® and its generics Emtricitabine/Tenofovir disoproxil have a Marketing Authorisation (AMM), which legally allows their sale. The AMM specifies the treatment indications and conditions of use (dosage, side effects, contraindications) in function of clinical trials conducted by the pharmaceutical companies.

The AMM for Truvada® was modified in early 2017 to add the indication of PrEP for the targeted populations (adults only) and solely according to the continuous schedule. Due to the laboratory not requesting it, the AMM does not currently include prescribing PrEP for the "on-demand" schedule, even though this was validated by the ANRS-Ipergay study and recommended by acknowledged scientific institutions (e.g. the Expert Group against HIV at the French Public Healthcare Authority). It is nevertheless possible to take PrEP on demand (see page 15).



- B ased on the recommendations from the WHO and the French National Sexual Health Strategy (SNSS), PrEP is for people who are at high risk of contracting HIV:
  - men who have sex with other men (MSM);
  - transgender individuals who have sex with men;
  - individuals from Sub-Saharan Africa and other regions where HIV is prevalent (e.g. French Guyana), especially women living in precarious situations;
  - sex workers exposed during unprotected sex;
  - intravenous drug users who share syringes.



Initiating a PrEP treatment with Emtricitabine/Tenofovir disoproxil is contra-indicated in the following cases:

- when an individual is HIV positive or of unknown HIV status:
- when signs or acute symptoms are present of HIV infections (flu-like symptoms, swollen glands, etc.);
- when an individual suffers from kidney problems characterised by a creatinine clearance of < 50 ml/min;</li>
- hypersensitivity to one of the product's active ingredients or excipients.

In any case, your physician will decide whether or not to prescribe you PrEP after analysing your risk of contracting HIV and after verifying any contra-indications. Even if you have a clear risk level, your physician may refuse to prescribe PrEP to you. In such a case, if you want, you may seek the opinion of another healthcare practitioner.







### **WOMEN AND PREP**

## A pill a day!

Women (cis- or transgender) who have vaginal intercourse should only follow the continuous schedule (one pill per day). The "on demand" schedule is not recommended, because the effectiveness of this treatment may be insufficient, based on current knowledge.

The WHO now believes that the treatment reaches its maximum effectiveness after seven days of continuous dosage, both for men and for women (see page 14).

## Do you want a baby?

If you are trying to get pregnant, are already pregnant, or if you are nursing, we advise you to talk to your family physician about PrEP.

# Contraception

Remember that PrEP is not a means of contraception. Therefore, in addition to PrEP, if you want to avoid getting pregnant, you must follow a contraception strategy that suits your lifestyle, personal history, and habits. PrEP does not interact with any form of contraception.

General practitioners, gynaecologists, and midwives are available to answer your questions, help you choose the form of contraception that best suits you, and prescribe it to you. You may also visit a family planning and education centre (CPEF) near you or visit any pharmacy if you require any form of emergency contraception, which they may be able to give you without a prescription.

For more information, please visit choisirsacontraception.fr and ivg.gouv.fr.



# How about minors?

At this time, PrEP is in theory not advised for adolescent minors, and in practice, we have never observed it being prescribed.

AIDES is fighting to lift this restriction, which is hindering prevention among minors who are vulnerable to HIV. It is also important that they be able to access this treatment anonymously, without needing parental authorisation.



o get PrEP, make an appointment at a hospital specialising in HIV treatment or at a free information, screen, and diagnostic centre – known as CEGIDD (formerly CDAG) – present in all departments in France.

You can download a PrEP consultation sheet at:

prep-info.fr/carte-des-consultations

## 1 / FIRST CONSULTATION

During your first visit, a physician will talk to you about the appropriateness and possibility of taking PrEP. They will check in particular to make sure there are no initial signs of HIV infection, and prescribe a series of tests to be conducted on site or at a lab. These tests will ensure that you have no contra-indication to PrEP (HIV-positive, kidney problems, etc.) and also screen for any STIs that need treatment.



# **Checking for STIs**

In addition to a blood test, a quarterly battery of tests should ideally include, depending on the context, a test for **chlamydia** and **gonorrhoea** at the following three "sites": **genital** (vagina/penis), **rectal** (anus) and **pharyngeal** (throat).

We have observed a wide range in what laboratories charge, and therefore costs borne by individuals... A "nomenclature of acts of medical biology" created by the French National Healthcare Service seeks to regulate this, but it is not very clear. AIDES is working on clearing up these matters, but in the

meantime, here is some advice: **consult your local CEGIDD first**, and then, as a default, ask your laboratory how much the exams will cost before taking them; **shop around for the best price**, if you can. Ultimately, never hesitate to talk about this on PrEP'Dial (see page 23).

## 2 / SECOND CONSULTATION

Your second visit will take place two to four weeks later. The physician will once again check to make sure there are no initial signs of HIV infection, and, depending on the test results, they may or may not issue the first prescription for PrEP. They will also ensure that you will be treated for any STIs.



## **Vaccinations**

You may be proposed several vaccinations as part of your sexual health monitoring. Some of these are highly recommended, such as hepatitis A, hepatitis B, and HPV (human papilloma virus).

## 3 / PICKING UP PREP

With your prescription in hand, you can go to any city or hospital pharmacy. The pharmacy may not have the medicine in stock, but they can always order it; it should be available that same day or the next day.

AIDES and the National Order of Pharmacists have prepared a PrEP guide for pharmacists, which is available at: prep-info.fr/professionnels-de-sante.



# What about generics?

Emtricitabine/Tenofovir disoproxil, originally sold under the trade name Truvada®, are now available in generic form. Regardless of the manufacturing laboratory, form, colour, or conditioning of the pills, the active ingredient is identical to Truvada® in terms of its effectiveness. The main difference is that it is 60% cheaper than Truvada® and, therefore, that it allows the health-care system to save money.

Due to a difference in excipients (i.e., all substances besides the active ingredient in a medication), you may experience slight nausea or diarrhoea. If these symptoms persist, try another generic and talk to your physician.

## 4 / QUARTERLY MONITORING

A PrEP prescription requires quarterly clinical and biological monitoring. This includes checking your HIV status and kidney functions, and testing for STIs. Your quarterly visit is also the best time to renew your PrEP prescription.







If you want, your primary care physician can take care of the quarterly monitoring and renewal of your PrEP prescription; however, you should consult a physician at a hospital HIV clinic or a CEGIDD office at least once a year.

There are tools to help general practitioners take care of PrEP users, especially a liaison letter to be filled out by the hospital or CEGIDD physician, as well as a National Healthcare Service form for the proper usage of the medication. Both are available at: prep-info.fr/professionnels-de-sante.

Whatever you decide about who will oversee you PrEP treatment, you should inform your primary care physician of this choice.

#### **SUPPORT**

Taking PrEP may involve some difficulties: understanding the instructions for taking the medicine, taking the medicine regularly (*i.e.* not forgetting to take it), questions about its effectiveness, the role of PrEP in relation to other prevention tools, the perception of PrEP among your entourage (lovers, friends, etc.), dealing with the medical community, the number of healthcare professionals involved, and so on. **So, don't hesitate to look for support, especially during the first few months!** See the section titled "PrEP Support" on page 22.

#### **HOW MUCH DOES IT COST?**

The medication is fully covered by the French National Healthcare System; therefore, pharmacies may not ask you to cover any costs out of pocket.

However, you may have to pay residual amounts for your medical consultations and biological tests.

- If you are having difficulties in paying out-of-pocket costs or do not have an insurance plan, go first to a CEGIDD, which are free by definition.
- If you lack the right to access the French Social Security system, we encourage
  you to visit the social services office at a hospital, a CEGIDD, or a healthcare
  access office (PASS). A social worker can help you access your rights.

Foreigners with an irregular immigration status residing in France, *i.e.* for an uninterrupted period of more than three months, may access the State Healthcare System (AME), which covers PrEP.

It is important that you have your *carte vitale* healthcare card and your supplementary insurance card, or to be able to justify your right to access the Social Security system (AME, complementary CMU, etc.) during your medical visits.

The medication is fully covered by the French National Healthcare System.









hen you are taking PrEP, the anti-retrovirals in your body prevent HIV from infecting cells, thereby blocking its reproduction.

# PrEP works properly when you take it properly!

All studies have shown that the key to PrEP's success lies in taking the medication properly, whatever the schedule chosen.

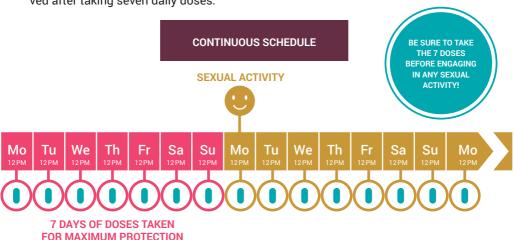
# There are two ways to take PrEP.



# PREP TAKEN ON A "CONTINUOUS" OR DAILY SCHEDULE, meaning one pill per day

You can take your dose with or in between meals, but it is recommended that you take it with at least a light snack. It is also recommended that you take your dose at the same hour each day to establish a routine.

Whatever your gender, sexual orientation, or type of sexual relationship (receptive, insertive, vaginal, anal, etc.), the WHO recommends that optimal protection is achieved after taking seven daily doses.



If you wish to stop taking PrEP when on the continuous schedule, the WHO recommends that you continue to take one pill per day for seven days after your last sexual encounter.

You may take PrEP "on demand" as long as you are not having receptive vaginal sex.



# The Marketing Authorisation and taking PrEP on demand

Due to Gilead (the manufacturing laboratory) not making the request, the Marketing Authorisation that sets the procedures for using Truvada® and its generics does not mention an on-demand use.

Therefore, you must be prescribed PrEP to be taken according to a continuous schedule. You are then free to take it "on demand" according to the physician's indications!

Please note that taking PrEP on demand is contra-indicated for people with hepatitis B.

The on-demand schedule requires that you take PrEP at least two hours before your first sexual encounter (see the diagram below). The advantage of the on-demand schedule is that it adapts to your sexuality; you can take PrEP for short periods and then stop doing so during periods of lesser sexual activity. You can also take it for several weeks or months.

To protect against one single sexual encounter (or an evening of sexual encounters), you must take **three doses**, which is equal to **four pills**:

# **FIRST DOSE**

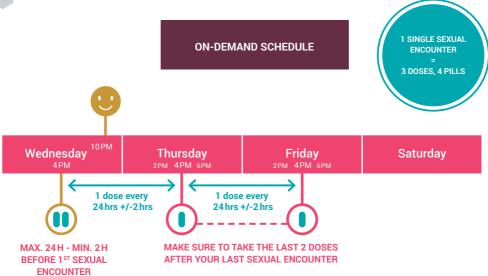
Two Emtricitabine/
Tenofovir disoproxil
pills to be taken
at the same time
between two and
24 hours before
your first sexual
encounter.

### **SECOND DOSE**

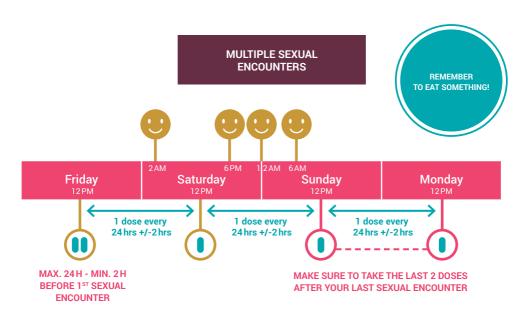
One Emtricitabine/ Tenofovir disoproxil pill to be taken roughly 24 hours (plus or minus two hours) after the first dose.

## THIRD DOSE

One Emtricitabine/ Tenofovir disoproxil pill to be taken roughly 24 hours (plus or minus two hours) after the second dose.



If you have other sexual relations more than 24 hours after taking the initial dose, continue to take one Emtricitabine/Tenofovir disoproxil pill per day (at the same time, plus or minus two hours), and don't forget that if you want to stop taking PrEP on an on-demand basis, you must always take two doses, spaced 24 hours apart, after your last sexual encounter.



If you have taken PrEP within the last seven days, you don't have to take two pills at once for the first dose; one is enough (which is slightly less toxic); however, you must still wait at least two hours before being protected once more.





24hrs +/-2hrs

24hrs +/-2hrs

24hrs +/-2hrs

# **CAREFUL**

**PERIOD WITHOUT** 

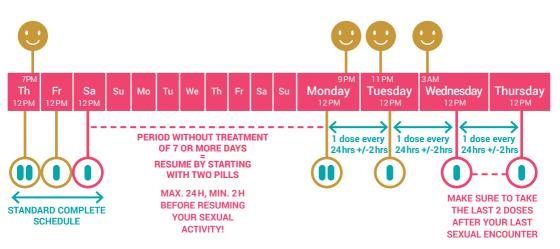
**TREATMENT OF 1-6 DAYS** 

To maintain a high level of effectiveness. never forget to take your pills.



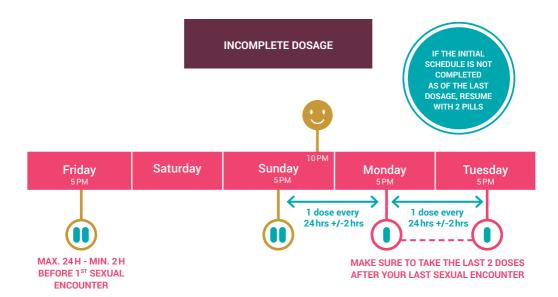
If you have not taken PrEP within the last seven days, you should take two pills as your first dose, as below:

RESUMING SEXUAL ACTIVITY
7 DAYS AFTER TAKING
YOUR LAST PILL





Please note that taking one or two pills on their own during this break (the interrupted initial schedule) does not count when calculating the seven days.



**PrEP's effectiveness is highest when you observe the dosage schedule.** If you forget to take one or more doses, or if they are taken too far apart, this will reduce your protection against HIV. The medication has to be present in your system in sufficient quantities to protect against HIV. For example, it has been shown that taking pills right before a sexual encounter, but not afterwards, does not protect against HIV.



# Post-exposure Prophylaxis (PEP)

If you forgot to take a dose or took one more than two hours after the scheduled time, and you have had an unprotected sexual encounter (without a condom), you may request emergency treatment (within 48 hours and ideally within the first four hours). The treatment is available at hospitals with dedicated HIV clinics, sometimes at a CEGIDD, or at night at an emergency room. To find out the address of the service closes to you, call Sida Info Service at 0 800 840 800 or visit sida-info-service.org.



# 1 YOU CAN ANTICIPATE THE TIME CHANGE BY PLANNING THE TIME

You can anticipate the time change by planning the time when you want to take your pill once you have arrived at your destination, and then taking the pill at the corresponding time in the time zone of your departure. This way you can anticipate the time difference from your normal time several days before your departure by shifting the time when you take the medicine by one hour or two each day.

For example: You usually take your pill every day at 8:00 PM in Paris. You are leaving for New York, which is six hours behind. You would like to keep taking your dose at 8:00 PM after you arrive, which corresponds to 2:00 AM, Paris time. Two days before you leave, begin to shift the time when you take you dose: on the first day, take it at 10:00 PM (which is 4:00 PM, New York time), on the second, at midnight (which is 6:00 PM, New York time), and once you arrive in New York, you can take it at 8:00 PM, New York time.

# 2 AFTER YOU ARRIVE AT YOUR DESTINATION

After you arrive at your destination, take your medicine two hours later each day of your stay, until the time that corresponds to the one when you usually take your dose in France.

For example: you take your dose every day at 9:00 PM. You fly to Bangkok, which is five hours ahead of Paris; therefore, 9:00 PM in Paris is 2:00 AM in Thailand. After you arrive, instead of taking your pill at 2:00 AM (9:00 PM, Paris time), take it at midnight, Bangkok time. The next day, take your dose at 10:00 PM, and the following day, at 9:00 PM.

Ultimately, the important thing is to maintain a sufficient quantity of medicine within your system to protect against HIV.

# **Apps for PrEP!**

#### AT-PrEP

The organisation Actions Traitements has created an app specifically for PrEPpers. The app is designed to be your "coach." It includes a system for reminding you when to take your dose (continuous or on-demand schedules), a list of medical interactions, a diary to remind you of your doctor's visits, and practical advice.

#### Medisafe®

To help you with taking your medicine (with or without time differences), you can also use the app Medisafe®, which reminds you when to take your dose and how many pills you have left, the history of your doses (which, for example, helps you remember if your last dose was five, six, or seven days ago, and therefore whether or not you should take one or two pills).



If you have any doubts or questions about how to take PrEP, don't hesitate to consult your pharmacist, your physician overseeing your PrEP treatment, or your PrEP support provider!



rEP support helps familiarise you with this new prevention tool, think about how to adapt it to your lifestyle and sexual practices, facilitate your relations with your healthcare providers, encourage your consistent taking of the medicine, and in general, to take charge of your sexual health as much as possible.

#### WHO ARE PREP SUPPORT PROVIDERS?

PrEP support providers are members of AIDES or other organisations (including Enipse, Acceptess-T, and Afrique Avenir) with training and experience in conducting sexual health interviews. Their approach is non-judgmental and they rely on their own personal experience, as well as that of other supported individuals taking PrEP.

They are subject to strict confidentiality regarding your exchanges, and they may only talk to healthcare providers if you consent to this. These interviews may be conducted together with a nurse or psychologist.

#### WHAT IS PREP SUPPORT?

You will generally be offered PrEP support at your first PrEP appointment at the hospital or CEGIDD. It takes the form of a confidential discussion in a closed room. If you prefer, it can also be conducted via phone or screen (Skype, WhatsApp). In any case, it is important to meet your support provider at least once to exchange contact information. You may then contact them in between your visits if you have any questions about PrEP or sexual health in general.

It is recommended that you have these interviews around your PrEP meetings during the first six months of use, but this is of course not required.



#### **EXCHANGES WITH OTHER PREP USERS**

A guide is fine, but nothing beats talking to other PrEP users!

- In many cities and regions, AIDES organises get-togethers for PrEP users.
   To find the AIDES office closest to you, please visit aides.org.
- The Facebook group "PrEP'Dial" is the largest francophone group for PrEP users; it is an independent space for users for support, debate, and news about PrEP. You are guaranteed to find answers to all your questions here! And of course, it's 24/7: facebook.com/groups/PrepDial.

Visit www.aides.org to find the AIDES office nearest you.

# HELPFUL LINKS

- facebook.com/groups/PrepDial: the largest francophone group for PrFP users
- prep-info.fr: this site has all published documents about PrEP, many links, references to studies and research on PrEP, as well as a space for healthcare professionals.
- ansm.sante.fr: the website for the French national agency for medicine and healthcare product safety.
- sexosafe.fr: the reference site for prevention for men who have sex with men (screening, condoms, STIs, PrEP, treatment as prevention, vaccinations, etc.), maintained by the French National Healthcare Service.
- Please visit seronet.info and vih.org, which are true goldmines of information about PrEP!
- To find out more about PrEP abroad, please visit:
  - prepwatch.org
  - pleaseprepme.global
  - prepineurope.org

# WHO ARE WE?

AIDES is France's largest organisation devoted to the fight against HIV/ AIDS, and it is present in 70 cities across the country. AIDES was co-investigator for the ANRS-Ipergay study, and it advocated heavily for free access to PrEP for everyone. It continues to work actively on making PrEP known to everyone and to help interested or concerned persons secure access to this medicine.

If you would like to help us, informational meetings about the organisation are held regularly in all cities where AIDES is present. To find the local AIDES chapter closes to you, please visit <u>aides.org</u>.

If you have any comments to make about this brochure, please contact us at: prep@aides.org.



