



## Instructions for use of Emtricitabine / Tenofovir disoproxil Krka to prevent HIV infection

### Introduction

Emtricitabine / Tenofovir disoproxil Krka 200mg / 245mg (FTC / TDF) is used as a prophylactic drug against pre-exposure prophylaxis (PrEP).

### Tip

#### *Exposure Control (PrEP):*

To prevent HIV transmission in a person (18 years and older) who, according to the risk assessment, is at increased risk of contracting sexual activity. This refers in particular to men who have sex with men (MSM).

### Check

Only LSH physicians with specialist recognition in infectious diseases may prescribe FTC / TDF. They, together with the outpatient nurses of the Infectious Diseases Department at LSH, oversee the assessment, treatment and follow-up of individuals on HIV prophylaxis (PrEP).

### Dosage and administration

1 tablet daily of FTC / TDF 200/245 mg.

#### *For high-risk MSMs, on-demand medication may be considered*

2 tablets of FTC / TDF 2-24 hours. for exposure 1 tablet of FTC /

TDF 24 hours. after exposure to 1 tablet of FTC / TDF 48 hours.

after exposure (but never more than 7 tablets per week)

### Assessment before treatment and follow-up

#### *First come*

Before taking a decision on prophylactic drug treatment with FTC / TDF, the individual in question meets with a nurse in the outpatient department of infectious diseases where:

- Risk assessment (see Figure 1).
  - Prevention education about sexually transmitted diseases, delivery of educational material and condoms. The
  - following studies were performed:
    - Antibody testing against HIV, syphilis and hepatitis B and C
    - Stroke from the throat, urethra and / or rectum measured by a nuclear acid test (PCR)
- Serum creatinine

MSM áhættumat			
		STIG	
1	Hvað ertu gamall í dag?	<18 ára	0
		18-28 ára	8
		29-40 ára	5
		41-48 ára	2
		>49 ára	0
2	Á síðustu 6 mánuðum, hversu mörgum karlmönnum hefur þú stundað kynlíf með?	>10	7
		6-10	4
		0-5	0
3	Á síðustu 6 mánuðum, hversu oft hefur þú stundað receptive endaþarmsmök (bottom) án smokks?	≥1	10
		0	0
4	Á síðustu 6 mánuðum, hversu margir af karlkyns rekkjunautum þínum voru HIV jákvæðir?	>1	8
		1	4
		<1	0
5	Á síðustu 6 mánuðum, hversu oft hefur þú stundað insertive endaþarmsmök (top) með HIV jákvæðum án smokks?	≥ 5	6
		0	0
6	Á síðustu 6 mánuðum, hefur þú notað amfetamín (spítt) eða metamfetamín?	Já	6
		Nei	0
STIG samtals*			
*Ef stigafjöldi er 10 eða meiri skal íhuga umfangsmeiri HIV forvarnir, þ.m.t. fyrirbyggjandi lyfjameðferð með FTC/TDF			
*Ef stigafjöldi er minni en 10 skal notast við hefðbundnar HIV forvarnir			

Figure 1. Risk assessment for MSM for FTC / TDF prophylaxis.

#### Another coming

An infectious disease specialist meets individuals with a positive risk assessment (> 10 points).

- Results of blood tests and sexually transmitted disease screening reviewed:
  - fourth generation HIV test
    - if an HIV test is positive at any time point or a person shows clinical signs of acute HIV infection, FTC / TDF treatment should be stopped immediately and the person referred to an HIV outpatient department for evaluation.
  - antibody testing against hepatitis viruses
  - other sexually transmitted diseases treated according to current guidelines.
- Information on FTC / TDF, efficacy and preventive value of drugs The
- following return periods are booked:
  - a call from a nurse after 4 weeks
  - blood test after 11 weeks
  - visit a nurse (and doctor) after 12 weeks Electronic research requests completed before the next visit.

#### Follow-up

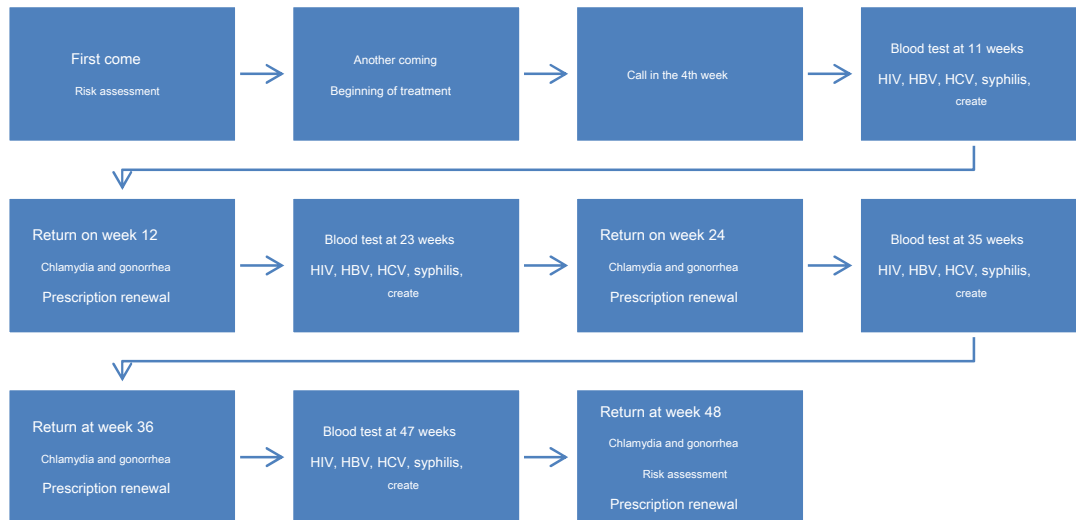
##### Phonecall

- The nurse calls the person in question 4 weeks after the start of treatment.

##### Return every 12 weeks

- A nurse (and, as the case may be, a specialist in infectious diseases) sees the person every 12 weeks during FTC / TDF medication.
- Research results (from week 11) reviewed:

- Fourth generation HIV test every 12 weeks.
- Kidney function measured every 12-24 weeks. Monitor:
  - 
  - symptoms of acute HIV infection, chlamydia and gonorrhea
  - Side effects and treatment adherence
- Prevention education and delivery of condoms. Repeat risk
- assessment annually.
- Booked return times.



**Figure 2.** Proposal for follow-up for FTC / TDF drug treatment over 1 year.

### Application process

An application is made for authorization to use the medicine to the LSH Medicines Committee. The application must state the patient's age, illness, skills assessment and medical status, together with information on previous treatment. If the patient meets the conditions of these instructions, a permit is granted for one year. If the patient needs further treatment, a new authorization must be applied for, as the evaluation of the effectiveness of the treatment is available. Disputes regarding the processing of an application shall be referred to the Medical Director of Landspítali, for a final ruling.

### Author and guarantor

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The guidelines were drafted in June 2018 and will be reviewed no later than three years later, but sooner if necessary.

**Sources:**

Centers for Disease Control and Prevention. (2017). Preexposure Prophylaxis for the Prevention of HIV Infection in the United States - 2017 Update. Clinical Practice Guideline.

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[http://www.eacsociety.org/files/guidelines\\_9.0-english.pdf](http://www.eacsociety.org/files/guidelines_9.0-english.pdf)