

This brochure was approved according to the guidelines of the Ministry of Health on May 2023

Information for Patient About Tenovamed Inovamed

which contains the active ingredients emtricitabine and tenofovir disoproxil fumarate, for the indication of pre-exposure prophylaxis (PrEP) treatment for the human immunodeficiency virus (HIV)

Inovamed
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This brochure contains important safety information and guidelines for taking Tenovamed Inovamed, for the indication of pre-exposure prophylaxis (prevention) against human immunodeficiency virus (HIV).

Read it carefully and keep it for future reference.

This brochure is to complete the information in the consumer's leaflet.

For full information about the medicinal product, see consumer's leaflet enclosed with the drug package.

If you have further questions, please refer to the doctor or pharmacist.

Reporting side effects:

Side effects can be reported to the Ministry of Health by using the online form for reporting side effects, found on the Ministry of Health homepage:

www.health.gov.il

or by entering the link:

<https://sideeffects.health.gov.il>

or through the registration holder:

pv@inovamed.co.il

Tenovamed Inovamed, which contains the ingredients emtricitabine and tenofovir disoproxil fumarate, is a prescription medicine, intended to reduce the risk of HIV infection in adults, in combination with safe sex practices.

What you should know before and while taking Tenovamed Inovamed, in order to reduce the risk for HIV infection:

- Tenovamed Inovamed, for the indication of PrEP, is intended to reduce the risk of HIV-1 infection, but only for patients who have been tested and found to be negative for the virus before beginning treatment with Tenovamed Inovamed.
- Mutations of HIV-1 that are resistant to the medicinal product have been detected in people who had been infected with HIV, were not diagnosed, and took the medicinal product without any other antiviral medicine to treat their HIV infection. You must therefore test negative for HIV-1 infection before starting treatment with Tenovamed Inovamed for PrEP. In addition, repeat the HIV tests at least every 3 months to make sure that your HIV status remains negative while on PrEP.

Do not take Tenovamed Inovamed unless you have been tested and found to be negative for HIV.

- Do not start or continue treatment with Tenovamed Inovamed for PrEP if signs and/or symptoms of acute HIV infection appear. Therefore, tell your doctor if you have had flu symptoms in the month prior to initiation of treatment with Tenovamed Inovamed for PrEP or at any time while taking the medicinal product for PrEP.
- If you have been involved in sexual contact that might have put you at risk for HIV-1 infection, it is important for you to know the signs and symptoms that might indicate recent HIV infection:
 - > Tiredness
 - > Fever
 - > Joint or muscle pain
 - > Headache
 - > Vomiting or diarrhea
 - > Rash
 - > Night sweats
 - > Enlarged lymph nodes in the neck or groin.

Take Tenovamed Inovamed according to the approved dosing regimen, which is one tablet a day, every day.

- Take Tenovamed Inovamed according to the doctor's instructions. If you are unsure, ask your doctor or pharmacist.
- The recommended dosage regimen is one tablet a day, every day, preferably with food. Do not take Tenovamed Inovamed in a different dosage regimen or stop taking it without being advised to do so by your doctor. Skipping doses or irregular intake of the medicinal product increases the risk for HIV-1 infection and for resistance to treatment with Tenovamed Inovamed in case of HIV-1 infection.
- **You must have routine HIV tests, at least every 3 months, while taking Tenovamed Inovamed for PrEP.**
- If there is any suspicion that you may have become infected with HIV, tell the doctor immediately. The doctor will arrange for a test to reconfirm that you are negative for the HIV-1 infection before you continue to take Tenovamed Inovamed.

You must take Tenovamed Inovamed every day, not just when you think you are at risk for an HIV infection.

- Do not skip doses or stop treatment without informing the doctor.
- Skipping a dose might put you at an increased risk for HIV infection.
- If you forget to take Tenovamed Inovamed, and less than 12 hours have passed from the time you usually take Tenovamed Inovamed, take the tablet as soon as possible, preferably with food. Take the next dose at your usual time.
- If more than 12 hours have passed from the time you usually take Tenovamed Inovamed, do not take the missed tablet and take the next dose at your usual time.

- If you vomited less than an hour after taking the tablet, take another tablet.
Do not take another Tenovamed Inovamed tablet if you vomited more than an hour after taking the tablet.

Take action in order to remain HIV negative while taking Tenovamed Inovamed.

Tenovamed Inovamed alone is not a complete treatment to prevent HIV infection, and does not protect against infection with other sexually transmitted diseases.

- Use Tenovamed Inovamed together with other measures to prevent infection, which include ensuring safe sexual conduct, including:
 - > Using a condom in order to reduce contact with semen, vaginal fluids or blood.
 - > Do not share needles, syringes or other medical equipment.
 - > Routine testing for other sexually transmitted diseases, such as syphilis, chlamydia and gonorrhoea is recommended, as infection with these diseases could increase the risk for becoming infected with HIV.
 - > Asking for information and support about reducing sexual conduct that could put you at higher risk for HIV infection.

Know your hepatitis B virus (HBV) infection status before starting to use Tenovamed Inovamed for PrEP

- If you have a background of hepatitis B infection, there is a substantial risk for an acute flare up of hepatitis and the aggravation of hepatic diseases after stopping Tenovamed Inovamed.
- Therefore, if you have been infected with hepatitis B, tell the doctor before beginning the treatment and if you wish to stop taking Tenovamed Inovamed.
- If you are negative for hepatitis B, it is recommended that you get the vaccine against hepatitis B before beginning Tenovamed Inovamed.

Tenovamed Inovamed's side effects

- As with all medicinal products, Tenovamed Inovamed could cause side effects.
- The most common side effects of the medicinal product include:
 - > Diarrhea
 - > Being sick (Vomiting)
 - > Feeling sick (Nausea)
 - > Dizziness
 - > Headache
 - > Rash
 - > Feeling weak

Tests also show:

- Decreased amount of phosphate in the blood.
- Elevated creatine kinase (an enzyme that could indicate muscle damage).

- Use of the medicinal product may cause serious side effects, including new renal (kidney) side effects and worsening of existing kidney diseases, as well as bone changes.

Therefore, before and during treatment with Tenovamed Inovamed for PrEP, you will have to undergo tests to check kidney function. You will have to tell the doctor if you have kidney disease, abnormal kidney function test results, or if you are taking other medicines.

- Bone problems (manifesting as persistent or worsening bone pain and sometimes with fractures) could also occur due to damage to the kidney.
Please tell your doctor if you have bone pain or fractures.
- Medicines containing a nucleotide analog, including Tenovamed Inovamed, could cause lactic acidosis (excess lactic acid in the blood). Fast and deep breathing, drowsiness and non-specific symptoms such as nausea, vomiting and stomach pains may be signs of this condition. Sometimes, this rare but serious side effect can be life-threatening.
Elevated lactic acid is more common in women, especially in case of obesity.
There is also a high risk of developing this condition if you have liver disease. If you experience these symptoms, refer to the doctor immediately.
- Patients with chronic liver disease, including hepatitis (jaundice) B or C, who are being treated with antiviral drugs, are at higher risk for developing serious hepatic (liver) complications that may be life-threatening. If you have an underlying liver disease (including viral hepatitis B or C), inform the doctor before starting treatment.
- Inform the doctor if you experience a side effect that does not go away or one of the side effects listed in the consumer's leaflet.
- For full information about the side effects of Tenovamed Inovamed, see the Tenovamed Inovamed's consumer's leaflet.

Pregnancy and breastfeeding

- Information about the safety of usage of Tenovamed Inovamed during pregnancy is limited, but does not indicate the formation of defects or toxic effects on the fetus.
- If you are pregnant, think you might be pregnant or are planning to become pregnant, tell the doctor.
- If you took Tenovamed Inovamed during pregnancy, the doctor may request to perform regular blood tests and other diagnostic tests to monitor the development of your child.
- **Do not breastfeed while taking Tenovamed Inovamed**, as the active ingredients in this medicine pass into human breast milk, and their effect on the baby is uncertain.

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