

PART III: CONSUMER INFORMATION

PrMylan-Emtricitabine/Tenofovir Disoproxil (Emtricitabine and Tenofovir Disoproxil Fumarate Tablets)

200 mg emtricitabine and 300 mg tenofovir disoproxil fumarate per tablet

This leaflet is part III of a three-part "Product Monograph" published when Mylan-Emtricitabine/Tenofovir Disoproxil was approved for sale in Canada and is designed specifically for consumers. This leaflet is a summary and will not tell you everything about Mylan-Emtricitabine/Tenofovir Disoproxil. Contact your healthcare professional if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for:

Mylan-Emtricitabine/Tenofovir Disoproxil is a type of medicine called an HIV (human immunodeficiency virus) nucleoside analog reverse transcriptase inhibitor (NRTI). Mylan-Emtricitabine/Tenofovir Disoproxil contains 2 medicines, emtricitabine and tenofovir disoproxil fumarate, (or tenofovir DF) combined in one pill.

Mylan-Emtricitabine/Tenofovir Disoproxil is used:

- **To treat HIV-1 Infection** when used with other anti-HIV medicines in adults.

OR

- **To help reduce the risk of getting HIV-1 infection** when used with safer sex practices in:
 - HIV-1 negative men who have sex with men, who are at high risk of getting infected with HIV-1 through sex.
 - Male-female sex partners when one partner has HIV-1 infection and the other does not.

This is sometimes called Pre-Exposure Prophylaxis or PrEP.

- Mylan-Emtricitabine/Tenofovir Disoproxil is for adults age 18 and older. Mylan-Emtricitabine/Tenofovir Disoproxil is not indicated in children under age 18 or adults over age 65.

What it does:

- **Use of Mylan-Emtricitabine/Tenofovir Disoproxil to treat HIV-1 infection:**

When used with other HIV-1 medicines to treat HIV-1 infection, Mylan-Emtricitabine/Tenofovir Disoproxil helps block HIV reverse transcriptase, a chemical in your body (enzyme) that is needed for HIV to multiply.

Mylan-Emtricitabine/Tenofovir Disoproxil lowers the amount of HIV in the blood (viral load).

Lowering the amount of HIV in the blood lowers the chance of infections that happen when your immune system is weak (opportunistic infections).

HIV infection destroys CD4 (T) cells, which are important to the immune system. The immune system helps fight infection.

After a large number of T cells are destroyed, acquired immune deficiency syndrome (AIDS) develops. Mylan-Emtricitabine/Tenofovir Disoproxil may also help to increase the number of T cells (CD4 cells).

Mylan-Emtricitabine/Tenofovir Disoproxil does not cure HIV-1 infection or AIDS. If you have HIV-1 infection, you must stay on continuous HIV therapy to control HIV infection and decrease HIV-related illnesses. People taking Mylan-Emtricitabine/Tenofovir Disoproxil may still get opportunistic infections or other conditions that happen with HIV infection. Opportunistic infections are infections that develop because the immune system is weak. Some of these conditions are pneumonia, herpes virus infections, and *Mycobacterium avium* complex (MAC) infections.

- **Use of Mylan-Emtricitabine/Tenofovir Disoproxil to reduce the risk of HIV-1 infection (PrEP indication):**

When used with safer sex practices, Mylan-Emtricitabine/Tenofovir Disoproxil may help to reduce the risk of getting HIV-1 infection:

- Mylan-Emtricitabine/Tenofovir Disoproxil works better to reduce the risk of getting HIV-1 when the medicines are in your bloodstream **before** you are exposed to HIV-1.

It is very important that you see your healthcare professional regularly while taking Mylan-Emtricitabine/Tenofovir Disoproxil.

Considerations when Mylan-Emtricitabine/Tenofovir Disoproxil is used for PrEP:

- Together with your healthcare professional, you need to decide whether Mylan-Emtricitabine/Tenofovir Disoproxil is right for you.
- Mylan-Emtricitabine/Tenofovir Disoproxil can only help reduce your risk of getting HIV-1 **before** you are infected.
- Do not take Mylan-Emtricitabine/Tenofovir Disoproxil to help reduce your risk of getting HIV-1 if:
 - you already have HIV-1 infection. If you are HIV-1 positive, you need to take other medicines with Mylan-Emtricitabine/Tenofovir Disoproxil to treat HIV-1. Mylan-Emtricitabine/Tenofovir Disoproxil by itself is not a complete treatment for HIV-1.
 - you do not know your HIV-1 infection status. You may already be HIV-1 positive. You need to take other HIV-1 medicines with Mylan-Emtricitabine/Tenofovir Disoproxil to treat HIV-1.
- Your healthcare professional will run tests to determine that you are HIV- negative before starting PrEP treatment.

When it should not be used:

Do not use Mylan-Emtricitabine/Tenofovir Disoproxil if:

- you are allergic (hypersensitive) to any of the ingredients in this formulation (see: **What the medicinal ingredients are; What the important nonmedicinal ingredients are**)

- Do not use Mylan-Emtricitabine/Tenofovir Disoproxil to reduce the risk of getting HIV if you already have HIV or do not know your HIV status.

What the medicinal ingredients are:

emtricitabine

tenofovir disoproxil fumarate (tenofovir DF)

What the important nonmedicinal ingredients are:

Croscarmellose Sodium, Lactose Monohydrate, Magnesium Stearate, and Microcrystalline Cellulose.

Coating: FD&C BLUE #2 / Indigo Carmine Aluminum Lake, Hypromellose, Lactose Monohydrate, Titanium Dioxide, and Triacetin.

What dosage forms it comes in:

Mylan-Emtricitabine/Tenofovir Disoproxil is available as tablets. Each tablet contains 200 mg of emtricitabine and 300 mg of tenofovir disoproxil fumarate (which is equivalent to 245 mg of tenofovir disoproxil), as active ingredients. The tablets are blue film-coated, capsule shaped, biconvex, beveled edge, debossed with “M” on one side of the tablet and “ET 24” on the other side.

WARNINGS AND PRECAUTIONS

Serious Warnings and Precautions

- The most serious possible side effect is harm to the kidneys, including damage to kidney cells, kidney tissue inflammation and kidney failure. Your healthcare professional may monitor your kidney function before beginning and while receiving Mylan-Emtricitabine/Tenofovir Disoproxil. Some patients treated with tenofovir disoproxil fumarate (a component of Mylan-Emtricitabine/Tenofovir Disoproxil) have had kidney problems. Your healthcare professional may need to perform additional blood tests if you have had kidney problems in the past or need to take another drug that can cause kidney problems.
- **If you are also infected with the Hepatitis B Virus, “flare-ups” of Hepatitis B Virus infection**, in which the disease suddenly returns in a worse way than before, can occur if you stop taking Mylan-Emtricitabine/Tenofovir Disoproxil. Do not stop taking Mylan-Emtricitabine/Tenofovir Disoproxil without your healthcare professional’s advice. If you stop taking Mylan-Emtricitabine/Tenofovir Disoproxil, tell your healthcare professional immediately about any new, unusual or worsening symptoms that you notice after stopping treatment. After you stop taking Mylan-Emtricitabine/Tenofovir Disoproxil, your healthcare professional will still need to check your health and take blood tests to check your liver for several months. Mylan-Emtricitabine/Tenofovir Disoproxil is not approved for the treatment of Hepatitis B Virus infection.
- The class of medicines to which Mylan-Emtricitabine/Tenofovir Disoproxil belong (NRTIs) can cause a condition called lactic acidosis, together with an enlarged liver. Non-specific symptoms such as nausea,

vomiting and stomach pain might indicate the development of lactic acidosis. This rare but serious side effect has occasionally been fatal. Lactic acidosis occurs more often in women, particularly if they are very overweight. You should consult your healthcare professional immediately if such symptoms occur while you are receiving Mylan-Emtricitabine/Tenofovir Disoproxil. The symptoms that may indicate lactic acidosis include: feeling very weak, tired or uncomfortable; unusual or unexpected stomach discomfort; feeling cold; feeling dizzy or lightheaded; suddenly developing a slow or irregular heartbeat. If you notice these symptoms, stop taking Mylan-Emtricitabine/Tenofovir Disoproxil and consult a healthcare professional immediately.

- Tenofovir DF caused harm to the bones of animals. Tenofovir DF reduced bone density in humans. If you notice bone pain, suffer a bone fracture, or other bone problem, consult your healthcare professional. If you have bone problems, you may wish to discuss calcium and/or vitamin D supplements with your healthcare professionals.
- Changes in body fat have been seen in some patients taking antiretroviral therapy. These changes may include increased amounts of fat in the upper back and neck (“buffalo hump”), breast, and around the trunk. Loss of fat from the legs, arms and face may also happen. The cause and long term health effects of these conditions are not known at this time.
- Mylan-Emtricitabine/Tenofovir Disoproxil should only be used for the PrEP indication if you are HIV-negative before and during treatment. Discuss with your healthcare professional if you have had a recent flu-like illness. Your healthcare professional will run tests to confirm that you are HIV negative before and during Mylan-Emtricitabine/Tenofovir Disoproxil treatment.

Do NOT take Mylan-Emtricitabine/Tenofovir Disoproxil if:

- you are on other medications that may affect your kidneys and have not discussed this with your healthcare professional.
- you have or are at known risk for any type of bone disease or bone related problems and have not discussed this with your healthcare professional.
- you are allergic to Mylan-Emtricitabine/Tenofovir Disoproxil or any of its ingredients. The medicinal ingredients are emtricitabine and tenofovir DF (see: **What the important nonmedicinal ingredients are**).
- you are already taking 3TC[®], ATRIPLA[®] Combivir[®], COMPLERA[®], DESCOVY[®], EMTRIVA[®], GENVOYA[®], ODEFSEY[™], Heptovir[®], Kivexa[®], STRIBILD[®], Triumeq[®], Trizivir[®], VEMLIDY[™] or VIREAD[®] because these medicines contain the same or similar active ingredients
- you are also taking HEPSERA[®] to treat your HBV infection

Changes in your immune system (Immune Reconstitution Syndrome) can happen when an HIV-1 infected person starts taking HIV medicines. Your immune system may get stronger and begin to fight infections that have been hidden in your body for a long time, or you could develop an autoimmune disease in which your immune system reacts against your own body [e.g.

Grave's disease (which affects the thyroid gland), Guillain-Barré syndrome (which affects the nervous system) or polymyositis (which affects the muscles)] and it may develop at any time, sometimes months later after the start of HIV therapy. Sometimes symptoms can be severe, so if you develop high temperature (fever), joint or muscle pain, redness, rash, swelling or fatigue, or any new symptoms, contact your healthcare professional right away.

Before taking Mylan-Emtricitabine/Tenofovir Disoproxil to reduce your risk of getting HIV-1 infection (PrEP indication):

- **You must get tested to be sure you are HIV-negative.** It is important that you also get tested at least every 3 months as recommended by your healthcare provider while taking Mylan-Emtricitabine/Tenofovir Disoproxil. **Do not take Mylan-Emtricitabine/Tenofovir Disoproxil to reduce the risk of getting HIV (PrEP) unless you are confirmed to be HIV-negative.**
- Tell your healthcare provider if you have any of the following symptoms within the last month before you start taking Mylan-Emtricitabine/Tenofovir Disoproxil or at any time while taking Mylan-Emtricitabine/Tenofovir Disoproxil:
 - tiredness
 - fever
 - sweating a lot (especially at night)
 - rash
 - vomiting or diarrhea
 - joint or muscle aches
 - headache
 - sore throat
 - enlarged lymph nodes in the neck or groin

These may be signs of HIV infection and you may need to have a different kind of test to diagnose HIV. If you are already taking Mylan-Emtricitabine/Tenofovir Disoproxil to prevent HIV-1 infection (PrEP), your healthcare provider may tell you to stop taking Mylan-Emtricitabine/Tenofovir Disoproxil until an HIV test confirms that you do not have HIV-1 infection.

Just taking Mylan-Emtricitabine/Tenofovir Disoproxil may not keep you from getting HIV. Mylan-Emtricitabine/Tenofovir Disoproxil does NOT always prevent HIV.

You must still practice safer sex at all times. Do not have any kind of sex without protection. Always practice safer sex by using a latex or polyurethane condom to lower the chance of sexual contact with semen, vaginal secretions, or blood.

You must also use other prevention methods to keep from getting HIV.

- Know your HIV-1 status and the HIV-1 status of your partners.

- While taking Mylan-Emtricitabine/Tenofovir Disoproxil, get tested at least every 3 months for HIV, as recommended by your healthcare provider. Ask your partners to get tested.
- If you think you were exposed to HIV-1, tell your healthcare provider right away. They may want to do more tests to be sure you are still HIV-negative.
- Get tested for other sexually transmitted infections such as syphilis and gonorrhea. These infections make it easier for HIV to infect you.
- Get information and support to help reduce risky sexual behavior.
- Have fewer sex partners.
- Do not miss any doses of Mylan-Emtricitabine/Tenofovir Disoproxil. Missing doses may increase your risk of getting HIV-1 infection.

BEFORE you use Mylan-Emtricitabine/Tenofovir Disoproxil (emtricitabine / tenofovir disoproxil fumarate) talk to your healthcare professional:

If you are pregnant or planning to become pregnant: Pregnant mothers should not take Mylan-Emtricitabine/Tenofovir Disoproxil unless specifically directed by the healthcare professional.

If you are a female who is taking Mylan-Emtricitabine/Tenofovir Disoproxil to prevent HIV infection (PrEP) and you become pregnant while taking Mylan-Emtricitabine/Tenofovir Disoproxil, talk to your healthcare provider about whether you should continue taking Mylan-Emtricitabine/Tenofovir Disoproxil.

Pregnancy Registry. There is a pregnancy registry for women who take antiviral medicines during pregnancy. The purpose of this registry is to collect information about the health of you and your baby. Talk to your healthcare provider about how you can take part in this Antiretroviral Pregnancy Registry.

If you are breast-feeding or planning to breastfeed: Do not breastfeed if you are taking Mylan-Emtricitabine/Tenofovir Disoproxil or have HIV. Emtricitabine and tenofovir DF, the two components of Mylan-Emtricitabine/Tenofovir Disoproxil, pass to your baby in your breast milk. You should not breastfeed because of the risk of passing HIV to your baby. Talk to your healthcare professional about the best way to feed your baby.

If you have other medical conditions: Let your healthcare professional know if you have other medical conditions, especially liver, bone and kidney problems.

If you are taking other medicines: Some medicines can interact when taken together, including prescription and non-prescription medicines and dietary supplements (see **INTERACTIONS WITH THIS MEDICATION**).

If you are taking didanosine: Taking didanosine and Mylan-Emtricitabine/Tenofovir Disoproxil may cause serious reactions

including lactic acidosis (too much acid in the blood), pancreatitis (inflamed pancreas) and nerve damage (neuropathy) (see **INTERACTIONS WITH THIS MEDICATION and SIDE EFFECTS AND WHAT TO DO ABOUT THEM**).

Mylan-Emtricitabine/Tenofovir Disoproxil should not be used with or soon after cidofovir, acyclovir, valacyclovir, ganciclovir, valganciclovir, aminoglycosides, or nonsteroidal anti-inflammatory drugs (NSAIDs), due to potential harm to the kidneys.

It is a good idea to keep a complete list of all the medicines that you take. Make a new list when medicines are added or stopped. Give copies of this list to all of your healthcare providers every time you visit your healthcare professional or fill a prescription.

Other Special Warnings:

Your blood sugar levels (glucose) or levels of fats (lipids) in your blood may increase with HIV treatment. Your doctor may order blood tests for you.

INTERACTIONS WITH THIS MEDICATION

Let your healthcare professional know if you are taking these or any other medications:

- Drugs that contain didanosine (VIDEX®, VIDEX EC®). Tenofovir DF (a component of Mylan-Emtricitabine/Tenofovir Disoproxil) may increase the amount of didanosine in your blood. You may need to be followed more carefully if you are taking Mylan-Emtricitabine/Tenofovir Disoproxil and didanosine together. Also, the dose of didanosine may need to be reduced.
- REYATAZ® (atazanavir sulfate), KALETRA® (lopinavir/ritonavir), PREZISTA® (darunavir), HARVONI® (ledipasvir/sofosbuvir), EPCLUSA™ (sofosbuvir/velpatasvir) or VOSEVI™ (sofosbuvir/velpatasvir/voxilaprevir). These medicines may increase the amount of tenofovir DF (a component of Mylan-Emtricitabine/Tenofovir Disoproxil) in your blood, which could result in more side effects. You may need to be followed more carefully if you are taking Mylan-Emtricitabine/Tenofovir Disoproxil together with REYATAZ®, KALETRA®, PREZISTA®, HARVONI®, EPCLUSA or VOSEVI together. Mylan-Emtricitabine/Tenofovir Disoproxil may decrease the amount of REYATAZ® in your blood. If you are taking Mylan-Emtricitabine/Tenofovir Disoproxil and REYATAZ® together, you should also be taking NORVIR® (ritonavir).
- Non-steroidal anti-inflammatory drugs.

PROPER USE OF THIS MEDICATION

Stay under a healthcare professional’s care when taking Mylan-Emtricitabine/Tenofovir Disoproxil. **Do not change your**

treatment or stop treatment without first talking with your healthcare professional.

Take Mylan-Emtricitabine/Tenofovir Disoproxil exactly as your healthcare professional prescribed it. Follow the directions from your healthcare professional, exactly as written on the label. Set up a dosing schedule and follow it carefully.

When used to treat HIV-1 infection, Mylan-Emtricitabine/Tenofovir Disoproxil is always used with other HIV-1 medicines.

If you take Mylan-Emtricitabine/Tenofovir Disoproxil to reduce your risk of getting HIV-1:

- you must also use other methods to reduce your risk of getting HIV.
- **take Mylan-Emtricitabine/Tenofovir Disoproxil every day,** not just when you think you have been exposed to HIV-1.

Avoid doing things that can increase your risk of getting HIV infection or spreading HIV infection to other people:

- Do not re-use or share needles or other injection equipment.
- Do not share personal items that can have blood or body fluids on them, like toothbrushes and razor blades.
- Do not have any kind of sex without protection. Always practice safer sex by using a latex or polyurethane condom to lower the chance of sexual contact with semen, vagina secretions, or blood.

Ask your healthcare provider if you have any questions on how to prevent getting HIV infection or spreading HIV infection to other people.

When your Mylan-Emtricitabine/Tenofovir Disoproxil supply starts to run low, get more from your healthcare professional. This is very important because the amount of virus in your blood may increase if the medicine is stopped for even a short time. The virus may develop resistance to Mylan-Emtricitabine/Tenofovir Disoproxil and become harder to treat.

Only take medicine that has been prescribed specifically for you. Do not give Mylan-Emtricitabine/Tenofovir Disoproxil to others or take medicine prescribed for someone else.

Do not use if seal over bottle opening is broken or missing.

Usual Adult dose:

For the treatment of HIV-1 infection:

- The usual dose of Mylan-Emtricitabine/Tenofovir Disoproxil is one tablet orally (by mouth) once a day, in combination with other anti-HIV medicines. Mylan-Emtricitabine/Tenofovir Disoproxil may be taken with or without a meal.

For prevention of HIV-1 infection (PrEP):

- The usual dose of Mylan-Emtricitabine/Tenofovir Disoproxil is one tablet orally (by mouth) once a day.
- Mylan-Emtricitabine/Tenofovir Disoproxil may be taken with or without a meal.

Overdosage:

If you think you have taken too much Mylan-Emtricitabine/Tenofovir Disoproxil, contact your healthcare professional, hospital emergency department or Regional Poison Control Centre, even if there are no symptoms.

Missed Dose:

It is important that you do not miss any doses. If you miss a dose of Mylan-Emtricitabine/Tenofovir Disoproxil and it is less than 12 hours from the time you usually take Emtricitabine/Tenofovir Disoproxil, then take the dose. If more than 12 hours has passed from the time you usually take Emtricitabine/Tenofovir Disoproxil, then wait until the next scheduled daily dose. **Do not** take more than 1 dose of Mylan-Emtricitabine/Tenofovir Disoproxil in a day. **Do not** take 2 doses at the same time. Call your healthcare professional if you are not sure what to do.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

The most common side effects of Emtricitabine tablets and Tenofovir Disoproxil Fumarate tablets are:

- Diarrhea
- Nausea
- Vomiting
- Dizziness
- Headache

Other side effects include:

- Stomach pain
- Indigestion
- Inflammation of the pancreas
- Sleeping problems
- Abnormal dreams
- Weakness
- Pain
- Shortness of breath
- Allergic reaction (including swelling of the face, lips, tongue or throat)
- Rash
- Flatulence (intestinal gas)
- Skin discoloration (small spots or freckles) may also happen with Mylan-Emtricitabine/Tenofovir Disoproxil

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect		Talk with your doctor or pharmacist		Stop taking drug and seek immediate emergency medical attention
		Only if severe	In all cases	
Rare	Effect: Kidney problems Symptoms You may have increased or decreased urination as well as increased thirst You may have swelling of your legs and feet You may feel listless and tired		✓ ✓ ✓	
Rare	Effect: Lactic acidosis Symptoms Feeling very weak or tired Unusual muscle-pain Stomach pain with nausea and vomiting Feeling cold especially in arms and legs Feeling dizzy or lightheaded Fast or irregular heartbeat		✓ ✓ ✓ ✓ ✓ ✓	
Very Rare	Effect: Hepatotoxicity (severe liver problems) with hepatomegaly (liver enlargement) and steatosis (fat in the liver) Symptoms			
	Jaundice (skin or the white part of eyes turns yellow) Urine turns dark Bowel movements (stools) turn light in color		✓ ✓ ✓	

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect	Talk with your doctor or pharmacist		Stop taking drug and seek immediate emergency medical attention
	Only if severe	In all cases	
Loss of appetite for several days or longer		✓	
Feeling sick to your stomach (nausea)		✓	
Lower stomach pain		✓	
Very Rare	Effect: Flare-ups of hepatitis B virus infection following drug discontinuation Symptoms Jaundice (skin or the white part of eyes turns yellow) ✓ Urine turns dark ✓ Bowel movements (stools) turn light in color ✓ Loss of appetite for several days or longer ✓ Feeling sick to your stomach (nausea) ✓ Lower stomach pain ✓		

Lactic acidosis is a medical emergency and must be treated in the hospital. You may be more likely to get lactic acidosis or serious liver problems if you are very overweight (obese) or have been taking nucleoside analog medicines, like Mylan-Emtricitabine/Tenofovir Disoproxil, for a long time.

Muscle pain, muscle weakness, bone pain and softening of the bone (infrequently contributing to fractures) have also been reported.

There have been other side effects in patients taking emtricitabine tablets or tenofovir disoproxil fumarate tablets. *This is not a complete list of side effects.* If you have questions about side effects, ask your healthcare professional. You should report any new or continuing symptoms to your healthcare professional right away. Your healthcare professional may be able to help you manage these side effects.

- Keep Mylan-Emtricitabine/Tenofovir Disoproxil and all other medications out of reach and sight of children.
- Store Mylan-Emtricitabine/Tenofovir Disoproxil tablets between 15°C and 30°C. Protect from moisture. It should remain stable until the expiration date printed on the label.
- Do not keep your medicine in places that are too hot or cold.
- Do not keep medicine that is out of date or that you no longer need. Return it to the nearest pharmacy and make sure that children will not find them.
- Keep Mylan-Emtricitabine/Tenofovir Disoproxil in its original container and keep the container tightly closed.

REPORTING SIDE EFFECTS

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/healthcanada/services/drugs-health-products/medeffect-canada.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

If you want more information about Mylan-Emtricitabine/Tenofovir Disoproxil:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website (<http://hc-sc.gc.ca/index-eng.php>); the manufacturer’s website www.mylan.ca, or by calling 1-844 596-9526

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HOW TO STORE IT

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