

How to Use HYFTOR[®] Your Step-by-Step Guide

Not an actual patient.
Individual results may vary.

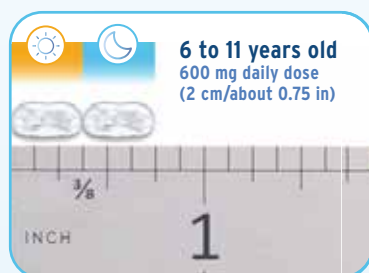
HYFTOR[®] is a prescription medicine used on the skin (topical) to treat patients 6 years of age and older who have facial angiofibroma—one of the most visible signs of tuberous sclerosis complex (TSC).

Below is your step-by-step guide to knowing when and how much HYFTOR[®] to apply.

How Much HYFTOR[®] to Use Daily

It's important to remember that your prescribed daily dose of HYFTOR[®] should be split, which means measuring and applying half in the morning and the other half at night.

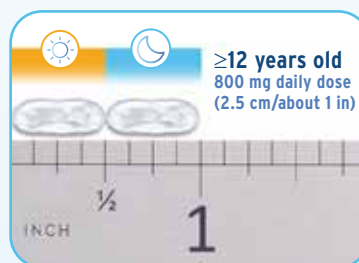
The following depicts the maximum recommended daily dosage, depending on your age, with tips for applying the appropriate amount.



For patients 6 to 11 years old

- Maximum daily dose is 600 mg, measuring 2 cm/about 0.75 in.
- Half the recommended daily dosage measures 0.375 in.

Apply half (0.375 in) in the morning and half at night



For patients 12 years and older

- Maximum daily dose is 800 mg, measuring 2.5 cm/about 1 in.
- Half the recommended daily dosage measures 0.5 in.

Apply half (0.5 in) in the morning and half at night

Applying HYFTOR[®]

Before you use HYFTOR[®], your healthcare provider or pharmacist should show you how to correctly measure your dose. Remember, it is important to adhere to your treatment plan and use HYFTOR[®] exactly as your healthcare provider tells you to use it.

HYFTOR[®] should be applied to the skin of the face affected with angiofibroma twice daily, in the morning and at bedtime. For each application, follow these steps:

- 1 Wash your hands before and after applying HYFTOR[®].
- 2 Do not cover, wrap, apply dressings, or bandage the skin area treated with HYFTOR[®].
- 3 If you plan on going outside, wear clothing that covers your skin. Talk with your doctor about other ways you can protect your skin from the sun.
- 4 Always store HYFTOR[®] in the refrigerator between 36°F to 46°F (2°C to 8°C), and keep it out of the light.

If the treated skin area does not improve within 12 weeks of treatment, be sure to tell your doctor.

What is HYFTOR[®]?

HYFTOR[®] is a prescription medicine that is used on the skin (topical) to treat adults and children 6 years of age and older with a type of noncancerous tumor called angiofibroma on your face caused by the genetic condition tuberous sclerosis.

It is not known if HYFTOR[®] is safe and effective in children under 6 years of age.

SELECT IMPORTANT SAFETY INFORMATION

Important: HYFTOR[®] is for use on the skin only (topical use). Do not use HYFTOR[®] in your mouth, eyes, or vagina.

Do not use HYFTOR[®] if you are allergic to sirolimus or any of the other ingredients in HYFTOR[®].

What is HYFTOR® (sirolimus topical gel) 0.2%?

HYFTOR® is a prescription medicine that is used on the skin (topical) to treat adults and children 6 years of age and older with a type of noncancerous tumor called angiofibroma on your face caused by the genetic condition tuberous sclerosis.

It is not known if HYFTOR® is safe and effective in children under 6 years of age.

IMPORTANT SAFETY INFORMATION CONTRAINDICATIONS

Important: HYFTOR® is for use on the skin only (topical use). Do not use HYFTOR® in your mouth, eyes, or vagina.

Do not use HYFTOR® if you are allergic to sirolimus or any of the other ingredients in HYFTOR®.

Before using HYFTOR®, tell your healthcare provider about all of your medical conditions, including if you:

- have a skin infection at the treatment site
- have high cholesterol or high triglycerides (fat or lipids) in your blood
- are scheduled to receive an immunization (vaccine). You should avoid receiving live vaccines during treatment with HYFTOR®. Vaccines may be less effective during treatment with HYFTOR®.
- are pregnant or plan to become pregnant. HYFTOR® may harm your unborn baby. You should not become pregnant during treatment with HYFTOR®.
 - Females who are able to become pregnant should use effective birth control (contraception) before starting treatment with HYFTOR®, during treatment, and for 12 weeks after your final dose of HYFTOR®. Talk to your healthcare provider about types of birth control that you can use during this time.
- are breastfeeding or plan to breastfeed. It is not known if HYFTOR® passes into your breast milk. You should not breastfeed during treatment with HYFTOR®.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

What should I avoid while using HYFTOR®?

Limit your exposure to sunlight and artificial light, such as tanning beds and ultraviolet light therapy, during treatment with HYFTOR®. Wear clothing that covers your skin if you need to go outside. Talk with your healthcare provider about other ways you can protect your skin from the sun.

What are possible side effects of HYFTOR®?

HYFTOR® may cause serious side effects, including:

- **Allergic reactions.** Serious allergic reactions have happened in people who have taken sirolimus by mouth. Stop using HYFTOR® and get medical help right away if you get any of these symptoms: swelling of your face, eyes, or mouth, trouble breathing or wheezing, throat tightness, chest pain or tightness, feeling dizzy or faint, rash or peeling of your skin.
- **Infections.** Serious infections, including infections that can happen when your immune system is weak, have happened in people who have taken sirolimus by mouth. Some people have developed a rare, serious brain infection called progressive multifocal leukoencephalopathy (PML) which can sometimes cause death. Stop using HYFTOR® and call your healthcare provider right away if you get symptoms of an infection including fever or chills.
- **Risk of cancer.** Lymphoma and other cancers, especially skin cancer, have happened in people who have taken sirolimus by mouth. Talk with your healthcare provider about your risk for cancer if you use HYFTOR®.
- **Increased levels of cholesterol and triglycerides (fat or lipids) in the blood** have happened in people who have taken sirolimus by mouth. Your healthcare provider will treat you for high lipid levels, if needed.
- **Lung or breathing problems.** Lung or breathing problems, including problems that have sometimes caused death, have happened in people who have taken sirolimus by mouth. Stop using HYFTOR® and get medical help right away if you get symptoms such as shortness of breath, new or worsening cough, or chest pain.

The most common side effects of HYFTOR® include dry skin, application site irritation, itching, acne, acne-like rash, eye redness, skin bleeding, and skin irritation.

HYFTOR® may cause fertility problems in males and females, which may affect your ability to have children. Talk to your healthcare provider if this is a concern for you.

These are not all the possible side effect of HYFTOR®, Call your doctor for medical advice about side effects. You may report side effects to FDA at **1-800-FDA-1088**.

Please see [Patient Information](#) for additional safety information.