Not an actual patient.
Individual results may vary.

The first and only topical gel for the treatment of facial angiofibroma in tuberous sclerosis complex (TSC) approved by the Food and Drug Administration for adults and children 6 years and older.

my VICTORY

Now approved—HYFTOR™ is a clear gel that contains the mTOR inhibitor sirolimus

HYFTOR™ is for patients 6 years of age and older who have facial angiofibroma—one of the most visible signs of TSC. Ask your doctor if HYFTOR™ is right for you and when it will be available to help you treat your facial angiofibroma.

HYFTOR™
(sirolimus topical gel) 0.2%

Learn more at www.HYFTOR.com

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.

Please see Important Safety Information on page 5 and Patient Information for additional safety information.

Not an actual patient.
Individual results may vary.

Facial Angiofibroma and TSC

Facial angiofibroma is a condition consisting of benign (noncancerous) tumors that appear as pinkish or reddish bumps and are usually located on the cheeks, nose, and chin. They are associated with the rare genetic disease tuberous sclerosis complex, or TSC. Although these tumors are benign, they can bleed, block the nasal openings, and cause disfigurement.

Facial angiofibroma occurs in approximately 75%-80% of TSC patients—making facial angiofibroma one of the most common skin conditions seen in TSC.

Although some patients are successfully treated with invasive treatments (like surgical removal, laser therapy, or dermabrasion), these procedures may require anesthesia.

Nobelpharma connect

We are dedicated to helping people living with facial angiofibroma associated with tuberous sclerosis complex (TSC). Ask your doctor about patient support programs from the makers of HYFTOR™ that may help you access your medication.

Please see Important Safety Information on page 5 and Patient Information for additional safety information.

About HYFTOR™

HYFTOR™ is a clear gel that contains 0.2% of the prescription medication sirolimus (an mTOR inhibitor). It is approved to treat facial angiofibroma in tuberous sclerosis complex (TSC) in adults and children 6 years of age and older.

How to Use HYFTOR™

HYFTOR™ should be applied to the skin of the face affected with angiofibroma twice daily, in the morning and at bedtime.

Store HYFTOR™ refrigerated at 36° to 46°F. Protect from light.

Tube not shown at actual size

The maximum recommended daily dosage is:

- Approximately 3/4 inch of gel (600 mg) for pediatric patients 6 to 11 years of age
- Approximately 1 inch of gel (800 mg) for adults and pediatric patients 12 years of age and older

Talk to your doctor about your dosage and how to apply HYFTOR™. HYFTOR™ is only for topical use on the area of the face affected with angiofibroma. The skin being treated with HYFTOR™ should not be covered with bandages, dressings, or wraps.

Wash your hands before and after applying HYFTOR™

Tell your healthcare provider if the treated skin area does not improve within 12 weeks of treatment.

Please see Important Safety Information on page 5 and Patient Information for additional safety information.

Select Important Safety Information (cont'd)

What should I avoid while using HYFTOR?

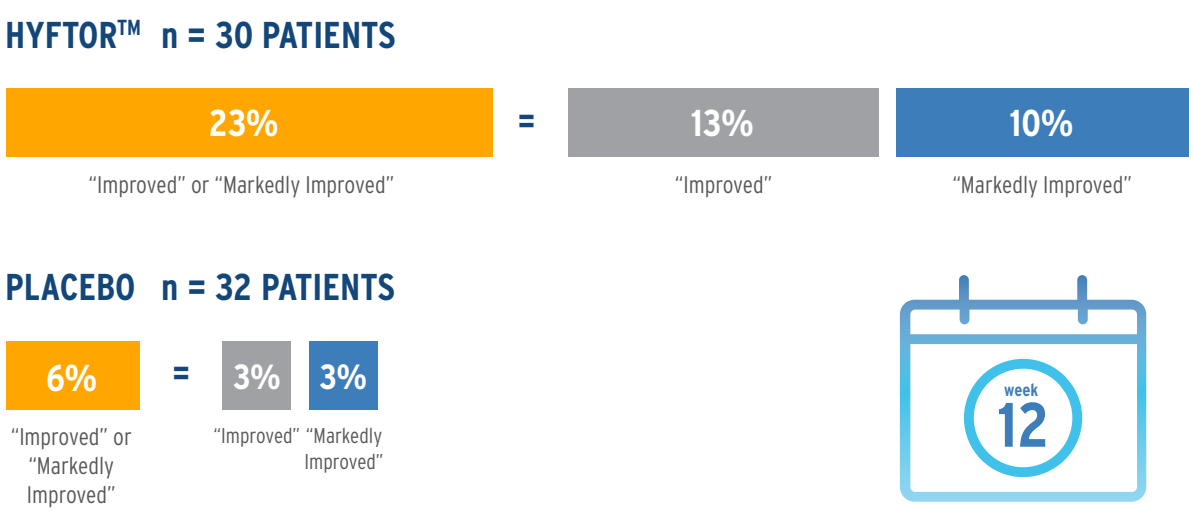
Limit your exposure to sunlight and artificial light, such as tanning beds and ultraviolet light therapy, during treatment with HYFTOR. Wear clothing that covers your skin if you need to go outside. Talk with your healthcare provider about other ways you can protect your skin from the sun.

HYFTOR™ Results

23% of patients were "improved" or "markedly improved" after 12 weeks in a clinical trial

- An assessment of "improved" was defined as at least a 50% reduction in size and a 2-level reduction in redness, and an assessment of "markedly improved" was defined as at least a 75% reduction in size and a 3-level reduction in redness
- 62 patients participated in the trial (including 25 patients between 6 and 18 years of age)
- 30 patients applied HYFTOR™ and 32 patients applied a placebo (a gel containing no medication) to their faces twice daily for 12 weeks
- Results were reported at the end of 12 weeks. The improvement in size and redness of facial angiofibromas was assessed by the investigator (live assessment) using the subjects' original baseline photographs as reference

Improvement in Facial Angiofibroma Associated with Tuberous Sclerosis at Week 12



Side Effects

The most common side effects, occurring in 1% or more of patients treated with HYFTOR™, are:

- Dry skin
- Application site irritation
- Itching
- Acne
- Acne-like rash
- Eye redness
- Skin bleeding
- Skin irritation

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 the FDA at 1-800-FDA-1088.

Before starting HYFTOR™, tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

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

Please see Important Safety Information on page 5 and Patient Information for additional safety information.

Learn more at www.HYFTOR.com

Nobelpharma®

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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.

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