

# Discussion Guide

## to prepare for your appointment

*Before your  
appointment*



### Preparation Checklist

The questions below can help you think about some of the topics that may come up at your next appointment. Sharing this information may help your healthcare team recommend a treatment plan that is right for you. Bring your answers with you to help guide your conversation with your healthcare provider.

### Note to Parents/Caregivers

It can be helpful to discuss these topics with your loved one before their appointment so you can both be prepared.

| Questions for you   | Answers |
|---|---------|
| <input type="checkbox"/> How is your facial angiofibroma? What is your current experience with the condition?   |         |
| <input type="checkbox"/> Has anything changed since your last appointment? Has your facial angiofibroma gotten worse or better?                               |         |
| <input type="checkbox"/> How are you treating your facial angiofibroma? How is it going? Are you still using it?  |         |
| <input type="checkbox"/> Are you experiencing any challenges with your current treatment? If so, what are they?   |         |
| <input type="checkbox"/> Are you experiencing any side effects?   |         |
| <input type="checkbox"/> Is anything else keeping you from continuing your treatment?   |         |
| <input type="checkbox"/> Are you having any trouble getting access to your current treatment? Are you having issues with insurance coverage or anything else? |         |
| <input type="checkbox"/> Are you interested in learning about any new treatment options?  |         |

### Select Important Safety Information

#### 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.

**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 full Important Safety Information on page 3 and Patient Information for additional safety information.**

# Discussion Guide

for you and your healthcare provider

*At your  
appointment*

HYFTOR™ is the first and only FDA-approved topical gel for facial angiofibroma associated with tuberous sclerosis complex in patients 6 years of age and older. The following questions can help guide the discussion to see if HYFTOR™ is right for you.

| Questions for your healthcare provider  | Answers |
|---|---------|
| <input type="checkbox"/> I heard there is a new topical treatment for facial angiofibroma. What is HYFTOR™? |         |
| <input type="checkbox"/> What are the benefits of HYFTOR™?  |         |
| <input type="checkbox"/> What are the risks of HYFTOR™? What are the possible side effects?                 |         |
| <input type="checkbox"/> How effective is HYFTOR™?  |         |
| <input type="checkbox"/> Would HYFTOR™ be good for me?  |         |
| <input type="checkbox"/> How can I get HYFTOR™? Is it available now?  |         |
| <input type="checkbox"/> Will my insurance cover HYFTOR™?   |         |



## Notes & Other Questions I Want to Ask

### Select Important Safety Information (cont'd)

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.

Please see full Important Safety Information on page 3 and [Patient Information](#) for additional safety information.

## 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.

## 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.

**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.