

First and Only FDA-Approved Treatment for Friedreich Ataxia in Patients 16 Years and Older

SKYCLARYS[®]
(omaveloxolone) 50 mg capsules

I CANNOT TREAT MY
FA PROGRESSION

Not actual patients.

WHAT IS SKYCLARYS?

► SKYCLARYS is used for the treatment of Friedreich ataxia in adults and children aged 16 years and older. It is not known if SKYCLARYS is safe and effective for use in children younger than 16 years of age

IMPORTANT SAFETY INFORMATION

What are the possible side effects of SKYCLARYS?

SKYCLARYS may cause serious side effects, including:

- **Increase in blood liver enzymes:** Some people taking SKYCLARYS have had an increase in the level of liver enzymes in their blood. Your healthcare provider will do liver function tests
- before you start taking SKYCLARYS
 - every month for the first 3 months after starting your treatment with SKYCLARYS
 - during certain times as needed while taking SKYCLARYS

If your liver enzymes increase, your healthcare provider may change your dose, stop treatment for some time, or completely stop treatment with SKYCLARYS.

Please see Important Safety Information throughout and full [Prescribing Information](#), including [Patient Information](#).

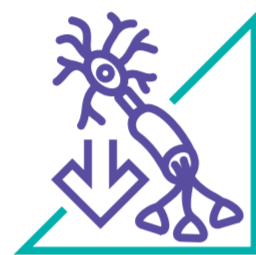
Understanding Friedreich Ataxia

What is FA?

Friedreich ataxia (FA) is a rare, progressive disease that damages the nervous system, causing you to lose control of your muscles over time.

What causes FA?

FA happens when a specific gene, called the frataxin gene (or *FXN*), does not function properly and cannot help nerve cells work the way they should. Ultimately, this leads to irreversible cell death.



Less cellular energy



Increased cell stress



Inflammation



Cell death

When do symptoms begin?

The first signs of FA typically appear during childhood or adolescence. However, it can take several years to confirm a diagnosis.

In its early stages, FA may cause you to feel clumsy or unbalanced and fall more often than usual. You may also notice that your feet and lower legs feel numb at times.

These are some of the most common early symptoms of FA:



Frequent falls



Feeling unbalanced



Loss of sensation



Tiredness

How is FA diagnosed?

A diagnosis of FA can be confirmed with a genetic test. It is important that the test include a Friedreich ataxia repeat expansion analysis. Your doctor can provide additional information about the specific test needed.

Understanding Friedreich Ataxia (cont'd)

What happens as FA progresses?

As you get older, FA continues to damage nerve cells, which leads to greater difficulty with things like:



Standing



Walking



Talking



Fine motor skills

It is common for many patients to lose some of their ability to balance while standing even before they receive a diagnosis of FA.

Most people with FA will need to use a wheelchair around

10 to 15 years

after they are first diagnosed.

In addition to difficulty moving and talking, FA may cause a serious heart condition called cardiomyopathy. With cardiomyopathy, the muscles in the heart become damaged, making it harder for the heart to pump blood.



Understanding the Modified Friedreich Ataxia Rating Scale (mFARS)

The mFARS measures FA progression

FA is a progressive disease. One way to measure progression is with the mFARS neurological exam. The mFARS is commonly used in clinical trials to evaluate how well potential treatments work. **A lower mFARS score means less physical impairment, while a higher score means more severe symptoms.**

The mFARS focuses on 4 key areas that relate to activities of daily living:

- ▶ Mouth and throat function
- ▶ Upper limb coordination
- ▶ Lower limb coordination
- ▶ Upright stability

Score range:

0 to 93 points

Average rate of progression:

+2 points per year

Average score for wheelchair use:

~65 points

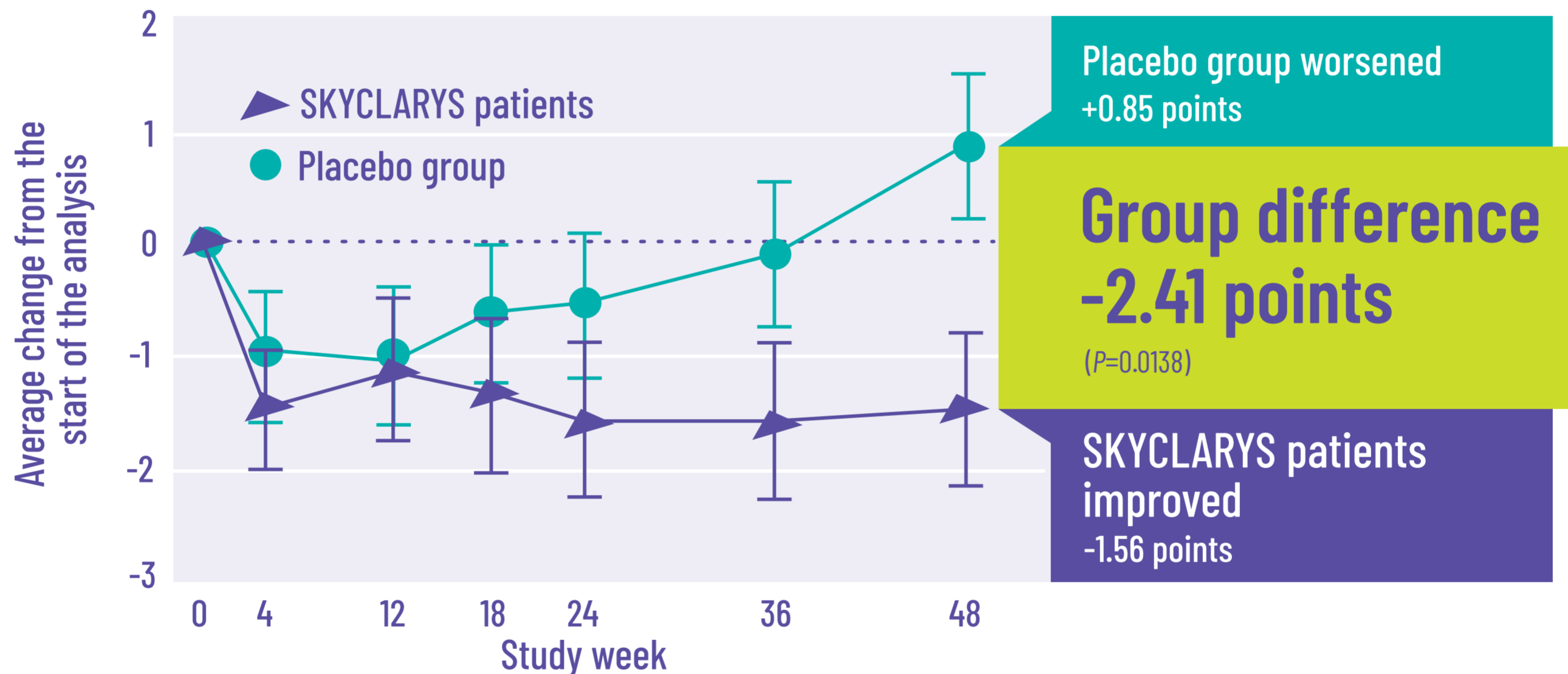
It is important to understand that the rate of FA progression will vary from person to person and that mFARS scores will change on an individual basis. For example, patients who are diagnosed at a younger age typically see their mFARS scores rise more quickly than older patients.

Less Physical Impairment Over Time With SKYCLARYS

Slowing FA progression with SKYCLARYS

Treatment with SKYCLARYS in the population of patients without pes cavus (n=82) resulted in statistically lower mFARS scores compared with patients taking placebo at 48 weeks.

This means that, on average, patients taking SKYCLARYS had less impairment after 48 weeks of treatment.



IMPORTANT SAFETY INFORMATION (cont'd)

What are the possible side effects of SKYCLARYS? (cont'd)

SKYCLARYS may cause serious side effects, including (cont'd):

- ▶ **Increase in a blood protein called B-Type Natriuretic Peptide (BNP).** BNP tells how well your heart is working. Your healthcare provider will check your BNP levels before your treatment with SKYCLARYS. Tell your healthcare provider if you have signs and symptoms of your heart not working well such as too much fluid in your body (fluid overload). Signs and symptoms may include:
 - sudden weight gain (3 pounds or more of weight gain in 1 day, or 5 pounds or more of weight gain in 1 week)
 - swelling in your arms, hands, legs, or feet (peripheral edema)
 - fast heartbeat (palpitations)
 - shortness of breath

If you have symptoms of fluid overload that is considered a side effect of SKYCLARYS, your healthcare provider may stop treatment with SKYCLARYS.

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Results From a 3-Year Exploratory Analysis

The open-label extension

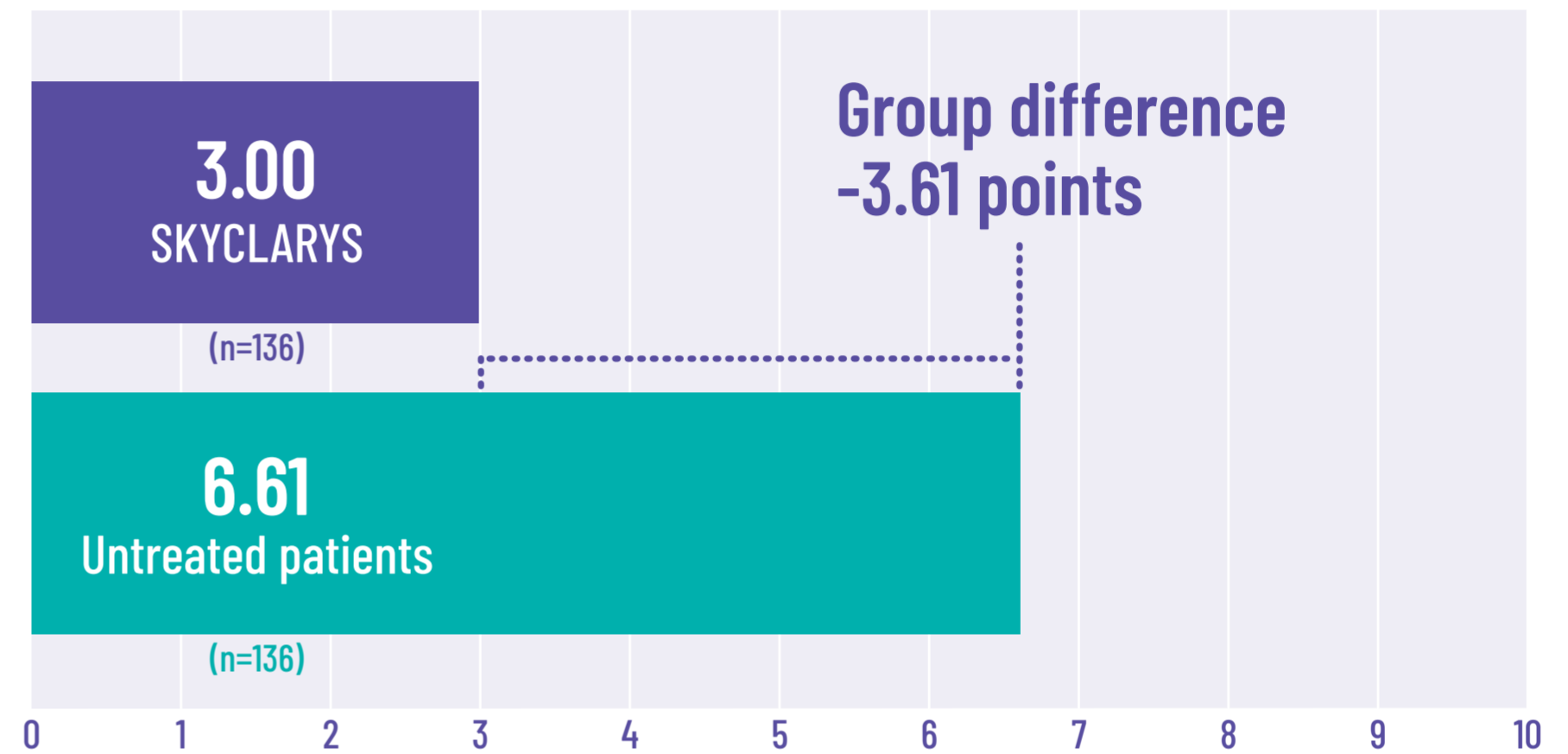
At the end of the clinical trial, all patients who participated were given the option to continue in a longer-term study called an open-label extension (OLE).

Before participating in the OLE, patients were asked to temporarily stop taking their treatment. Then, all patients were given SKYCLARYS, including those who had received a placebo in the clinical trial.

Comparing SKYCLARYS to natural progression

After 3 years, researchers conducted a follow-up study. They took the results from the OLE and compared them with untreated patients in a natural history study. This kind of study is called an “exploratory analysis” and is not the same as a clinical trial. Because of that, there are some limitations to the study and the results should be interpreted cautiously.

Average change in mFARS score after 3 years



Lower mFARS scores were observed in patients treated with SKYCLARYS after 3 years relative to a matched set of untreated patients from a natural history study.

IMPORTANT SAFETY INFORMATION (cont'd)

What are the possible side effects of SKYCLARYS? (cont'd)

SKYCLARYS may cause serious side effects, including (cont'd):

- **Changes in cholesterol levels.** Increases in low density lipoprotein cholesterol (LDL-C) or bad cholesterol and decreases in high density lipoprotein cholesterol (HDL-C) or good cholesterol have happened during treatment with SKYCLARYS. Your healthcare provider will check your cholesterol levels before and during your treatment with SKYCLARYS

Please see Important Safety Information throughout and full [Prescribing Information](#), including [Patient Information](#).



Safety and Side Effects

What are the possible side effects of SKYCLARYS?

SKYCLARYS may cause serious side effects, including:

Increase in blood liver enzymes

Some people taking SKYCLARYS have had an increase in the level of liver enzymes in their blood. Your healthcare provider will do liver function tests

- ▶ before you start taking SKYCLARYS
- ▶ every month for the first 3 months after starting your treatment with SKYCLARYS
- ▶ during certain times as needed while taking SKYCLARYS

If your liver enzymes increase, your healthcare provider may change your dose, stop treatment for some time, or completely stop treatment with SKYCLARYS.

Increase in a blood protein called B-Type Natriuretic Peptide (BNP)

BNP tells how well your heart is working. Your healthcare provider will check your BNP levels before your treatment with SKYCLARYS. Tell your healthcare provider if you have signs and symptoms of your heart not working well such as too much fluid in your body (fluid overload). Signs and symptoms may include:

- ▶ sudden weight gain (3 pounds or more of weight gain in 1 day, or 5 pounds or more of weight gain in 1 week)
- ▶ swelling in your arms, hands, legs, or feet (peripheral edema)
- ▶ fast heartbeat (palpitations)
- ▶ shortness of breath

If you have symptoms of fluid overload that is considered a side effect of SKYCLARYS, your healthcare provider may stop treatment with SKYCLARYS.

Changes in cholesterol levels

Increases in low density lipoprotein cholesterol (LDL-C) or bad cholesterol and decreases in high density lipoprotein cholesterol (HDL-C) or good cholesterol have happened during treatment with SKYCLARYS. Your healthcare provider will check your cholesterol levels before and during your treatment with SKYCLARYS.

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Safety and Side Effects (cont'd)

What are the most common side effects?

In the clinical trial, the most common side effects of SKYCLARYS were elevated liver enzymes, along with headache, nausea, stomach pain, and tiredness. Some people also experienced diarrhea, muscle aches, and pain in the mouth, throat, or neck. These are not all the possible side effects of SKYCLARYS. Call your doctor for medical advice about side effects.

Most common side effects*

Side effects	SKYCLARYS patients	Untreated patients
Elevated liver enzymes (AST/ALT)	37%	2%
Headache	37%	25%
Nausea	33%	13%
Stomach pain	29%	6%
Tiredness	24%	14%
Diarrhea	20%	10%
Muscle aches and pain	20%	15%
Mouth, throat, or neck pain	18%	6%
Influenza	16%	6%
Vomiting	16%	12%
Muscle spasms	14%	6%
Back pain	13%	8%
Decreased appetite	12%	4%
Rash	10%	4%

*Defined as affecting 10% or more of patients and more SKYCLARYS patients than untreated patients.

AST/ALT=aspartate aminotransferase/alanine aminotransferase.

These are not all the possible side effects of SKYCLARYS. For more information, ask your healthcare provider or pharmacist. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

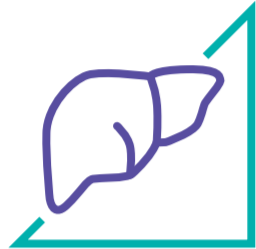
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Dosing and Administration

What should I do before I start taking SKYCLARYS?

Before taking SKYCLARYS, tell your healthcare provider about all of your medical conditions, including if you:



have liver problems



have a history of heart problems,
including heart failure



have a high level of fat in your
blood (high blood cholesterol)

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements such as St John's wort.

- ▶ Taking SKYCLARYS with other medicines can cause serious side effects
- ▶ SKYCLARYS may affect the way other medicines work, and other medicines may affect how SKYCLARYS works
- ▶ Know the medicines you take. Keep a list of them to show to your healthcare provider and pharmacist when you get a new medicine

Family planning with SKYCLARYS

Pregnancy: Tell your doctor if you are pregnant or plan to become pregnant. It is not known if SKYCLARYS will harm your unborn baby.

Birth control: Women who use hormonal birth control should use another form of birth control such as a non-hormonal intrauterine system or an extra non-hormonal birth control such as condoms while using SKYCLARYS and for 28 days after stopping SKYCLARYS.

Breastfeeding: Tell your doctor if you are breastfeeding or plan to breastfeed. It is not known if SKYCLARYS passes into your breast milk. Talk to your healthcare provider about the best way to feed your baby if you take SKYCLARYS.

What should I avoid while taking SKYCLARYS?

- ▶ Do not drink grapefruit juice or eat grapefruit. These may change the amount of SKYCLARYS in your blood

Please see **Important Safety Information** above and full [Prescribing Information](#), including [Patient Information](#).



Not actual patients.

SKYCLARYS[®]
(omaveloxolone) 50 mg
capsules

Dosing and Administration (cont'd)

How do I take SKYCLARYS?

SKYCLARYS is a once-daily oral treatment for FA.

The recommended dose is 150 mg

Each SKYCLARYS capsule is 50 mg

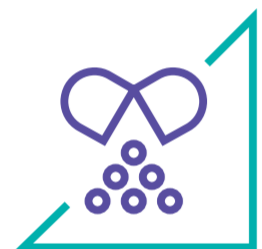
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3
capsules



Standard administration:

- ▶ Take SKYCLARYS on an empty stomach at least 1 hour before eating
- ▶ Swallow SKYCLARYS capsules whole. Do not crush or chew



Sprinkle administration:

If you are not able to swallow whole capsules:

- ▶ Take SKYCLARYS capsules on an empty stomach at least 1 hour before eating
- ▶ If SKYCLARYS capsules cannot be swallowed whole, the capsules may be opened and the entire contents of both halves sprinkled onto 2 tablespoonfuls (30 mL) of applesauce
- ▶ Stir the mixture
- ▶ Swallow all the mixture of medicine and applesauce right away. Do not store the mixture of medicine and applesauce to use at a later time
- ▶ The contents of the SKYCLARYS capsules should not be mixed with milk or orange juice
- ▶ Do not administer SKYCLARYS by an enteral feeding tube

If you miss a dose, then you should skip the missed dose and take the next dose at the regular time the next day. Do not double your next dose or take more than the prescribed dose

What should I avoid while taking SKYCLARYS?

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Biogen REACH

Biogen REACH is an informational and support resource for you and your caregivers to explore ways to access SKYCLARYS.



Biogen REACH enrollment

Your doctor **must** complete and submit a Start Form before you can speak with a Care Navigator and access REACH support offerings.

Your doctor may ask you to provide information to complete the Patient sections of the form. **You or your authorized caregiver will need to sign the form** to access extra support offerings.*

*You are not required to enroll in Biogen REACH to receive a prescription for SKYCLARYS.



Care Navigators

Once enrolled in Biogen REACH, **Care Navigators** will help you navigate your journey of starting and continuing with your SKYCLARYS prescription.

Care Navigators will be your primary point of contact for Biogen REACH and may provide answers to questions about your:

- ▶ Insurance and copays
- ▶ Copay assistance
- ▶ At-home prescription delivery



Scan the QR code or visit BiogenREACH.com to find support for getting access to SKYCLARYS.

You or your healthcare provider can speak with a **Care Navigator** by calling **1-844-98-REACH**. Care Navigators are available 8 am-8 pm ET, Monday through Friday (except holidays).



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Biogen REACH (cont'd)



Specialty pharmacy

Your SKYCLARYS prescription will be delivered to you by a specialty pharmacy

The Biogen REACH exclusive specialty pharmacy, Biologics, will contact you to confirm the delivery address and collect any copayments or coinsurance that may be required for each monthly supply of your SKYCLARYS prescription. SKYCLARYS is not available at retail pharmacies.

The specialty pharmacy may also contact you to inquire about your:

- ▶ SKYCLARYS prescription
- ▶ Insurance benefits and copays
- ▶ Ability to get copay assistance



Affordability options

Find out if you are eligible

Options may be available to help you afford your SKYCLARYS prescription whether you are insured, underinsured, or uninsured.*

Once enrolled in Biogen REACH, you may speak with a **Care Navigator** who can help you explore your eligibility for affordability options by calling 1-844-98-REACH.

*Subject to eligibility and program terms and conditions. Biogen REACH affordability options are not healthcare insurance.



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**I CANNOT DO MORE
TO TREAT MY FA**



Got questions about SKYCLARYS?

Talk to your doctor and visit our site for more information. Scan the QR code or visit [SKYCLARYS.com](https://www.skyclarys.com).

Not an actual patient.



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Intended for a US audience.

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