

The First and Only FDA-Approved Treatment for Friedreich Ataxia (FA) in Patients 16 Years and Older

# *I want to slow my FA progression,* **THAT'S WHY I'M MAKING MOVES TO CHOOSE SKYCLARYS\***

\*In a 48-week clinical trial, treatment with SKYCLARYS resulted in less physical impairment over time versus placebo, as measured by the modified Friedreich Ataxia Rating Scale.

Matt: Avid cyclist, professional writer

Taking SKYCLARYS since 2023

Patients featured are paid spokespersons for Biogen.

**SKYCLARYS**<sup>®</sup>  
(omaveloxolone) 50 mg capsules

## WHAT IS SKYCLARYS?

- ▶ SKYCLARYS<sup>®</sup> (omaveloxolone) 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
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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](#).**

## ABOUT FA

# Understanding Friedreich ataxia



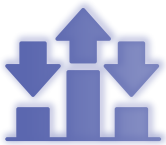
### What is Friedreich ataxia (FA)?

FA is a rare, genetic, progressive disease that damages the nervous system, causing you to lose control of your muscles over time. It 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.



### How is FA diagnosed?

On average, diagnosing FA takes about 3 years. An FA diagnosis 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.



### How is progression measured?

One way to measure FA progression is with the modified Friedreich Ataxia Rating Scale (mFARS) neurological exam, which is commonly used in clinical trials to evaluate how well potential FA treatments work. The mFARS exam evaluates 4 key areas that relate to everyday activities.

Key mFARS areas	Possible activities affected
Lower limb coordination	Putting on socks and shoes
Upright stability	Walking, sitting in a car, standing in a line, or showering
Upper limb coordination	Getting dressed, eating, brushing teeth, typing, pointing, reaching, or turning a doorknob
Mouth and throat function	Speaking clearly and coughing

mFARS scores range from 0 to 93 points. **A lower mFARS score means less physical impairment, while a higher score indicates poorer functional ability.**

Understanding that mFARS scores can vary is important when discussing the rate of FA progression.

The rate of FA progression is different for each person, so mFARS scores will change depending on the individual. For example, people who are diagnosed at a younger age typically see their mFARS scores rise more quickly than people who are diagnosed when they are older.

~ 2 points per year is the average rate of FA progression on the mFARS exam

# FA is a progressive disease that can lead to the loss of functional abilities over time

FA symptoms become apparent: falls, clumsiness, feeling unbalanced, loss of sensation, tiredness

Lower limb coordination continues to decline

Mobility aids such as canes or walkers may become helpful

Speech starts to sound slurred

Hands and arms become less coordinated

Many patients require the use of a wheelchair 10 to 15 years after symptoms first appear

Complications from FA, such as diabetes or cardiomyopathy, become more serious

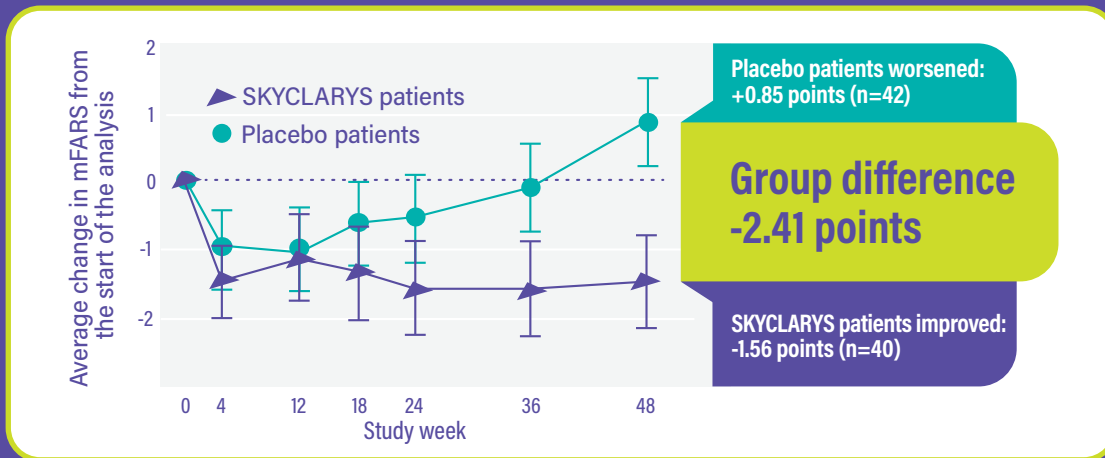
## SLOWER PROGRESSION

# SKYCLARYS has been shown to slow down FA progression

### Results from the clinical trial

Treatment with SKYCLARYS resulted in statistically lower mFARS scores compared with untreated patients at 48 weeks.\*

This means that, on average, patients taking SKYCLARYS had less impairment after 48 weeks of treatment compared with untreated patients in the clinical trial.



\*In the population of patients without pes cavus (n=82).

Chris: Fisherman, outdoorsman

Taking SKYCLARYS since 2023



# Results from a 3-year exploratory analysis

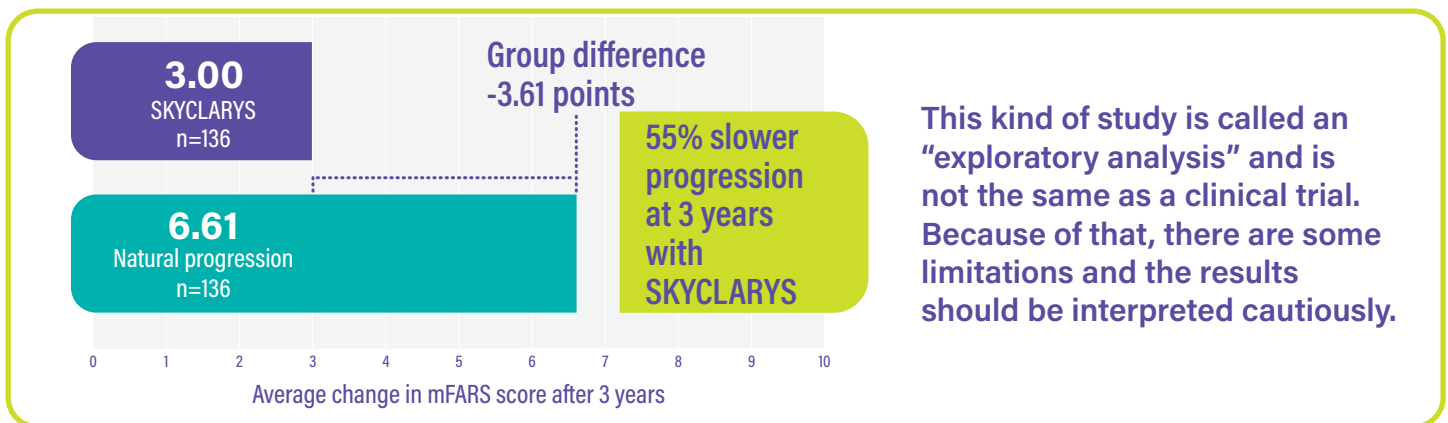


At the end of the clinical trial, all patients who participated were given the option to continue in a longer-term study called an open-label extension.

Before participating in the open-label extension study, patients were asked to temporarily stop taking their treatment. Then, all patients were given SKYCLARYS, including those who had not been on treatment in the clinical trial.

## Comparing SKYCLARYS to natural progression

After 3 years, researchers took the results from the open-label extension study and compared them with a matched set of untreated patients in the Friedreich Ataxia Clinical Outcome Measures Study (FA-COMS). FA-COMS is an ongoing natural history study that measures the progression of more than a thousand FA patients to determine just how the condition progresses.



*Lower mFARS scores were observed in patients treated with SKYCLARYS after 3 years compared with a matched set of patients from FA-COMS.*

### 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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## SAFETY

# 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

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#### **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.

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- ▶ 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.

### **IMPORTANT SAFETY INFORMATION (cont'd)**

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

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Jacob: Youth mentor, motivational speaker  
Taking SKYCLARYS since 2023

**SKYCLARYS**<sup>®</sup>  
(omaveloxolone) 50 mg capsules



## What are the most common side effects?

In the clinical trial, the most common side effects were elevated liver enzymes, along with headache, nausea, stomach pain, and tiredness. Some people also experienced diarrhea and muscle aches and pain. 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%

AST=aspartate aminotransferase; ALT=alanine aminotransferase.

\*Defined as affecting 20% or more of patients and more SKYCLARYS patients than untreated patients.



**Libby: Yoga enthusiast,  
interior designer**

**Taking SKYCLARYS since 2023**



## What should I do before I start taking SKYCLARYS?

Keep your healthcare provider in the loop! Make sure to inform them about all your medical conditions, including:



### Liver problems



### History of heart problems, including heart failure



### High 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 healthcare provider if you are pregnant or plan to become pregnant. It is not known if SKYCLARYS will harm your unborn baby. There is a pregnancy registry for women who are pregnant and are taking SKYCLARYS. The purpose of this registry is to collect information about the health of you and your baby. Your healthcare provider can enroll you or you may enroll yourself by calling 1-866-609-1785 or by sending an email to [SkyclarysPregnancySurveillance@ppd.com](mailto:SkyclarysPregnancySurveillance@ppd.com).

**Birth control:** Women who use hormonal birth control should use another form of birth control such as a nonhormonal intrauterine system or an extra nonhormonal 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 doctor about the best way to feed your baby if you take SKYCLARYS.

*Talk to your doctor about any  
side effects you may experience.*

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## DOSING AND ADMINISTRATION

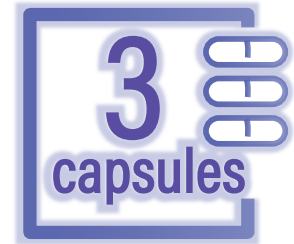
# SKYCLARYS is a once-daily oral treatment for FA

### How do I take SKYCLARYS?

The recommended dose is 150 mg

Each SKYCLARYS capsule is 50 mg

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#### Standard administration:

- ▶ Take SKYCLARYS on an empty stomach, at least 1 hour before or 2 hours after eating
- ▶ Swallow SKYCLARYS capsules whole. Do not crush or chew



#### Sprinkle administration:

If you are not able to swallow whole capsules:

- ▶ Take SKYCLARYS on an empty stomach, at least 1 hour before or 2 hours after eating
- ▶ If SKYCLARYS capsules cannot be swallowed whole, the capsules may be opened and the entire contents of both halves sprinkled onto 2 tablespoons (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?

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

*Follow your doctor's instructions carefully  
when taking SKYCLARYS.*

## ADHERENCE

For the best chance to slow your FA, take SKYCLARYS as your doctor prescribes

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*According to the World Health Organization, not keeping up with medications can lessen the benefits of treatment.*

Here are some suggestions that may help you follow your doctor's directions:



Set up phone reminders to take your medicine every day



Mark your calendar for follow-up appointments



Document your experience so you are ready for a conversation with your doctor



Ask your doctor for advice about managing side effects

### IMPORTANT SAFETY INFORMATION (cont'd)

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

**The most common side effects of SKYCLARYS include:** increased liver enzymes (ALT/AST), headache, nausea, stomach pain, tiredness, diarrhea, and muscle pain.

**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)
- ▶ are pregnant or plan to become pregnant. It is not known if SKYCLARYS will harm your unborn baby. 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
- ▶ Pregnancy exposure registry: There is a pregnancy registry for women who are pregnant and are taking SKYCLARYS. The purpose of this registry is to collect information about the health of you and your baby. Your healthcare provider can enroll you or you may enroll yourself by calling 1-866-609-1785 or by sending an email to [SkyclarysPregnancySurveillance@ppd.com](mailto:SkyclarysPregnancySurveillance@ppd.com)
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## ACCESS AND RESOURCES

# Get support for accessing your SKYCLARYS prescription with Biogen REACH

REACH is an access resource committed to helping people with FA receive SKYCLARYS quickly, easily, and affordably.

### Enroll in REACH to explore your eligibility for affordability options

Your doctor must complete and submit a Start Form before you can access REACH support offerings.\* Once enrolled in REACH, you will be assigned a Family Access Manager (FAM) and a Lead Case Manager (LCM).

FAM	LCM	Biologics
<p>Your FAM will be your main point of contact for questions or concerns about the logistics surrounding treatment. Your FAM can assist with things such as:</p> <ul style="list-style-type: none"><li>▶ Access to medication</li><li>▶ REACH services</li><li>▶ Information about other eligible programs</li></ul>	<p>Your FAM will connect you with your LCM if you have questions about access. Your LCM can help you:</p> <ul style="list-style-type: none"><li>▶ Understand your insurance status and SKYCLARYS treatment plan</li><li>▶ Facilitate communication with Biologics</li></ul>	<p>Biologics is the Biogen REACH exclusive specialty pharmacy and will collect any copayments or coinsurance needed for your SKYCLARYS prescription. They may also contact you about your:</p> <ul style="list-style-type: none"><li>▶ SKYCLARYS prescription</li><li>▶ Insurance benefits and copays</li><li>▶ Eligibility for copay assistance</li></ul>

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

### Ongoing REACH support

REACH support does not end after you get access to SKYCLARYS. Registered pharmacists are here to support you throughout your SKYCLARYS treatment journey. Customized ongoing support services will be offered through the specialty pharmacy based on your individual needs and applicable program requirements.

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

Whether or not you are insured, if SKYCLARYS is right for you, the REACH program may be able to help\*

**95%**

of commercially insured patients have **\$0 out-of-pocket costs** per month.†

**94%**

of Medicare patients have **\$15 or less in out-of-pocket costs** per month.‡



**If you are uninsured, the REACH program can help you determine financial assistance options.**

If you have limited income or resources, you may qualify for Medicare Part D Extra Help. Extra Help is a subsidy program for Medicare prescription drug plans, deductibles, and prescription copays. Patients eligible for Extra Help may pay as little as \$0 to \$11.20<sup>‡</sup> for SKYCLARYS.

Approximately 27% of Medicare Part D enrollees already benefit from Extra Help, and it is estimated that 3 million people are not currently enrolled but may be eligible.

Apply online at [ssa.gov/medicare/part-d-extra-help](https://ssa.gov/medicare/part-d-extra-help) or by calling **1-800-772-1213**.

\*Subject to eligibility and program terms and conditions. REACH affordability options are not healthcare insurance. Federal and state laws and other factors may prevent or otherwise restrict eligibility. People covered by Medicare, Medicaid, Veterans Affairs (VA), the Department of Defense (DoD), or any other federal plans are not eligible to enroll.

†As of July 2024.

‡As of January 2024.



A man with dark hair, wearing a blue t-shirt and dark shorts, is sitting in a wheelchair in a grassy field. He is smiling and looking towards the camera. In the background, there is a large building with a corrugated metal roof, possibly a barn or farm structure. The sky is clear and blue. There are some decorative purple and blue lines in the background.

*More than 2000 patients have been  
prescribed SKYCLARYS worldwide.\**

\*Based on commercial patients, early access patients, and clinical trial participants through July 2024.

# IMPORTANT SAFETY INFORMATION



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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.

**Please see full [Prescribing Information](#), including [Patient Information](#).**

# DISCOVER WHAT'S NEXT WITH SKYCLARYS

Whether or not you are insured, Biogen REACH may be able to help you receive your SKYCLARYS prescription quickly, easily, and affordably.\*

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Patients featured are paid spokespersons for Biogen.



## 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.biogen.com/skyclarys).

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Intended for a US audience.

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