

Access Within REACH

The Biogen REACH program: A patient access resource for SKYCLARYS® (omaveloxolone) 50 mg capsules

WHAT IS SKYCLARYS?

- SKYCLARYS® (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
 - 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 on [pages 6 and 7](#) and full [Prescribing Information](#), including [Patient Information](#).



Scan the QR code
to learn more about
Biogen REACH



REACH is here to help throughout your treatment journey with SKYCLARYS® (omaveloxolone)



REACH Enrollment

Getting started

Your doctor **must** complete and submit a Start Form, with your signed consent, in order to 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 support offerings.* You may sign this form at your doctor's office, or a Lead Case Manager (LCM) can send you a link to sign electronically.

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



Support Team

Your Biogen REACH team is here to support you

Once enrolled in REACH, an LCM and Family Access Manager (FAM) will help you navigate your journey when starting and throughout treatment with SKYCLARYS.

Your FAM will be your primary point of contact for the REACH team, providing support by working through the logistics associated with getting your SKYCLARYS prescription. Your LCM will keep track of all your information through every step of your journey.



Specialty Pharmacy

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

The 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 such as Walgreens, CVS, etc.

The specialty pharmacy may also contact you to discuss 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 you are enrolled in REACH, an LCM can help you explore your eligibility for affordability options by calling **1-844-987-3224**.

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.‡

†Subject to eligibility and program terms and conditions. REACH affordability options are not healthcare insurance. ‡As of July 2024.

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Get started with REACH in 4 steps

1

Physician's Office Submits Prescription and Start Form to REACH*

Once your provider has decided to prescribe you SKYCLARYS, they will send a Start Form (prescription included) to REACH. Once received, an LCM will contact you to introduce the REACH program services and get your consent for participation.

*Patients do not need to enroll in all patient support services to access prescribed medication.

The welcome call is the first point of contact between you and REACH

2

Benefits Investigation and Verification

REACH will contact your insurance company to understand your coverage benefits for SKYCLARYS. REACH will identify which documentation your insurance company requires to review the prescription request submitted for approval and share this information with you and your provider.

REACH will identify insurance requirements for SKYCLARYS access

3

Prescription Review Process

The physician's office submits all the necessary documentation to the insurance company. REACH will follow up regularly with payers throughout the insurance approval process. Once your insurance approves SKYCLARYS, REACH will contact you to inquire if help is needed in exploring financial assistance options for accessing SKYCLARYS.

REACH follows the insurance approval process and can support you with financial assistance for SKYCLARYS

4

Receiving Product

A pharmacy representative will contact you to discuss treatment dosing and confirm shipping address.

SKYCLARYS will be shipped directly to you using the address provided

Please see Important Safety Information on [pages 6 and 7](#) and full [Prescribing Information](#), including [Patient Information](#).

The Biogen REACH program is a patient access resource for SKYCLARYS® (omaveloxolone)

Working with your Biogen REACH support team

FAM (Family Access Manager): FAMs are your primary point of contact for the REACH team, providing support by working through the logistics associated with getting your SKYCLARYS prescription. FAMs work closely with patients and prescribers to help in the steps required to access therapy, including:

- Prior authorization and reauthorization
- Specialty pharmacy support (if applicable)
- Patient support resources and tools throughout the treatment journey
- Education and answers to questions about the disease, financial support, and insurance. FAMs stay in touch throughout the treatment journey to provide the best possible patient experience

LCM (Lead Case Manager): Your Biogen LCM is your treatment case manager, keeping track of all your information through every step of your journey. Some things they can help with include:

- Initiating contact with you once your Start Form is received
- Coordinating your first shipments of SKYCLARYS
- Acting as an intermediary with the specialty pharmacy
- Managing patient support services such as financial assistance enrollment and mobile labs

You or your healthcare provider can call **1-844-987-3224** 8:30 AM-8 PM ET, Monday through Friday (except holidays), to speak with a representative from the REACH support team.

Ongoing REACH support



Your SKYCLARYS prescription will be delivered to you by a specialty pharmacy. SKYCLARYS is not available at retail pharmacies.

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.



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

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

Please remember that your doctor should be your primary resource for any questions related to Friedreich ataxia and SKYCLARYS.

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Importance of taking SKYCLARYS® (omaveloxolone) as prescribed



Medication adherence means agreeing to a treatment with your healthcare provider and consistently taking the medication as prescribed. Talk to your doctor about your SKYCLARYS treatment. A treatment plan is important, especially for progressive diseases like Friedreich ataxia.

Taking SKYCLARYS

- SKYCLARYS is taken as 3 capsules once daily
- Follow your doctor's instructions carefully when taking SKYCLARYS
- SKYCLARYS should be taken on an empty stomach at least 1 hour before you eat
- It is important to avoid eating grapefruit or drinking grapefruit juice while taking SKYCLARYS, as it may affect the way SKYCLARYS works in your body
- If you are not able to swallow whole capsules, talk to your doctor for information about opening SKYCLARYS capsules:
 - SKYCLARYS capsules may be opened and the entire contents of both halves sprinkled onto 2 tablespoonfuls (30 mL) of applesauce
 - Stir the mixture
 - Swallow all of the mixture and applesauce right away. Do not store the mixture 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

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

Keep in mind, difficulties can arise such as:

- Prescription access roadblocks
- Forgetting to order refills
- Financial hardships
- Appropriate treatment adherence

When difficulties arise, REACH is here to help you during your SKYCLARYS treatment. REACH offers resources designed to help you improve your health literacy, maximize your prescription benefits, and take SKYCLARYS as prescribed.

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SKYCLARYS® (omaveloxolone) Indication and Important Safety Information

SKYCLARYS (skye klar' is)

WHAT IS SKYCLARYS?

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 - 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

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

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SKYCLARYS® (omaveloxolone) Indication and Important Safety Information (cont'd)

SKYCLARYS (skye klar' is)

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
- 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

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

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

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 Important Safety Information on [pages 6 and 7](#) and full [Prescribing Information](#), including [Patient Information](#).

Additional support throughout your treatment journey

Ongoing Support

REACH support does not end after getting access to medication.

Registering for REACH means getting access to several additional resources that can help you. These include:

- Financial support for eligible patients
- SKYCLARYS refill calls from a pharmacy representative

After your doctor prescribes SKYCLARYS and submits a Start Form, the REACH support team works to help you stay informed and address barriers to treatment.

Advocacy Groups

You can also access several advocacy groups to connect with FA support groups, find activities, and join events, including those listed below.

National Ataxia Foundation (NAF): ataxia.org

The NAF is an organization specializing in improving the lives of people with ataxia, including FA, through support, education, and research. Resources are available to patients and caregivers to find neurologists and ataxia clinics in their area, including Ataxia Centers of Excellence (ACE).

Friedreich's Ataxia Research Alliance (FARA): curefa.org

FARA is an organization dedicated to the pursuit of research to find treatments and a cure for FA. Patients and caregivers can connect with providers at one of their Collaborative Research Network Sites.

Disclaimer: Organization names and site information are provided for convenience and informational purposes. They are not controlled or endorsed by Biogen.



Scan the QR code or visit SKYCLARYS.com to learn more about SKYCLARYS.

You or your healthcare provider can also call 1-844-987-3224 8:30 AM-8 PM ET, Monday through Friday (except holidays), to speak with a representative from the REACH support team.

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