



Dear Friedreich Ataxia (FA) Community:

We are excited to kick off 2024 with momentum.

SKYCLARYS® (omaveloxolone) received approval in the European Union for adults and adolescents aged 16 years and older. We would like to sincerely thank the FA community, including people who participated in the clinical studies, their families, patient advocacy groups, and the medical community who together made this approval possible.

In addition, as a result of continuing research, the SKYCLARYS label in the United States has been updated to include sprinkle administration for patients who have difficulty swallowing a whole capsule. We hope this additional option provides added support to the patient community.

Finally, Biogen remains committed to bringing SKYCLARYS to younger patients with high unmet need.

#### **Approval of SKYCLARYS in European Union**

On Feb. 12th, the European Commission authorized SKYCLARYS® (omaveloxolone) for the treatment of FA in adults and adolescents aged 16 years and older. SKYCLARYS is approved as the first treatment for FA across all 27 European Union member states, as well as other European countries.

Following this approval, Biogen is now working with the local governments and reimbursement authorities in each EU country to ensure that eligible European patients can have access to this treatment.

#### **Updated Sprinkle Administration included in U.S. Prescribing Information**

The FDA label for SKYCLARYS was recently updated to include an additional administration option due to unmet need within the FA community.

- 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



**Additional considerations:**

**How should I take SKYCLARYS?**

- Take SKYCLARYS exactly as your healthcare provider tells you to take it
- Take SKYCLARYS capsules on an empty stomach at least 1 hour before eating
- Swallow SKYCLARYS capsules whole. Do not crush or chew
- If SKYCLARYS capsules cannot be swallowed whole, the capsules may be opened and the entire contents of both halves sprinkled onto 2 tablespoons (30mL) of applesauce
  - Stir the mixture
  - Swallow all of 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

**Please see Important Safety Information below and additional Patient Information and full Prescribing Information [here](#).**

Anyone considering this medication should discuss if SKYCLARYS is the appropriate treatment with their physician.

This information is not intended to replace discussions with your healthcare provider.

**Commitment to Children with FA**

We understand there have been many questions from the community regarding Biogen's research plans for the pediatric population. We recognize the urgent need to advance potential pathways for access to this important population and acknowledge how incredibly challenging it is for the patients and families who are waiting for treatment.

As a first step, Biogen is working to initiate a small clinical trial (a Phase 1 study) this summer to identify the appropriate dose of SKYCLARYS for the pediatric population. This study will look to enroll 20 pediatric FA patients aged 2-15 years at 1-2 sites in the United States. Following a single-dose evaluation of the safety, tolerability, and pharmacokinetics of omaveloxolone, participants will have the opportunity to move into an open label extension. We will continue to work with FARA and the study site investigator to notify the community when the study can begin enrolling volunteers.

In addition, we are working with a sense of urgency to engage regulators and refine our broader FA pediatric development plan. This is a priority for Biogen and we will provide updates to the community as soon as possible.

We are thankful for your understanding as we work as thoroughly and as fast as possible to bring SKYCLARYS to patients who may benefit across all age groups around the world.



## SKYCLARYS® (omaveloxolone) INDICATION and IMPORTANT SAFETY INFORMATION

### 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.

- **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.



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

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

Sincerely,  
Biogen Patient Advocacy Team