

**First and Only FDA-Approved Prescription  
Medicine for Friedreich's Ataxia**

**SKYCLARYS™**  
(omaveloxolone) 50 mg capsules

# **WHAT TO EXPECT WITH SKYCLARYS**

Not an actual patient.

**SKYCLARYS is used for the treatment of Friedreich's ataxia in adults and children 16 years of age and older.**

Please see **Important Safety Information** on page 6 and full **Prescribing Information** and **Patient Product Information**.

# SKYCLARYS Is a Once-Daily Oral Treatment for FA

**Take SKYCLARYS exactly as your healthcare provider tells you to take it**

Each SKYCLARYS capsule is 50 mg

The recommended dose is 150 mg



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

## **It is important to avoid certain things when taking SKYCLARYS:**

These may affect the way SKYCLARYS works in your body.



Grapefruit



Grapefruit juice

SKYCLARYS may reduce the efficacy of hormonal 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.

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.

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# SKYCLARYS Safety and Special Considerations

## What are the possible side effects of SKYCLARYS?

The most common side effects of SKYCLARYS include increased liver enzymes (ALT/AST), headache, nausea, stomach pain, tiredness, diarrhea, and muscle pain. These are not all the possible side effects of SKYCLARYS. Call your doctor for medical advice about side effects.

### Most common side effects in the clinical trial\*

| 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 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%                 |

You may report side effects to FDA at 1-800-FDA-1088.

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

ALT=alanine aminotransferase;  
AST=aspartate aminotransferase.



# Monitoring Your Health While Taking SKYCLARYS

SKYCLARYS may cause serious side effects. These include an increase in blood liver enzymes, increase in a blood protein called B-type natriuretic peptide (BNP), and changes in cholesterol levels.

As you continue taking SKYCLARYS, your doctor will monitor you for potentially serious changes in these areas.

## Liver enzymes

Some people taking SKYCLARYS have had an increase in the level of liver enzymes in their blood. Your doctor 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 doctor may change your dose during treatment, stop treatment for some time, or completely stop treatment with SKYCLARYS.

## BNP

BNP tells how well your heart is working. Your doctor will check your BNP levels before your treatment with SKYCLARYS. Tell your doctor 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 doctor may stop treatment with SKYCLARYS.

## Cholesterol

Increases in LDL-C, or bad cholesterol, and decreases in HDL-C, or good cholesterol, have happened during treatment with SKYCLARYS.

Your doctor will check your cholesterol levels before and during your treatment with SKYCLARYS.



**Talk with your doctor about any questions  
you have about taking SKYCLARYS.**



Not an actual patient.

**SKYCLARYS**  
(omaveloxolone) 50 mg  
capsules



# I CAN NOT DO MORE TO TREAT MY FA



## Got questions about SKYCLARYS?

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



Not an actual patient.

## IMPORTANT SAFETY INFORMATION

### What is SKYCLARYS?

SKYCLARYS is used for the treatment of Friedreich's ataxia in adults and children 16 years of age and older.

### Before taking SKYCLARYS, tell your healthcare provider about all 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. Some medications interact with SKYCLARYS. **Keep a list of your medicines to show to your healthcare provider and pharmacist when you get a new medicine.**

### 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 during treatment, 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) | ► tiredness   |
| ► headache                          | ► diarrhea    |
| ► nausea                            | ► muscle pain |
| ► stomach pain                      |               |

These are not all the possible side effects of SKYCLARYS. Call your doctor for medical advice about side effects.

**You are encouraged to report negative side effects of prescription drugs to the FDA.**

Visit [www.fda.gov/medwatch](http://www.fda.gov/medwatch) or call 1-800-FDA-1088. You may also report side effects to Reata Pharmaceuticals, Inc., at 1-800-314-3934.

For additional information about SKYCLARYS, please see the full [Prescribing Information](#) and [Patient Product Information](#).

US-SKY-2300092 v1.0

Intended for a US audience.

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