

First and Only FDA-Approved Prescription Medicine for Friedreich Ataxia



FREQUENTLY ASKED QUESTIONS ABOUT
**FRIEDREICH ATAXIA
AND SKYCLARYS**

Not an actual patient.

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

Please see Important Safety Information on page 4 and full Prescribing Information and Patient Product Information.



What is Friedreich ataxia?

Friedreich ataxia (FA) is an inherited, progressive, debilitating, and degenerative neuromuscular disorder. It is the most common inherited ataxia.

Symptoms usually appear between the ages of 10 and 15 years. These can include frequent falls, feeling unbalanced, loss of sensation, and fatigue. Patients typically require wheelchair use around 10 to 15 years after experiencing the first symptoms. Average life expectancy for patients with FA is 37.5 years.



What is SKYCLARYS?

SKYCLARYS is the first prescription medicine approved by the FDA for the treatment of FA. In a clinical trial, patients taking SKYCLARYS had significantly slower FA progression compared with untreated patients.



Who can take SKYCLARYS?

SKYCLARYS is approved for patients with Friedreich ataxia aged 16 years and older.



Are there any side effects with SKYCLARYS?

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

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



How is SKYCLARYS taken?

SKYCLARYS is a once-daily oral treatment for FA. Each SKYCLARYS capsule is 50 mg, and the recommended dose is 150 mg. This means you will need to take 3 capsules every day. Some patients may need to take less than 150 mg a day depending on what other medications they are taking or if they have certain liver problems. Patients should follow their doctor's instructions carefully when taking SKYCLARYS.



Is assistance available to help patients access SKYCLARYS?

Reata REACH is an informational and support resource for you and your caregivers to explore ways to access prescribed Reata medicines, including SKYCLARYS. REACH offers information about REACH enrollment, Care Navigators, specialty pharmacy, and affordability options.

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).

Please see Important Safety Information on [page 4](#) and full [Prescribing Information](#) and [Patient Product Information](#).

SKYCLARYS
(omaveloxolone) 50 mg
capsules



NOTES

If you have more questions about SKYCLARYS, write them down and be sure to ask your doctor at your next visit.

Please see Important Safety Information on [page 4](#) and
full [Prescribing Information](#) and [Patient Product Information](#).

SKYCLARYS
(omaveloxolone) 50 mg
capsules



I CANNOT DO MORE TO TREAT MY FA



Got questions about SKYCLARYS? Talk to your doctor about SKYCLARYS or visit our site for answers. Click the QR code or visit SKYCLARYS.com to find support for getting access to SKYCLARYS.

Not an actual patient.

IMPORTANT SAFETY INFORMATION

What is SKYCLARYS?

SKYCLARYS is used for the treatment of Friedreich 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)
- headache
- nausea
- stomach pain
- tiredness
- diarrhea
- muscle 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 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](#).

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Intended for a US audience.

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