SKYCLARYS™ (omaveloxolone) 50 mg capsules

Not an actual patient.

FREQUENTLY ASKED QUESTIONS ABOUT FRIEDREICH'S ATAXIA AND SKYCLARYS

What is Friedreich's ataxia?

Friedreich's ataxia (FA) is an inherited, progressive, debilitating, and degenerative neuromuscular disorder.[1] It is the most common inherited ataxia.[2] Onset of symptoms typically occurs between the ages of 10 and 15 years, and can include falls, imbalance, reflex loss, sensation loss, and tiredness.[1-3] Patients typically require wheelchair use around 10 to 15 years after experiencing the first symptoms.[1] Average life expectancy for patients with FA is 37.5 years.[1]

What is SKYCLARYS?

SKYCLARYS is a prescription medicine indicated for the treatment of Friedreich's ataxia in adults and adolescents aged 16 years and older.[4]

In the pivotal MOXIe trial, treatment with SKYCLARYS resulted in significantly lower scores on the modified Friedreich's Ataxia Rating Scale relative to placebo, meaning less impairment for treated patients.[4]

Who can take SKYCLARYS?

SKYCLARYS is approved for patients aged 16 years and older. There are no contraindications for treatment with SKYCLARYS. Consider avoiding treatment with SKYCLARYS in patients taking strong CYP3A4 inhibitors, strong or moderate CYP3A4 inducers, or in patients with severe hepatic impairment. Lower doses of SKYCLARYS (<150 mg) may be appropriate for some patients taking CYP3A4 inhibitors or for patients with moderate hepatic impairment. Please consult the full Prescribing Information for complete details.[4]

Are there any adverse reactions to SKYCLARYS?

The most common adverse reactions (≥20% and greater than placebo) were elevated liver enzymes (aspartate aminotransferase [AST] and alanine aminotransferase [ALT]), headache, nausea, abdominal pain, fatigue, diarrhea, and musculoskeletal pain.[4]

In addition to elevated liver enzymes (AST/ALT), treatment with SKYCLARYS can cause an increase in B-type natriuretic peptide (BNP, a marker of cardiac function) and changes in cholesterol. Consult the full Prescribing Information for details about monitoring patients in these areas.[4]

How is SKYCLARYS taken?

The approved dose of SKYCLARYS is 150 mg. It is taken as 3 capsules of 50 mg each once a day.[4] A lower dose of SKYCLARYS (<150 mg) may be appropriate for some patients taking CYP3A4 inhibitors or inducers, or patients with hepatic impairment. Consult the full Prescribing Information for specific dosing considerations for these patients.[4]

Is assistance available to help patients access SKYCLARYS?

Reata REACH is an informational and support resource for patients and caregivers to explore ways to access prescribed Reata medicines such as SKYCLARYS. Within the REACH Patient Center, patients and caregivers can find information about REACH enrollment, Care Navigators, working with a specialty pharmacy, and affordability options. More information is available at ReataREACH.com or by calling 1-844-98-REACH.

Please see Important Safety Information below. Click here for full Prescribing Information.

SKYCLARYS™
(omaveloxolone) 50 mg capsules

Get started with SKYCLARYS:
Submit a Start Form today at ReataREACH.com. Reata REACH is here to support your eligible patients with FA.

Visit hcp.SKYCLARYS.com for more information.

Not an actual patient.

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

Elevation of Aminotransferases: Treatment with SKYCLARYS can cause an elevation in hepatic transaminases (alanine aminotransferase [ALT] and aspartate aminotransferase [AST]). The incidence of elevations of ALT or AST above 5 times and 3 times the upper limit of normal (ULN) was 16% and 31%, respectively, in patients treated with SKYCLARYS. There were no cases of concomitant elevation of transaminases and total bilirubin observed. Maximum increases in ALT and AST occurred within 12 weeks after starting SKYCLARYS. Increases in serum aminotransferases were generally asymptomatic and reversible following discontinuation of SKYCLARYS. Patients with clinically significant liver disease were excluded from the pivotal study.

Monitor ALT, AST, and total bilirubin prior to initiation of SKYCLARYS, every month for the first 3 months of treatment, and periodically thereafter. If transaminases increase to levels greater than 5 times the ULN, or greater than 3 times the ULN with evidence of liver dysfunction (e.g., elevated bilirubin), immediately discontinue SKYCLARYS and repeat liver function tests as soon as possible. If transaminase levels stabilize or resolve, SKYCLARYS may be reinitiated with an appropriate increased frequency of monitoring of liver function.

Elevation of B-Type Natriuretic Peptide: Treatment with SKYCLARYS can cause an increase in B-type natriuretic peptide (BNP), a marker of cardiac function. A total of 14% of patients treated with SKYCLARYS had an increase from baseline in BNP value above the ULN (100 pg/mL), compared to 4% of patients who received placebo. The incidence of elevation of BNP above 200 pg/mL was 4% in patients treated with SKYCLARYS. Cardiomyopathy and cardiac failure are common in patients with Friedreich's ataxia. Patients were excluded from the pivotal study if they had BNP levels > 200 pg/mL prior to study entry, or a history of clinically significant left-sided heart disease and/or clinically significant cardiac disease, with the exception of mild to moderate cardiomyopathy associated with Friedreich's ataxia. Whether the elevations in BNP are related to SKYCLARYS or cardiac disease associated with Friedreich's ataxia is unclear.

Elevations in BNP may indicate cardiac failure and should prompt an evaluation of cardiac function. Check BNP prior to initiation of SKYCLARYS. Monitor patients for the signs and symptoms of fluid overload, such as sudden weight gain (3 pounds or more of weight gain in one day, or 5 pounds or more of weight gain in a week), peripheral edema, palpitations, and shortness of breath. If signs and symptoms of fluid overload develop, worsen, or require hospitalization, evaluate BNP and cardiac function, and manage appropriately. Management of fluid overload and heart failure may require discontinuation of SKYCLARYS.

Lipid Abnormalities: Treatment with SKYCLARYS can cause changes in cholesterol. In the pivotal study, 29% of patients treated with SKYCLARYS reported elevated cholesterol above ULN at one or more time points. Mean increases were observed within 2 weeks of initiation of SKYCLARYS and returned to baseline within 4 weeks of discontinuing treatment. A total of 16% of patients treated with SKYCLARYS had an increase in low-density lipoprotein cholesterol (LDL-C) from baseline, compared to 8% of patients who received placebo. The mean increase in LDL-C for all SKYCLARYS-treated patients was 23.5 mg/dL at 48 weeks. A total of 6% of patients treated with SKYCLARYS had decreases in high-density lipoprotein cholesterol (HDL-C) from baseline compared to 4% of patients who received placebo. The mean decrease in HDL-C for all SKYCLARYS-treated patients was 5.3 mg/dL at 48 weeks.

Assess lipid parameters prior to initiation of SKYCLARYS and monitor periodically during treatment. Manage lipid abnormalities according to clinical guidelines.

CONTRAINDICATIONS

None.

ADVERSE REACTIONS

Adverse reactions reported in 10% or more of patients and greater than placebo were elevated liver enzymes (AST/ALT) (37%), headache (37%), nausea (33%), abdominal pain (29%), fatigue (24%), diarrhea (20%), musculoskeletal pain (20%), oropharyngeal pain (18%), influenza (16%), vomiting (16%), muscle spasms (14%), back pain (13%), decreased appetite (12%), rash (10%).

DRUG INTERACTIONS

- Moderate or Strong CYP3A4 Inhibitors: Avoid concomitant use. Consider SKYCLARYS dosage reduction with monitoring if use is unavoidable.
- Moderate or Strong CYP3A4 Inducers: Avoid concomitant use.
- Hormonal Contraceptives: Counsel females to use an alternative contraceptive method (e.g., non-hormonal intrauterine system) or additional non-hormonal contraceptive (e.g., condoms) during concomitant use and for 28 days after discontinuation of SKYCLARYS.

This is not a complete list of potential drug interactions.

Specific Population: The effects on milk production and the breastfed infant are unknown. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for SKYCLARYS and any potential adverse effects on the breastfed infant from SKYCLARYS or from the underlying maternal condition.

To report SUSPECTED ADVERSE REACTIONS, contact Reata Pharmaceuticals, Inc. at 1-800-314-3934 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

INDICATION

SKYCLARYS is indicated for the treatment of Friedreich's ataxia in adults and adolescents aged 16 years and older.

For more information about SKYCLARYS, click here for full Prescribing Information.

US-SKY-2300055 v3.0

References: 1. Parkinson MH, Boesch S, Nachbauer W, Mariotti C, Giunti P. Clinical features of Friedreich's ataxia: classical and atypical phenotypes. *J Neurochem.* 2013;126(suppl 1):103-117. **2.** Fogel BL, Perlman S. Clinical features and molecular genetics of autosomal recessive cerebellar ataxias. *Lancet Neurol.* 2007;6(3):245-257. **3.** National Institute of Neurological Disorders and Stroke. Friedreich Ataxia Fact Sheet. November 15, 2021. Accessed March 16, 2022. https://www.ninds.nih.gov/Disorders/Patient-Caregiver-Education/Fact-Sheets/Friedreichs-Ataxia-Fact-Sheet. **4.** Skyclarys. Prescribing information. Reata Pharmaceuticals, Inc; 2023.

Intended for a US HCP audience.

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