

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

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

Please see Important Safety Information on pages 8 and 9, and full Prescribing Information and Patient Product Information.

Understanding Friedreich Ataxia

What is FA?

Friedreich ataxia (FA) is a rare, progressive disease that damages the nervous system, causing you to lose control of your muscles over time.

What causes FA?

FA happens when a specific gene, called the frataxin gene (or *FXN*), does not function properly and cannot help nerve cells work the way they should. Ultimately, this leads to irreversible cell death.



Less cellular energy



Increased cell stress



Inflammation



Cell death

When do symptoms begin?

The first signs of FA usually show up in childhood between the **ages of 10 and 15 years**, though symptoms may appear long before a diagnosis is made.

In its early stages, FA may cause you to feel clumsy or unbalanced and fall more often than usual. You may also notice that your feet and lower legs feel numb at times.

These are some of the most common early symptoms of FA:



Frequent falls



Feeling unbalanced



Loss of sensation



Tiredness

How is FA diagnosed?

A diagnosis of FA can be confirmed with a genetic test. It is important that the test include a Friedreich Ataxia Repeat Expansion Analysis.

Your doctor can provide additional information about the specific test needed.

Understanding Friedreich Ataxia (cont'd)

What happens as FA progresses?

As you get older, FA continues to damage nerve cells, which leads to greater difficulty with things like:





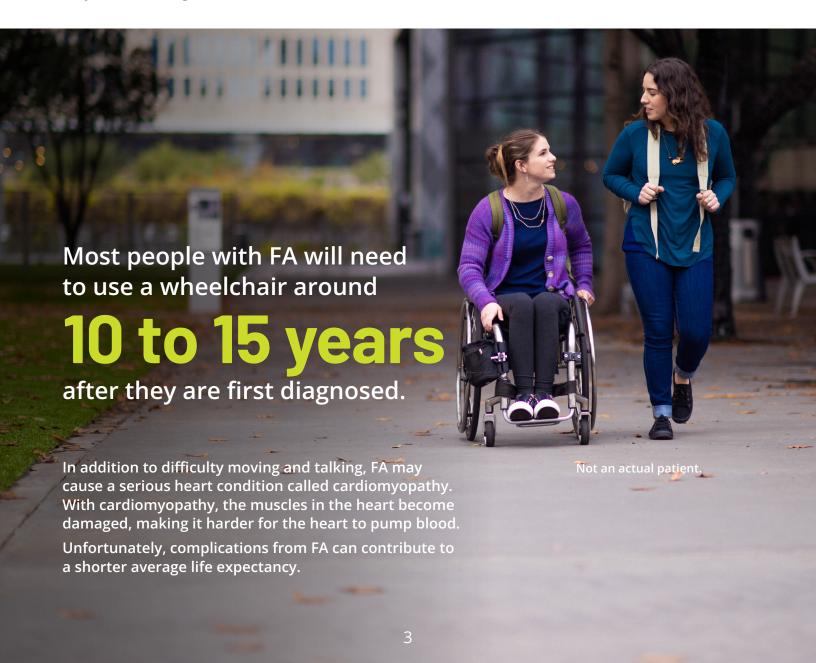




Talking

Fine motor skills

It is common for many patients to lose some of their ability to balance while standing even before they receive a diagnosis of FA.



Less Physical Impairment Over Time With SKYCLARYS

Understanding the modified Friedreich Ataxia Rating Scale (mFARS)

FA is a progressive disease. One way to measure progression is with the mFARS neurological exam. The mFARS is commonly used in clinical trials to evaluate how well potential treatments work. A lower mFARS score means less physical impairment, while a higher score means more severe symptoms.

The mFARS focuses on 4 key areas that relate to activities of daily living:

- Mouth and throat function
- ▶ Upper limb coordination
- Lower limb coordination
- Upright stability

Score range:

Average rate of progression:

Average score for wheelchair use:

0 to 93 points

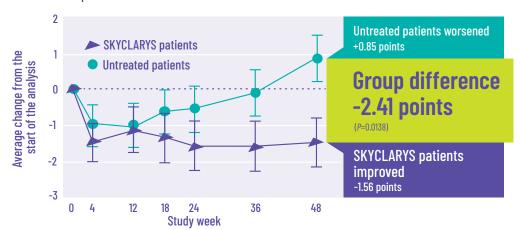
+2 points per year

~65 points

It is important to understand that the rate of FA progression will vary from person to person and that mFARS scores will change on an individual basis. For example, patients who are diagnosed at a younger age typically see their mFARS scores rise more quickly than older patients.

Slowing FA progression with SKYCLARYS

SKYCLARYS was tested against untreated patients in a 48-week clinical trial that included 103 patients with FA. At the end of the trial, patients who received SKYCLARYS showed an improvement in their mFARS scores compared with untreated patients.



SKYCLARYS may cause serious side effects, including:

- ➤ Increase in blood liver enzymes. 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

Please see Important Safety Information on <u>pages 8 and 9</u>, and full <u>Prescribing Information</u> and <u>Patient Product Information</u>.



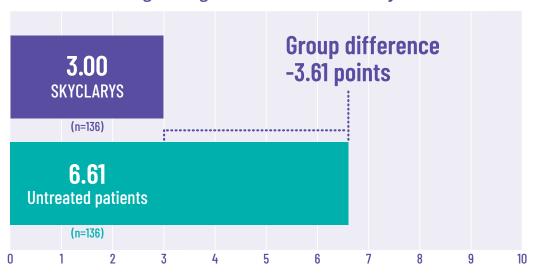
Less Physical Impairment Over Time With SKYCLARYS (cont'd)

Results of a 3-year follow-up study

People who took part in the clinical trial were given a chance to continue taking SKYCLARYS for a longer-term study called an open-label extension (OLE). Nearly all participants—98%—opted to continue in the OLE.

After 3 years, researchers conducted a follow-up study. They took the results from the OLE and compared them with untreated patients in a natural history study. This kind of study is called an "exploratory analysis," and is not the same as a clinical trial. Because of that, there are some limitations to the study and the results should be interpreted cautiously.

Average change in mFARS score after 3 years



Lower mFARS scores were observed in patients treated with SKYCLARYS after 3 years relative to a matched set of untreated patients from a natural history study.

SKYCLARYS may cause serious side effects, including:

- ➤ 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.
- ➤ Changes in cholesterol levels. Your healthcare provider will check your cholesterol levels before and during your treatment with SKYCLARYS.

Please see Important Safety Information on <u>pages 8 and 9</u>, and full <u>Prescribing Information</u> and <u>Patient Product Information</u>.



What to Expect With SKYCLARYS

What are the possible side effects of SKYCLARYS?

In the clinical trial, the most common side effects of SKYCLARYS were elevated liver enzymes, along with headache, nausea, stomach pain, and tiredness. Some people also experienced diarrhea, muscle aches, and pain in the mouth, throat, or neck. These are not all the possible side effects of SKYCLARYS. Call your doctor for medical advice about side effects.

Most common side effects*

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 aches and 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%

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

AST/ALT=aspartate aminotransferase/alanine aminotransferase.

Is there anything else I should know?

Tell your doctor if you experience any sudden changes in weight while taking SKYCLARYS, as this may be a sign of a serious heart condition.

Your doctor will continue to monitor your liver enzymes, as well as your cholesterol and levels of a certain protein in your blood, while taking SKYCLARYS.

Not an actual patient.



What to Expect With SKYCLARYS (cont'd)

How do I take SKYCLARYS?

SKYCLARYS is a once-daily oral treatment for FA.

Each SKYCLARYS capsule is 50 mg

The recommended dose is 150 mg



- ➤ Take SKYCLARYS exactly as your healthcare provider tells you to take it
- > SKYCLARYS should be taken on an empty stomach at least 1 hour before you eat
- 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

Are there any interactions I should know about?

It is important to avoid certain things when taking SKYCLARYS as they may change the amount of SKYCLARYS in your blood.



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.

Follow your doctor's instructions carefully when taking SKYCLARYS.



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.

- - 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.



IMPORTANT SAFETY INFORMATION (cont'd)

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 <u>www.fda.gov/medwatch</u> 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 <u>Prescribing Information</u> and <u>Patient Product Information</u>.

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The REACH (Reata Education, Access & Care Helpline) Patient Center

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.



REACH enrollment

Your doctor *must* complete and submit a Start Form before you can speak with a Care Navigator and 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 extra support offerings.*

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



Care Navigators

Once enrolled in REACH, **Care Navigators** will help you navigate your journey of starting and continuing with your SKYCLARYS prescription.

Care Navigators will be your primary point of contact for REACH and may provide answers to questions about your:

- Insurance and copays
- Copay assistance
- ➤ At-home prescription delivery
- Options to speak with a specialty pharmacist or nurse



Scan the QR code or visit **ReataREACH.com** to find support for getting access to SKYCLARYS.

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).



The REACH Patient Center (cont'd)



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.

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

- SKYCLARYS prescription
- Side-effect management
- 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 enrolled in REACH, you may speak with a **Care Navigator** who can help you explore your eligibility for affordability options by calling 1-844-98-REACH.

*Subject to eligibility and program terms and conditions. REACH affordability options are not healthcare insurance.





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Intended for a US audience.

