

**PATIENT INFORMATION**  
**SKYCLARYS® (skye klar' is)**  
**(omaveloxolone)**  
**capsules, for oral use**

**What is SKYCLARYS?**

SKYCLARYS is used for the treatment of Friedreich's 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.

**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.

**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 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.
- 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.

**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.

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

**How should I store SKYCLARYS?**

- Store SKYCLARYS at room temperature between 68°F to 77°F (20°C to 25°C)

**Keep SKYCLARYS and all medicines out of the reach of children.**

**General information about the safe and effective use of SKYCLARYS.**

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use SKYCLARYS for a condition for which it was not prescribed. Do not give SKYCLARYS to other people, even if they have the same symptoms you have. It may harm them. You can ask your healthcare provider or pharmacist for information about SKYCLARYS that is written for health professionals.

**What are the ingredients in SKYCLARYS?**

**Active ingredient:** omaveloxolone

**Inactive ingredients:** croscarmellose sodium, magnesium stearate, pregelatinized starch, silicified microcrystalline cellulose. The hard capsule shells contain FD&C Blue #1, ferric oxide yellow, hypromellose, titanium dioxide, and white edible ink.

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