PATIENT INFORMATION
SUNHARBO® (sun har boe)
(asundexian)
tablets, for oral use

What is Sunharbo?

Sunharbo is a prescription medicine used to lower the risk of stroke in adults with recent:

- stroke caused by a clot that blocks blood flow in the brain (ischemic stroke), **or**
- high-risk mini stroke (transient ischemic attack or TIA).

Sunharbo is not for strokes caused by clots that come from the heart.

Sunharbo should be used in combination with another medicine that helps prevent blood clots (antiplatelet medicine).

It is not known if Sunharbo is safe and effective in children.

Before taking Sunharbo, tell your healthcare provider about all your medical conditions, including if you:

- plan to have surgery or a medical or dental procedure. You should stop taking Sunharbo for at least 24 hours before any planned surgery or procedures.
- have liver problems.
- are pregnant or plan to become pregnant. It is not known if Sunharbo will harm your unborn baby.
  Females who are able to become pregnant:
  - Talk with your healthcare provider about pregnancy planning during treatment with Sunharbo.
  - If you are exposed to Sunharbo during pregnancy, talk to your healthcare provider and contact Bayer Healthcare Pharmaceuticals Inc. at 1-888-842-2937.
- are breastfeeding or plan to breastfeed. It is not known if Sunharbo passes into your breast milk. **Do not** breastfeed during treatment with Sunharbo and for 5 days after your last dose. Talk to your healthcare provider about the best way to feed your baby during treatment with Sunharbo.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Sunharbo may affect the way other medicines work, and other medicines may affect how Sunharbo 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 Sunharbo?

- Take Sunharbo exactly as your healthcare provider tells you to take it.
- Take Sunharbo 1 time a day, with or without food.
- Swallow Sunharbo tablets whole.
- If you cannot swallow Sunharbo tablets whole, talk to your healthcare provider about other ways to take Sunharbo.
- If you miss a dose of Sunharbo, take it as soon as possible on the same day. If it cannot be taken on the same day, skip the missed dose and take your next scheduled dose at your regular time.
- If you take too much Sunharbo, call your healthcare provider or go to the nearest hospital emergency room right away.

What are the possible side effects of Sunharbo?

The most common side effect of Sunharbo is diarrhea.

This is not the only possible side effect of Sunharbo.

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 Sunharbo?

- Store Sunharbo at room temperature between 68°F to 77°F (20°C to 25°C).
- Store Sunharbo in the original bottle.
- The bottle contains a drying agent (desiccant) to help keep the tablets dry. **Do not** remove the desiccant from the bottle.
- Sunharbo prepared in a syringe for feeding tube (nasogastric or gastric tube) dosing can be stored between 36°F to 86°F (2°C to 30°C) for up to 24 hours.

Keep Sunharbo and all medicines out of the reach of children.

General information about the safe and effective use of Sunharbo.

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

What are the ingredients in Sunharbo?
Active ingredient: asundexian
Inactive ingredients: croscarmellose sodium, magnesium stearate, and povidone. The film coating contains ferric oxide red, ferric oxide yellow, hypromellose, and polyethylene glycol 3350.

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For more information, go to www.sunharbo.com or call 1-888-842-2937.

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