Sunharbo (asundexian) explained: the first factor XIa inhibitor approved for secondary stroke prevention

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Short answer: on 9 November 2026 the US FDA approved Sunharbo (asundexian) 50 mg tablets, the first factor XIa (FXIa) inhibitor, for use with antiplatelet therapy to reduce stroke risk after a recent mild-to-moderate non-cardioembolic ischemic stroke or a high-risk transient ischemic attack (TIA). The agency says the OCEANIC-STROKE trial showed a 26% reduction in ischemic stroke against placebo. This explainer is for information, not clinical advice.

TL;DR The short version

- On 9 November 2026 the US FDA approved Sunharbo (asundexian), the first factor XIa inhibitor, with antiplatelet therapy after a recent mild-to-moderate non-cardioembolic stroke or high-risk TIA.
- The FDA says the OCEANIC-STROKE trial of 12,327 adults showed a 26% reduction in ischemic stroke against placebo.
- Overall major bleeding was similar but gastrointestinal bleeding was more common; this explainer is information, not clinical advice.

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What was approved?

The FDA announcement says Sunharbo is approved for adults, in combination with antiplatelet therapy, to reduce the risk of stroke after a recent mild-to-moderate non-cardioembolic ischemic stroke (a stroke from a clot that did not originate in the heart) or a high-risk TIA. It is not approved for stroke prevention in patients with atrial fibrillation. The FDA granted Fast Track and Priority Review, and the approval went to Bayer HealthCare Pharmaceuticals.

The evidence the FDA cites

- OCEANIC-STROKE was a multicentre, randomised, double-blind, placebo-controlled phase 3 study of 12,327 adults with a recent non-cardioembolic ischemic stroke (NIH Stroke Scale of 15 or less) or high-risk TIA.
- Participants were randomised to Sunharbo or placebo within 72 hours of symptom onset, and both groups also received antiplatelet therapy.
- Sunharbo 50 mg once daily reduced the risk of ischemic stroke by 26% compared with placebo over a median treatment of 14.2 months, according to the FDA.

Safety information in the announcement

- The overall rate of major bleeding was similar between groups, but was higher with Sunharbo in patients older than 75 and during the first 90 days of treatment.
- Gastrointestinal bleeding occurred more often with Sunharbo than placebo.
- The most frequent adverse reaction, in 3% or more of treated patients, was diarrhoea.
- Use with medicines that are both P-gp and strong CYP3A4 inducers, such as carbamazepine, is not recommended because they may reduce effectiveness. It is not recommended in moderate or severe hepatic impairment.
- It should be withheld at least 24 hours before elective surgery or invasive procedures, and for at least 24 hours after thrombolysis for acute ischemic stroke.

What is new compared with earlier approaches

The FDA describes this as the first approval of a factor XIa inhibitor, a new class for this indication, and as a “meaningful advance” for secondary stroke prevention, a quote attributed to Hylton V. Joffe of the agency’s drug centre. Existing options in the same setting are antiplatelet therapies; this approval is for use in combination with them.

Limitations and open questions

- The FDA announcement is a summary. Prescribing decisions depend on the full label, which was not part of what was read.
- The trial population was restricted to non-cardioembolic stroke or high-risk TIA of specific severity, within 72 hours; extending to others is not established by this approval.
- Bleeding trade-offs by age and time on treatment need individual risk assessment, and long-term data beyond the median 14.2 months are not in the announcement.

How clinicians can apply the information

1. Confirm the indication: recent non-cardioembolic ischemic stroke or high-risk TIA, with antiplatelet therapy, and not for atrial fibrillation stroke prevention.
2. Screen interacting medicines, in particular combined P-gp and strong CYP3A4 inducers, and assess liver function.
3. Weigh bleeding risk, with extra attention to age over 75 and the first 90 days.
4. Plan peri-procedural holds and review the full prescribing information.

What it means for practice

For stroke teams this adds a new class to discuss in secondary prevention pathways. For health-technology teams it is another reason to keep drug-interaction and procedure-hold rules in decision support up to date. Readers interested in acute stroke trials can see LATE-MT and MILD-MT.

Frequently asked questions

- **What is Sunharbo?** The brand name of asundexian 50 mg tablets, approved by the FDA on 9 November 2026.
- **What is a factor XIa inhibitor?** A new class of medicine; the FDA describes Sunharbo as the first approved in it.
- **Is it for atrial fibrillation?** No, the FDA says it is not approved for stroke prevention in atrial fibrillation.
- **How much did it reduce stroke?** The FDA says by 26% versus placebo over a median 14.2 months in OCEANIC-STROKE.

Related reading

- LATE-MT: thrombectomy 24 to 72 hours
- MILD-MT: thrombectomy for mild stroke
- Smartwatch hypertension detection

Sources and currency

Sources were read on 24 November 2026. Products, rules and standards change, so check the linked originals before you rely on any detail. This is general information and not medical advice.

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Sources and further reading

1. US Food and Drug Administration. FDA Approves First Factor XIa Inhibitor to Help Prevent Stroke in Certain Adults at High Risk. 9 November 2026. fda.gov/news-events/press-announcements/fda-approves-first-factor-xia-inhibitor-help-prevent-stroke-certain-adults-high-risk.

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