Sovateltide

Also called: IRL-1620; IRL 1620; PMZ-1620; SPI-1620; Tycamzzi

What it is

An endothelin-B receptor agonist peptide (Tycamzzi) approved in India in 2023 for ischaemic stroke; not FDA-approved; a 514-patient phase 3 is recruiting.

Approval status

Not FDA Approved. Approved in India in May 2023 for cerebral ischaemic stroke within 24 hours of onset (PubMed 37486545). Not FDA-approved: openFDA's Drugs@FDA index returns no record (searched October 3, 2026). A 514-patient phase 3 (NCT05691244) is recruiting (ClinicalTrials.gov, read October 3, 2026).

Dosing, as printed in the page's Recommended Dosing box

Used in human trials

No manufacturer dose exists for this use: these are amounts given in published trials, not recommendations.

Protocol and source	Dose	Frequency	Duration	Route
Trial: acute ischaemic stroke within 24 hours (phase 3, India) **[Human study]** PMID 39542995	0.3 µg/kg per dose	Three doses 3 hours apart on days 1, 3 and 6	One week	Intravenous

Educational information, not medical advice. Each dose above is tagged with its source: an approved label, a published human study, animal data, or amounts reported by users. None is a recommendation for you. An unapproved compound has no established safe or effective human dose, and products sold for "research use only" are not made or tested for people. Talk to a doctor before acting on anything on this site, including before you start, stop or change any medicine or dose.

Key human evidence

The first 3 of the 4 human studies carded on the page (11 study cards in all):

- **Phase 3 in ischaemic stroke** (Human, 2024). In 158 randomised patients, mRS 0-2 at day 90 was more frequent with sovateltide (OR 2.75, 95% CI 1.37-5.57), as was NIHSS 0-5 (OR 2.67); 72.50% vs 51.28% improved by 2 or more mRS points; intracranial haemorrhage 8.75% vs 8.97%. **PMID 39542995**
- **Phase 2 in ischaemic stroke** (Human, 2021). In 40 patients, sovateltide was well tolerated with no drug-related adverse events; mRS improvement of 2 or more points occurred in 60% vs 40% (p = 0.0519) and Barthel Index gains of 40 or more in 64% vs 36% (p = 0.0112). **PMID 33428177**
- **Routine care in India** (Human, 2026). In a prospective observational study at one Indian hospital, stroke patients given sovateltide as part of routine care had better functional score distributions at 30, 60 and 90 days than those on standard therapy alone; the authors stress the findings are associations, not causation. **PMID 41731809**

Interactions

A PubMed search for interaction studies of this compound with any drug (October 3, 2026, 13 records) found none in people. That is not evidence that it is safe to combine with anything.

Side effects and cautions

Reported side effects	Contraindications and cautions
• No drug-related adverse events in the 40-patient phase 2 stroke trial • Intracranial haemorrhage at a similar rate to placebo in phase 3 (8.75% vs 8.97%) • Febrile neutropenia and neutropenia when combined with docetaxel in cancer	• Intracranial haemorrhage • Recurrent stroke • Patients receiving endovascular therapy

Five questions to ask

1. Sovateltide is listed here as "Not FDA Approved". What does the evidence on this sheet mean for someone in my situation, and is there an approved treatment I should consider instead?
2. Here are the medicines and supplements I take. Do any of them interact with Sovateltide? This sheet records none published, which does not mean none exist.
3. Which side effects should make me stop and call you, for example no drug-related adverse events in the 40-patient phase 2 stroke trial?
4. Do any of the cautions on this sheet apply to me, such as: Intracranial haemorrhage?
5. What should we check before I start and while I am on it (blood tests, blood pressure, weight), and how often?

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