Solnatide

Also called: AP301; AP-301; TIP peptide; TIP-peptide; Solnatida

What it is

Solnatide (AP301, the TIP peptide) is a cyclic 17-residue copy of TNF's lectin-like domain that binds the alpha subunit of the epithelial sodium channel and holds it open, speeding clearance of fluid from the air sacs (PMIDs 24077967, 25029038). Inhaled, it missed the primary measurements of its phase 2a ARDS trial and a COVID-19 ARDS pilot (PMIDs 28750677, 40280364), while a 20-patient transplant pilot reported shorter ventilation (PMID 29055604). It is approved nowhere.

Approval status

In Clinical Trials. Not approved anywhere. Drugs@FDA (openFDA) holds no application for solnatide or AP301 (searched November 4, 2026). FDA granted orphan designation on February 8, 2016 for generalized systemic pseudohypoaldosteronism type 1, and the EU register holds EU/3/15/1549 (primary graft dysfunction after lung transplantation, October 9, 2015) and EU/3/15/1591 (pseudohypoaldosteronism type 1B, December 14, 2015). The phase 2a ARDS trial missed its primary endpoint (PMID 28750677) and the phase 2b trial NCT03567577 completed in December 2024 with no results posted.

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
Study: COVID-19 ARDS pilot trial **[Human study]** PMID 40280364	100 mg	Twice a day	7 days	Inhaled (nebulised)
Study: first-in-man single doses in healthy men **[Human study]** PMID 24515273	Single doses up to 120 mg	Once	Single dose	Inhaled (nebulised)

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 7 human studies carded on the page (29 study cards in all):

• **First study in people: single inhaled doses** (Human, 2014). Forty-eight healthy men were randomised in six ascending dose groups, up to a single 120 mg inhalation, three on drug for each on placebo. Everyone completed the protocol. There were no serious, local or dose-limiting adverse events, and spirometry, exhaled nitric oxide, vital signs, ECG and laboratory tests showed no pattern by dose or time. Peak blood levels stayed below 2.5 ng/mL even in the highest groups, which the authors read as the drug staying largely in the lung. **PMID 24515273**

• **Phase 2a in ARDS: no change in lung water** (Human, 2017). Forty ventilated adults with ARDS were randomised to inhaled drug or saline twice daily for seven days. The main measurement, baseline-adjusted change in extravascular lung water index by thermodilution, did not differ between groups (p = 0.196), and neither did oxygenation, ventilation pressures, lung injury score or 28-day mortality. Inhalation was well tolerated. A post-hoc subgroup of patients with a baseline SOFA score of 11 or more showed less lung water and lower ventilation pressures, which the authors presented as a hypothesis for later trials. **PMID 28750677**

• **Pilot study after lung transplantation** (Human, 2017). Twenty recipients who developed primary graft dysfunction after a first lung transplant were randomised one to one to nebulised drug or placebo twice daily for up to seven days. Oxygenation improved more in the treated group by 72 hours (p = 0.049), and intubation was shorter, about two days against nearly four (p = 0.02). Intensive care stay trended shorter without reaching significance, everyone survived 30 days, and no severe adverse events were recorded. The authors stress that a 20-patient pilot was not powered for firm conclusions. **PMID 29055604**

Interactions

A PubMed search for interaction studies of this compound with any drug (November 4, 2026, 0 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 serious, local or dose-limiting adverse events in 48 healthy men given single inhaled doses, including no hoarseness, cough or bronchospasm (PMID 24515273) • Inhalation described as well tolerated in the 40-patient phase 2a ARDS trial, with no difference in 28-day mortality (PMID 28750677) • No severe adverse events and 100% survival at 30 days in the 20-patient lung transplant pilot (PMID 29055604) • In the COVID-19 ARDS pilot, adverse and serious adverse events occurred in both arms and none was judged related to the study drug (PMID 40280364) • Very little of the peptide reaches the bloodstream after inhalation, with peak levels under 2.5 ng/mL at the highest doses tested (PMID 24515273)	• Only inside a clinical trial: it is approved nowhere and is not a product anyone can be prescribed • Not shown to help the main outcome of any completed placebo-controlled trial; the positive findings are from a 20-patient pilot and post-hoc subgroups • Its mechanism needs living alveolar lining cells, and in a pig model where that lining was destroyed the benefit disappeared (PMID 24070340) • No effect at all in a severe viral pneumonia model in mice (PMID 25047452) • Children, pregnancy and breastfeeding were excluded from the trials

Five questions to ask

1. Solnatide is listed here as "In Clinical Trials". 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 Solnatide? 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 serious?
4. Do any of the cautions on this sheet apply to me, such as: Only inside a clinical trial: it is approved nowhere and is not a product anyone can be prescribed?
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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