Tifuvirtide

Also called: T-1249; T1249

What it is

Tifuvirtide (T-1249) is a 39-amino-acid synthetic peptide from HIV-1 gp41 that blocks the virus from fusing with cells. In a 115-patient phase 1/2 study, daily subcutaneous doses up to 192 mg lowered viral load by a median 1.96 log10 at the top dose over 14 days, with injection-site reactions in 57% (PMID 14999611); in 53 adults failing an enfuvirtide-containing regimen it cut viral load by a median 1.26 log10 over ten days, their virus being 116-fold less susceptible to enfuvirtide but only 2-fold less susceptible to this peptide (PMID 15747252). Over 48 weeks the effect faded and susceptibility fell about ninety-fold (PMID 18184079). Development was discontinued in 2004, which a later class review attributes to a formulation problem (PMID 23092277); it was never approved anywhere.

Approval status

Discontinued. Never approved. Drugs@FDA and the openFDA label endpoint return no record for tifuvirtide or T-1249, and the European Medicines Agency's medicines database holds no entry (both read November 4, 2026). ClinicalTrials.gov lists a single study, Trimeris's phase 1/2 rollover study NCT00048217, last updated in 2005. A 2004 note in AIDS Reviews records the discontinuation of clinical development (PMID 15168742) and a 2013 review of the class attributes the halt to a formulation problem (PMID 23092277).

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: dose escalation in treatment-experienced adults **[Human study]** PMID 14999611	6.25 to 192 mg/day	Daily	14 days	Subcutaneous
Trial: adults with virus replicating on enfuvirtide **[Human study]** PMID 15747252	192 mg/day	Daily	10 days, continued to 48 weeks in the rollover study	Subcutaneous

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 3 human studies carded on the page (23 study cards in all):

• **First study in people: 115 adults, 14 days, dose escalation** (Human, 2004). An open-label phase 1/2 study gave the peptide alone, by injection under the skin, to 115 adults with HIV-1 for two weeks at daily doses from 6.25 mg to 192 mg. The group was heavily treated, with a median CD4 count of 57 cells per microlitre and a median of eleven previous antiretroviral drugs. No dose-limiting toxicity appeared. Viral load fell further at higher doses: the median largest fall from baseline ranged from 0.29 log10 copies/mL in the lowest dose group to 1.96 log10 in the highest. Injection-site reactions were the most common adverse event, in 57% of participants. **PMID 14999611**

• **Adults whose virus had escaped enfuvirtide: 53 patients, 10 days** (Human, 2005). Adults with detectable virus while taking an enfuvirtide-containing regimen replaced enfuvirtide with 192 mg of this peptide daily and left the rest of the failing regimen in place. Measured against the susceptibility of fusion-inhibitor-naive virus, their isolates were 116-fold less susceptible to enfuvirtide but only 2-fold less susceptible to the new peptide. Over ten days the median viral load fell by 1.26 log10 copies/mL, and 73% of patients fell by at least one log. Neither baseline susceptibility measure predicted who responded. Injection-site reactions, mostly mild, occurred in 64%. **PMID 15747252**

• **A year of dosing: the early gain faded and resistance accumulated** (Human, 2007). Patients who had completed the ten-day study rolled over into continued dosing, with envelope genotype and phenotype measured at weeks 8, 16 and 48. The median viral load fall was about 1.5 log10 copies/mL at week two but only about 0.5 log10 at 48 weeks. Susceptibility drifted from 1.8-fold to about 93-fold below the fusion-inhibitor-naive baseline, alongside further change in gp41 residues 36 to 45, most often G36D or N43K, with a substitution at position 50 in about a third of patients and some changes in the second heptad repeat. **PMID 18184079**

Interactions

A PubMed search for interaction studies of this compound with any drug (November 4, 2026, 1 record) 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
• Injection-site reactions in 57% of 115 patients in the first study, and in 64% of 53 patients in the second, where they were described as generally mild (PMIDs 14999611, 15747252) • No dose-limiting toxicity was identified up to 192 mg a day over 14 days (PMID 14999611) • Loss of effect with continued dosing: the viral load fall shrank from about 1.5 log10 at week two to about 0.5 log10 at 48 weeks as resistance accumulated (PMID 18184079) • No study examined it beyond 48 weeks, and none enrolled children, pregnant women or people without HIV	• Not a medicine anywhere: no regulator has reviewed it and no phase 3 trial was ever run • Never given to anyone without HIV-1 infection in any study read, and never tested as prevention in people • Nothing is known about its use with other drugs in people; the only interaction work is a cell experiment combining it with other fusion inhibitors (PMID 19493996) • Tested athletes: see the Sport (WADA) row below

Five questions to ask

1. Tifuvirtide is listed here as “Discontinued”. 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 Tifuvirtide? This sheet records none published, which does not mean none exist.
3. Which side effects should make me stop and call you, for example injection-site reactions in 57% of 115 patients in the first study?
4. Do any of the cautions on this sheet apply to me, such as: Not a medicine anywhere: no regulator has reviewed it and no phase 3 trial was ever run?
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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