Setmelanotide

Approved human use · product-specific labels.



Guide prepared November 13, 2026 · profile review dates retained

KEEP IN MIND Evidence applies to the studied formulation, route, population and outcome—not every product sharing a name.

01 What is it?

Setmelanotide activates the melanocortin-4 receptor, part of the brain circuitry regulating hunger. IMCIVREE has narrowly defined uses in particular genetic obesity disorders and acquired hypothalamic obesity. It is not an approved treatment for general obesity. [1]

02 Potential benefits

Can reduce hunger and weight in specifically eligible rare-disease populations. Targets the MC4 receptor pathway. [1]

03 Evidence & its limits

Eligibility depends on the diagnosis and label. Warnings include depression and suicidal ideation, changes in pigmentation and moles, and sexual arousal effects. The acquired hypothalamic obesity population has additional concerns involving adrenal insufficiency and sodium imbalance. [1]

04 Risks & unknowns

Not approved for general obesity. Skin pigmentation changes, sexual effects, and mood-related warnings matter. [1]

05 Status & scope

IMCIVREE has narrowly defined uses in specified genetic obesity disorders and acquired hypothalamic obesity. It is not approved for general obesity; eligibility depends on the current label. [1]

06 The question to ask

Does the evidence match the exact product, route, condition and outcome being discussed? Check the full record and its review dates. This summary is selective; the product label and clinical assessment contain additional warnings and contraindications.

SOURCES / Tap a reference to open

[1] Full evidence record, references and review dates
[2] FDA Drugs@FDA database
[3] IMCIVREE 2026 prescribing information
[4] FDA initial approval announcement

Selective educational summary, not treatment or dosing advice. Existing profile review dates retained; no independent clinical review.