

For people 4 years and older

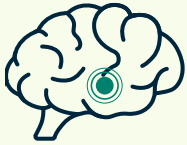
IMCIVREE works where acquired HO starts—inside the brain

IMCIVREE is the first and only treatment designed to reduce weight and hunger in people living with acquired hypothalamic obesity (HO).

What is acquired HO?

Acquired HO is a unique condition that begins when a brain tumor or injury affects part of the brain called the hypothalamus and results in weight gain that continues over time.

Injury to the hypothalamus can permanently damage the melanocortin-4 receptor (MC4R) pathway, which regulates hunger, fullness, and metabolic rate (calorie use).



Only IMCIVREE targets MC4R pathway impairment in the brain, the root cause of weight gain and hunger in people living with acquired HO.

How was IMCIVREE studied?

IMCIVREE was studied over the course of 1 year in a clinical study that included 142 children and adults aged 4 years and older with acquired HO. People were randomly assigned to receive IMCIVREE or a placebo (meaning they were not treated with IMCIVREE).

What is IMCIVREE?

IMCIVREE is a prescription medicine used in adults and children 4 years of age and older with acquired hypothalamic obesity (HO) to help them lose weight and keep the weight off.

IMCIVREE is not for use in people with the following conditions because it may not work:

- Other types of obesity not related to acquired HO or other FDA-approved uses of IMCIVREE, including obesity associated with other genetic conditions and general obesity

It is not known if IMCIVREE is safe and effective in children under 4 years of age with acquired HO.

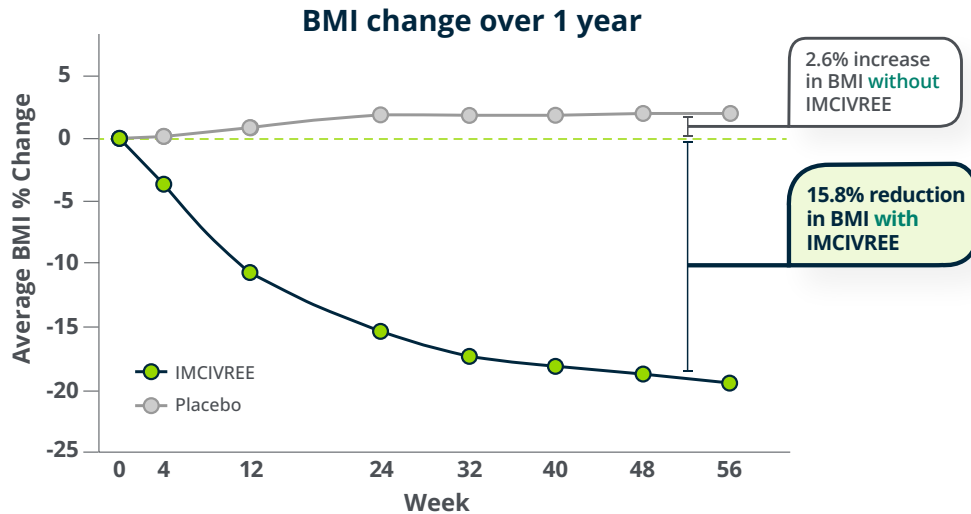
Important Safety Information

Do not use IMCIVREE if you have had a serious allergic reaction to it or any of its ingredients. Serious allergic reactions, including anaphylaxis, can happen.

Please see Important Safety Information throughout, and [full Prescribing Information](#) and [Patient Information](#).

Significant weight reduction with IMCIVREE

After 1 year, adults and children 4 years and older taking IMCIVREE saw a reduction in body mass index (BMI), while those not taking IMCIVREE (placebo) saw an increase.



18.4%
average BMI
reduction compared
with those not
taking IMCIVREE
after 1 year
Results were consistent
across age groups.

Significant hunger reduction in people taking IMCIVREE compared with people not taking IMCIVREE



**Greater hunger
reduction
with IMCIVREE**

After 1 year, **people 12 years and older taking IMCIVREE saw a larger drop in hunger scores** (2.3 points with IMCIVREE vs 1.4 points without IMCIVREE, a difference of 0.8 points).

How hunger was measured in the study: People in the study completed a daily hunger questionnaire from the start of the study through 1 year. They rated their hunger on a scale from 0 to 10, with 10 being the hungriest possible and 0 meaning not hungry at all.

Important Safety Information (cont'd)

Before you use IMCIVREE, tell your healthcare provider about all your medical conditions, including if you:

- Have or have had areas of darkened skin, including skin discoloration (hyperpigmentation)
- Have or have had depression, or suicidal thoughts or behavior
- Have kidney problems

Please see Important Safety Information throughout, and [full Prescribing Information](#) and [Patient Information](#).

Most common side effects of IMCIVREE

These side effects include:

- Darkening of the skin (hyperpigmentation)
- Injection site reactions
- Nausea
- Headache
- Diarrhea
- Stomach pain
- Vomiting
- Depression
- Erection that happens without any sexual activity in males

These are not all the possible side effects of IMCIVREE. Call your doctor for medical advice about side effects.

Skin changes with IMCIVREE

A general darkening of the skin (hyperpigmentation) is expected because of how IMCIVREE works. Darkening of the skin went away after people stopped using IMCIVREE. You should have a full-body skin exam before starting and during treatment with IMCIVREE to check for skin changes.

If you have adrenal insufficiency and/or diabetes insipidus (also called arginine vasopressin deficiency), talk to your healthcare provider. Please see additional Important Safety Information.

Personalized support along the IMCIVREE journey

Rhythm InTune Patient Education Managers (PEMs)* can help you:



Understand your insurance coverage



Get started on Rhythm treatment



Access educational resources



Connect to a community

Rhythm
InTune

CLICK OR SCAN
TO CONNECT
WITH A PEM



*Patient Education Managers are employees of Rhythm Pharmaceuticals and do not provide medical care or advice. We encourage you to always speak to your healthcare providers regarding your medical care.

Important Safety Information (cont'd)

Before you use IMCIVREE, tell your healthcare provider about all your medical conditions, including if you: (cont'd)

- Are pregnant or planning to become pregnant. Losing weight while pregnant may harm your unborn baby. Your healthcare provider may stop your treatment with IMCIVREE if you become pregnant. Tell your healthcare provider if you become pregnant or think you might be pregnant during treatment with IMCIVREE
- Are breastfeeding or plan to breastfeed. It is not known if IMCIVREE passes into your breast milk. You should not breastfeed during treatment with IMCIVREE

Please see Important Safety Information throughout, and [full Prescribing Information](#) and [Patient Information](#).

Talk to your doctor and visit aHO.IMCIVREE.com for more information on IMCIVREE and acquired HO.

Important Safety Information (cont'd)

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

See the detailed Instructions for Use that come with your IMCIVREE to learn how to prepare and inject IMCIVREE, and how to properly throw away (dispose of) used syringes and needles.

What are the possible side effects of IMCIVREE?

IMCIVREE may cause serious side effects, including:

- **Male and female sexual function problems.** IMCIVREE can cause an erection that happens without any sexual activity in males (spontaneous penile erection) and unwanted sexual reactions (changes in sexual arousal that happen without any sexual activity) in females. If you have an erection lasting longer than 4 hours, get emergency medical help right away
- **Depression and suicidal thoughts or actions.** You or a caregiver should call your healthcare provider right away if you have any new or worsening symptoms of depression, suicidal thoughts or behaviors, or any unusual changes in mood or behavior
- **Serious allergic reactions.** Stop taking IMCIVREE and get medical help right away if you have any symptoms of a serious allergic reaction including: swelling of your face, lips, tongue, or throat; problems breathing or swallowing; severe rash or itching; fainting or feeling dizzy; rapid heartbeat
- **Increased skin pigmentation, darkening of skin lesions (moles or nevi) you already have, and development of new skin lesions.** These changes happen because of how IMCIVREE works in the body

and will go away when you stop using IMCIVREE. You should have a full body skin exam before starting and during treatment with IMCIVREE to check for skin changes

- **Adrenal insufficiency.** If you have acquired HO and adrenal insufficiency, your healthcare provider should evaluate your adrenal function before starting IMCIVREE. You or your caregiver should call your healthcare provider if you have changes in feeling tired or exhausted (fatigue), lack of energy (lethargy), mental status, or dizziness, or fever, or signs of infection during treatment with IMCIVREE. Your healthcare provider should monitor and adjust any medicines that may be affected during treatment
- **Low sodium levels in the blood.** If you have acquired HO and diabetes insipidus, you or your caregiver should watch for signs of dehydration. You or your caregiver should contact your healthcare provider if you have changes in fluid intake or urine output, confusion, lethargy, or nausea and vomiting during treatment with IMCIVREE. Your healthcare provider should closely monitor sodium levels in your blood and adjust your other medicines if needed

The most common side effects of IMCIVREE

include darkening of the skin, injection site reactions, nausea, headache, diarrhea, stomach pain, vomiting, depression, and an erection that happens without any sexual activity in males.

These are not all the possible side effects of IMCIVREE. Call your doctor for medical advice about side effects. You are encouraged to report negative side effects of prescription drugs to FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

Please see Important Safety Information throughout, and [full Prescribing Information](#) and [Patient Information](#).