



# IMCIVREE<sup>®</sup>

setmelanotide injection

**IMCIVREE** is used to manage weight in adults and children aged 6 and older with obesity due to POMC, PCSK1 or LEPR deficiency.

POMC = pro-opiomelanocortin, PCSK1 = proprotein convertase subtilisin/kexin type 1, LEPR = leptin receptor

**IMCIVREE<sup>®</sup>**  
setmelanotide injection

For more information, please see Important Safety Information on page 11 or refer to the Patient Medication Information in the Product Monograph.

**Rhythm<sup>®</sup>**  
PHARMACEUTICALS



Actor portrayals.

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# What is POMC, PCSK1 or LEPR Deficiency?

POMC, PCSK1 or LEPR deficiency are rare genetic conditions that cause changes in the brain, which can lead to obesity.



These conditions occur when both copies of the relevant gene (one inherited from the mother and one from the father) have a specific change, or variant.

## POMC deficiency

POMC stands for  
pro-opiomelanocortin

## PCSK1 deficiency

PCSK1 stands for  
proprotein convertase  
subtilisin/kexin type 1

## LEPR deficiency

LEPR stands for leptin  
receptor

**A change in the *POMC* gene**  
(POMC deficiency)

**A change in the *PCSK1* gene**  
(PCSK1 deficiency)

**A change in the *LEPR* gene**  
(LEPR deficiency)



Severe obesity  
early in life



Intense hunger

In people with obesity due to POMC, PCSK1 or LEPR deficiency, these genetic changes affect how the brain controls feelings of hunger, which can lead to weight gain.

People living with POMC, PCSK1 or LEPR deficiency may experience intense, hard-to-control hunger. This feeling is not their fault. Changes in POMC, PCSK1 or LEPR genes can stop a key area of the brain that controls hunger from working properly.

The key area of the brain that communicates being hungry or satisfied is known as the hypothalamus.



Think of the hypothalamus as a neighborhood within the brain.



In this neighborhood, there are roads that allow trucks to travel to and from the brain. One road is called the melanocortin-4 receptor, or **MC4R** pathway.



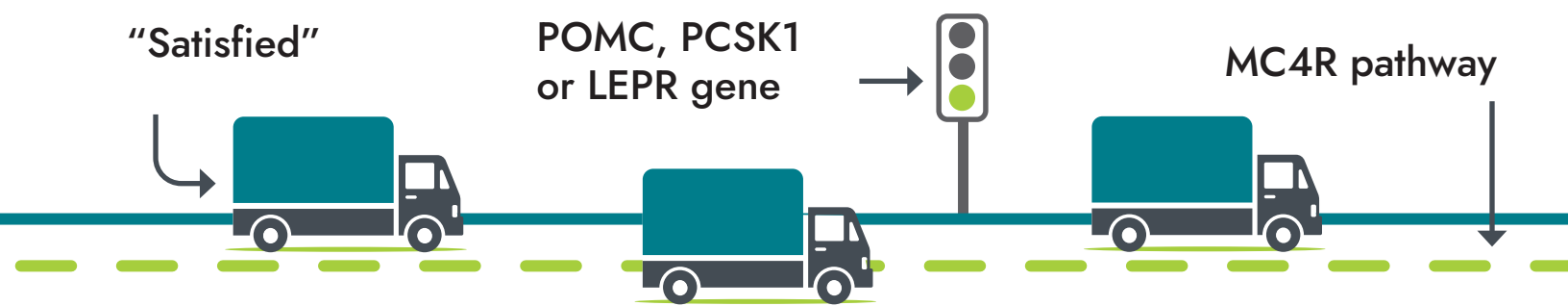
The trucks on this road deliver messages between the body and the brain. These messages control hunger.



On this road, there is a traffic light, or POMC, PCSK1 or LEPR genes, that helps guide the trucks to deliver their messages.

# What causes hunger and obesity in POMC, PCSK1 or LEPR deficiency?

In people living with POMC, PCSK1 or LEPR deficiency, the signals that turn hunger “off” don’t work correctly in the brain.

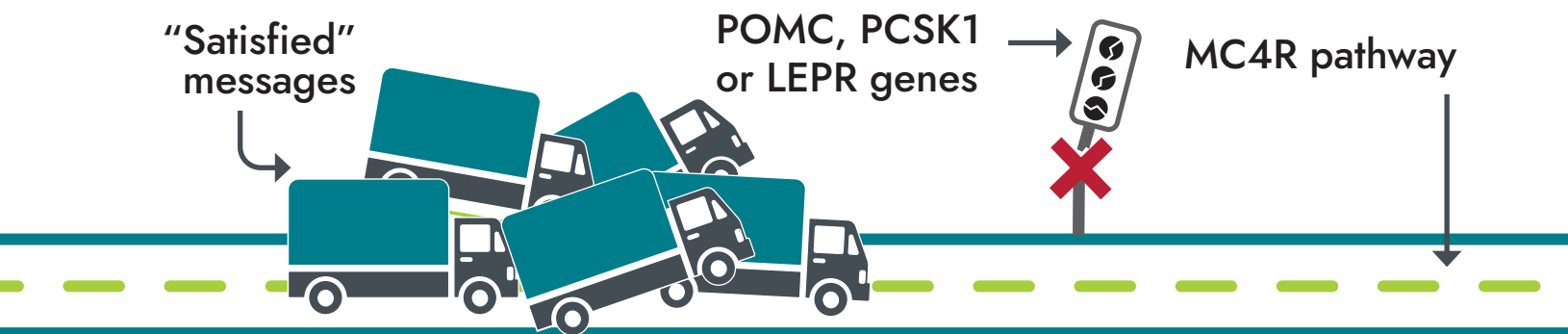


When the POMC, PCSK1 or LEPR gene is normal, without a variant (or change), the traffic light works correctly. The road (MC4R pathway) is open, and the trucks can deliver messages to the brain that the body is satisfied and doesn’t need more food.

## How does IMCIVREE work?

IMCIVREE is designed to re-establish function to the “road” (MC4R pathway) so trucks can deliver messages to the brain that the body is satisfied.

In people living with POMC, PCSK1 or LEPR deficiency, the traffic light is broken due to the **change in the POMC, PCSK1 or LEPR genes**



When the POMC, PCSK1 or LEPR genes have variants (or change), the traffic light is broken, which causes a traffic jam. The trucks can no longer travel along the road (MC4R pathway) to properly deliver messages to the brain that the body is satisfied and doesn't need more food. Instead, the body believes that it's still hungry.



Think of IMCIVREE as a traffic officer. When the traffic light is broken, the traffic officer directs trucks on the road (MC4R pathway), allowing them to deliver messages to the brain that the body is satisfied and doesn't need more food.

This is how IMCIVREE works to help the pathway work properly.



## What are the possible side effects of IMCIVREE?

Side effects from using IMCIVREE include:

- ◆ Injection site reactions
- ◆ Stomach (belly) pain
- ◆ Weakness
- ◆ Nausea
- ◆ Headache
- ◆ Dizziness
- ◆ Throwing Up
- ◆ Back Pain
- ◆ Dry Mouth
- ◆ Diarrhea
- ◆ Fatigue

Contact your healthcare professional if you are experiencing side effects.

**Taking IMCIVREE may cause a general darkening of the skin (hyperpigmentation).**



**Before IMCIVREE**



**During IMCIVREE treatment**



**After stopping IMCIVREE**

*Example of hyperpigmentation*

- ◆ IMCIVREE may also cause darkening of existing skin growth, such as moles or spots on the skin.
- ◆ These changes happen because of how IMCIVREE works in the body and will usually go away when you stop using IMCIVREE.
- ◆ Your healthcare professional will check your skin before starting and during your treatment with IMCIVREE.

These are not all the possible side effects of IMCIVREE. Please review all the possible side effects of IMCIVREE in the Patient Information and talk to your healthcare professional about any questions you may have.

## Other warnings you should know about:

- ◆ **Sexual problems:** IMCIVREE can cause unwanted sexual reactions in both men and women. Men had erections at times other than sex (spontaneous penile erection) with IMCIVREE. If you have an erection lasting more than 4 hours, **get medical help right away.**
- ◆ **Mental health problems:** IMCIVREE may cause new or worsening symptoms of depression, suicidal thoughts or behaviors, or any unusual changes in your mood or behavior. Call your healthcare professional right away if your mental health changes in unexpected ways, and if you become suicidal (think about harming or killing yourself or plan or try to do so).
- ◆ **Skin problems:** IMCIVREE may change your skin colour. This includes darkening of your skin or skin lesions (moles or spots on the skin), you already have. These changes happen because of how IMCIVREE works in the body and will usually go away when you stop using IMCIVREE. Your healthcare professional will check your skin before starting and during your treatment with IMCIVREE.

## Children:

- ◆ **Do not give** IMCIVREE to children younger than 6 years old since IMCIVREE has NOT been approved for use in children below this age.
- ◆ Benzyl alcohol is a preservative in IMCIVREE. Benzyl alcohol can cause serious side effects, including death, in premature and low-birth weight infants who have received medicines that contain benzyl alcohol. Do not give IMCIVREE to a newborn or infant.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

## The following may interact with IMCIVREE:

No relevant drug-drug interactions are known. Inform your healthcare professional of any other medications you are taking.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take IMCIVREE. Talk about any health conditions or problems you may have, including if you:

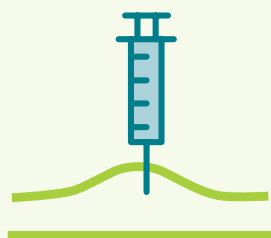
- ◆ Have or have had any of the following conditions:
  - areas of darkened skin, including skin discoloration (hyperpigmentation).
  - depression, mood problems, suicidal thoughts or behaviour problems.
  - kidney or liver problems.
- ◆ Are pregnant or planning to become pregnant. Losing weight while pregnant will harm your unborn baby. Your healthcare professional will stop your treatment with IMCIVREE if you become pregnant. Tell your healthcare professional 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 breastmilk. You should not breastfeed during treatment with IMCIVREE.



# How is IMCIVREE given?

IMCIVREE is a once-daily injection used to help reduce weight in people living with POMC, PCSK1 or LEPR deficiency.

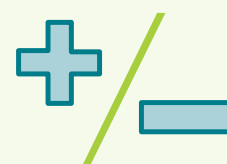
IMCIVREE is given:



As an injection  
under the skin of your  
belly (stomach) area



One time each day when you  
first wake up. IMCIVREE may  
be given at home



With or  
without food

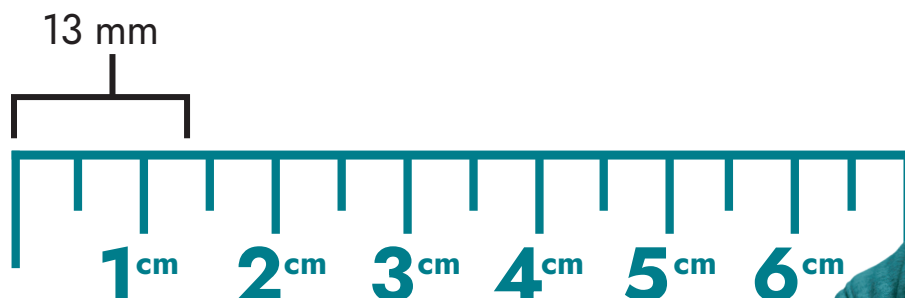
Do not try to inject IMCIVREE at home unless you have been trained by a healthcare professional.

You should use a different injection site each time you give an injection, at least 1 inch away from the area you used for your previous injection, and 2 inches away from your belly button. You may want to use a calendar or diary to record your injection sites.

Please refer to the **Patient Medication Information** in the **Product Monograph** for injection instructions.

Because IMCIVREE is injected under the skin, the needle is short and thin:

- ◆ The IMCIVREE needle is 6 to 13 mm in length



Please see the [How to Give IMCIVREE Guide](#) for illustrated, step-by-step instructions for giving an IMCIVREE injection. You can also refer to the [Patient Medication Information](#) in the [Product Monograph](#) for injection instructions.



Actor portrayal.



## Your source for personalized support

Rhythm InTune is a support program designed for caregivers and people living with rare genetic diseases of obesity, including POMC, PCSK1 or LEPR deficiency.

If you're interested in speaking with the Rhythm InTune Program about the education and support Rhythm InTune can offer you or the person you care for, you can email or call us at:



[imcivree@bayshore.ca](mailto:imcivree@bayshore.ca)



1-833-654-2155

Fax: 1-833-350-3887

## What can Rhythm InTune do for you?

Rhythm provides resources, education, and information tailored to fit the unique needs of people living with rare genetic diseases of obesity, including POMC, PCSK1 or LEPR deficiency.

**Rhythm InTune can help you:**



Understand your  
insurance coverage



Access resources



Get started on  
IMCIVREE

Your Rhythm InTune Program is affiliated with Rhythm Pharmaceuticals and does not provide medical care or advice. We encourage you to always speak to your healthcare professional regarding your medical care.



Actor portrayals.

# Getting started on IMCIVREE

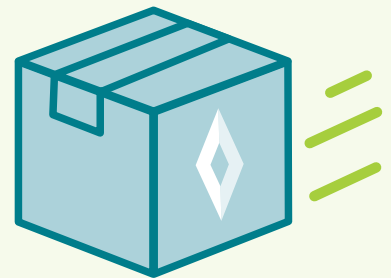
## Learning to inject IMCIVREE

Injection training is offered before you start IMCIVREE. Training can be given by your healthcare professional or coordinated through Rhythm InTune.



## Starting on IMCIVREE

Home delivery of IMCIVREE is available through Bayshore Specialty Pharmacy, or Rhythm InTune can work with your pharmacy of choice. You should start IMCIVREE at your starting dose as directed by your healthcare professional.



**Rhythm InTune provides personalized support and educational resources and programs throughout treatment to help you start and stay on IMCIVREE.**

## Staying on IMCIVREE

Your healthcare professional will regularly check how well IMCIVREE is working and may adjust your dose if necessary.



# Important notes and reminders

This is a space to write down important notes or reminders for yourself or the person you care for living with POMC, PCSK1 or LEPR deficiency. These can include any questions you want to remember to ask your healthcare professional about POMC, PCSK1 or LEPR deficiency, or IMCIVREE, or any resources you would like to request from Rhythm InTune.

Do not try to inject IMCIVREE at home unless you have been trained by a healthcare professional.

You should use a different injection site each time you give an injection, at least 1 inch away from the area you used for your previous injection, and 2 inches away from your belly button. You may want to use a calendar or diary to record your injection sites.

Please refer to the [Patient Medication information](#) in the [Product Monograph](#) for injection instructions.

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# Important notes and reminders

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**IMCIVREE** is used to manage weight in adults and children aged 6 and older living with POMC, PCSK1 or LEPR deficiency.

**Want to learn more about POMC, PCSK1 or LEPR deficiency or IMCIVREE?**

Talk to your healthcare professional. For additional education and support, contact Rhythm InTune at:



[imcivree@bayshore.ca](mailto:imcivree@bayshore.ca)



1-833-654-2155

Fax: 1-833-350-3887



Actor portrayal.