



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

# Your Treatment Journal

Your tool to track your IMCIVREE treatment.

Please see Important Safety Information on pages 2-3, and [full Prescribing Information](#) and [Patient Information](#).

## 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
- 2 years of age and older with obesity due to Bardet-Biedl syndrome (BBS) to help them lose weight and keep the weight off
- 2 years of age and older with obesity due to the genetic conditions pro-opiomelanocortin (POMC), proprotein convertase subtilisin kexin type 1 (PCSK1), or leptin receptor (LEPR) deficiency, to help them lose weight and keep the weight off

Your healthcare provider should order a genetic test to confirm POMC, PCSK1, or LEPR deficiency before you start using IMCIVREE.

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

- Obesity due to suspected POMC, PCSK1, or LEPR deficiency not confirmed by genetic testing or with benign or likely benign genetic testing results
- Other types of obesity not related to acquired HO, BBS, or POMC, PCSK1, or LEPR deficiency, including obesity associated with other genetic conditions and general obesity

It is not known if IMCIVREE is safe and effective in children under 2 years of age.

## 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.

**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
- 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

**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


## Important Safety Information (cont'd)

- **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](http://www.fda.gov/medwatch) or call 1-800-FDA-1088.





# Staying on track with your IMCIVREE treatment

You've made an important decision by starting treatment with IMCIVREE. We created this journal to help you track your treatment.

Use this journal to record the details of each IMCIVREE injection:

- Date
- Time of injection
- Injection site used
- Any important notes or information about the injection, such as:
  - Changes to your dose made by your doctor
  - Anything you want to share with your doctor

It's a good routine to record your injection in this journal each day. This not only allows you to keep track of your treatment, but also easily share this information with your doctor at appointments.

In addition to the journal, we've included a Weight Tracker and a Hunger Tracker. These tools can help you monitor changes that occur on your treatment journey.



# Rhythm InTune is your source for personalized support

Rhythm InTune provides resources, education, and information tailored to fit the unique needs of people living with certain forms of obesity.\*



Talk to your doctor and Rhythm InTune about arranging training on how to prepare and inject IMCIVREE.

## Have questions?

If you are interested in speaking with a Rhythm InTune Patient Education Manager<sup>†</sup>, you can email or call us at:



[patientsupport@rhythmtx.com](mailto:patientsupport@rhythmtx.com)



[1-855-206-0815](tel:1-855-206-0815)

\*Acquired hypothalamic obesity (HO), obesity due to Bardet-Biedl syndrome (BBS), obesity due to POMC, PCSK1, or LEPR deficiency

<sup>†</sup>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 provider regarding your medical care.

POMC=proopiomelanocortin; PCSK1=proprotein convertase subtilisin/kexin type 1; LEPR=leptin receptor.

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

Please see Important Safety Information on pages 2-3, and [full Prescribing Information](#) and [Patient Information](#).



# Giving an IMCIVREE injection

There are 3 recommended areas in which to inject IMCIVREE:

- Back of upper arms
- Belly
- Front of the middle thighs

Be sure to rotate your injection site each day. You should always choose a site at least 1 inch away from the area you used for your previous injection. If you choose your belly (abdomen), make sure to choose an area at least 2 inches from the belly button.

IMCIVREE should be given once daily at the beginning of the day, with or without food.

To see illustrated, step-by-step instructions for giving an IMCIVREE injection, please refer to the **IMCIVREE Injection Guide** in your **Getting Started Kit**.

**Watch the injection training  
video for further instruction**



# Each vial contains multiple doses

The number of doses in each vial will depend on your individual dose. Please note the vial will not be filled to the top with medicine. Only fill the syringe with the amount of IMCIVREE needed for your prescribed dose. The table below shows the maximum number of doses included in each vial based on different prescribed doses.

Prescribed dose	Maximum number of doses per vial
0.5 mg (0.05 mL)	20
1 mg (0.1 mL)	10
2 mg (0.2 mL)	5
3 mg (0.3 mL)	3



10-mg/1-mL  
multiple-dose vial

Only use the number of doses per vial as listed in this table. Dispose of any leftover medicine.



Do not combine vials of IMCIVREE for your injection. Use one vial that contains enough medicine for your prescribed dose.

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

Please see Important Safety Information on pages 2-3, and [full Prescribing Information](#) and [Patient Information](#).

Example only. You do not need to follow the injection sites listed.

Date	Time	Injection Site	Notes (Ex: Dose, expiration date, notes for your doctor)
4/12/22	8:30 AM	Belly - Left of belly button	Opened new vial: Lot 12345
4/13/22	8:32 AM	Belly - Right of belly button	
4/14/22	8:31 AM	Left thigh	
4/15/22	9:36 AM	Back of right arm	

REMINDER: IMCIVREE® (setmelanotide) should be given once daily at the beginning of the day, with or without food, and the injection site should rotate each day.

8 Please see Important Safety Information on pages 2-3, and [full Prescribing Information](#) and [Patient Information](#).



























# Track your progress

## Highlights of your week

What has your experience been on IMCIVREE? To keep a record for you and your doctor, it may be helpful for you to keep track of your thoughts, feelings, or observations. This chart allows you to record any noticeable highlights from week to week.

Share these weekly highlights with your doctor.

Week	Date	Weekly Highlights
1	4/19	<i>Didn't get seconds at dinner!</i>

# Track your progress

## Weight Tracker

Some people find it helpful to track their weight. If you want to track it, this tool may help. When tracking your weight, record it:

- On the same day each week
- First thing in the morning, before you eat
- In the same way (e.g., with or without clothes)

Note your weight before starting IMCIVREE and then weekly while on treatment. Sharing your weight history with your doctor before starting IMCIVREE may be helpful.

Show this weight tracker to your doctor at your next appointment.

Date	Time	Weight	Height
(Before starting IMCIVREE) 4/12	7:30 AM	260 lbs	5'5"
4/19	7:30 AM	258 lbs	5'5"



# Track your progress

## Hunger Tracker

Some people may find it helpful to track their hunger while on treatment. The table provided may help you track your feelings of hunger over time. Use the table below to record any notes you have related to your hunger and how it may impact your daily routine. Topics to consider may include food intake, time spent thinking about food vs. concentrating on other things, changes in routines, etc.

Share these notes with your doctor to show how your hunger may have changed.

Assess your hunger once before starting IMCIVREE and then every day while on treatment.

Date	Time	Notes
4/10 (Before starting IMCIVREE)	3:00 PM	Woke up very tired, was still hungry after breakfast, had trouble concentrating after lunch

Additional rows for tracking your hunger during treatment can be found on the following pages.







## Need another IMCIVREE Treatment Journal?



Contact Rhythm InTune and  
we'll send you another one



[patientsupport@rhythmtx.com](mailto:patientsupport@rhythmtx.com)



1-855-206-0815

For more information on IMCIVREE, visit [IMCIVREE.com](https://www.imcivree.com)

Please see Important Safety Information on pages 2-3, and  
[full Prescribing Information](#) and [Patient Information](#).