

FDA approved for people 2 years and older with obesity due to Bardet-Biedl syndrome (BBS)

Discover what's possible when you

# TARGET<sup>the</sup> SOURCE

IMCIVREE works where obesity due to BBS starts—inside the brain.



*Actor portrayals*

## What is IMCIVREE?

IMCIVREE is a prescription medicine used in adults and children 2 years of age and older with obesity due to Bardet-Biedl syndrome (BBS) 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 BBS 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 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.

**Please see Important Safety Information throughout, and full Prescribing Information and Patient Information.**

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



**IMCIVREE is the first and only treatment to target MC4R pathway impairment in the brain, a root cause of obesity and hunger in people living with BBS.**

*Actor portrayals*

### 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
- 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.**

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# What is Bardet-Biedl syndrome (BBS)?

**Bardet-Biedl (pronounced BAR-day BEED-el) syndrome, also known as BBS, is a rare genetic disease that can cause obesity**

BBS has a wide range of symptoms that can impact many systems in the body

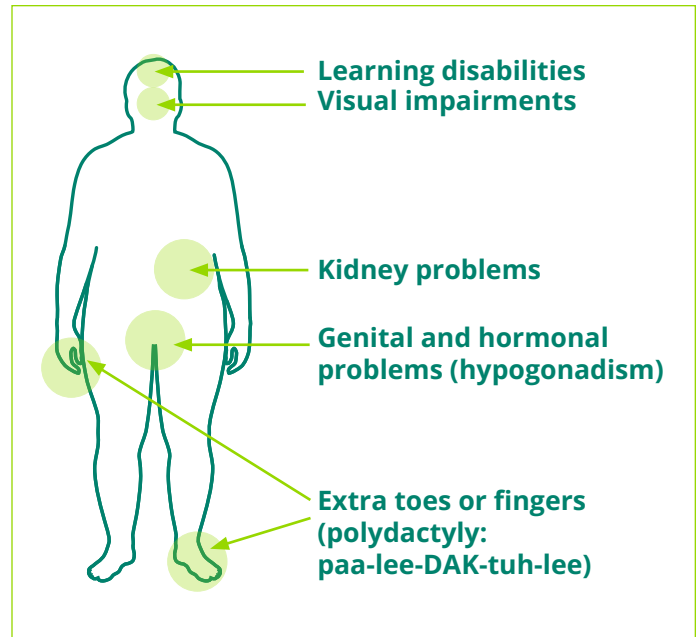
## Early-onset obesity

- Many people with BBS have weight gain that starts at a young age, even as young as 2 years

## Hyperphagia (hi-per-FAY-juh)

- Hyperphagia is insatiable hunger, also described as a constant, hard-to-control hunger

The symptoms of BBS may affect multiple parts of the body, vary in severity, and change with age. While the symptoms shown here are some of the most common, not all people with BBS will experience every symptom listed here.



## Additional symptoms of BBS may include:

- **Brain:** speech delay, developmental delay, poor coordination, partial or total loss of smell
- **Endocrine:** diabetes
- **Heart:** congenital heart disease
- **Skeletal:** dental problems, shorter toes or fingers than normal, webbed toes or fingers

## Hunger and obesity due to BBS come from the brain

Unlike other forms of obesity, obesity due to BBS is caused by variants, or changes, in a BBS gene. BBS genes are inherited, meaning they are passed down from parent to child, and affect how the brain controls hunger.

**People living with BBS may experience constant, hard-to-control hunger.  
This feeling is not their fault.**

# The key area of the brain that controls hunger or fullness is known as the hypothalamus (pronounced hy-puh-THAL-uh-mus)

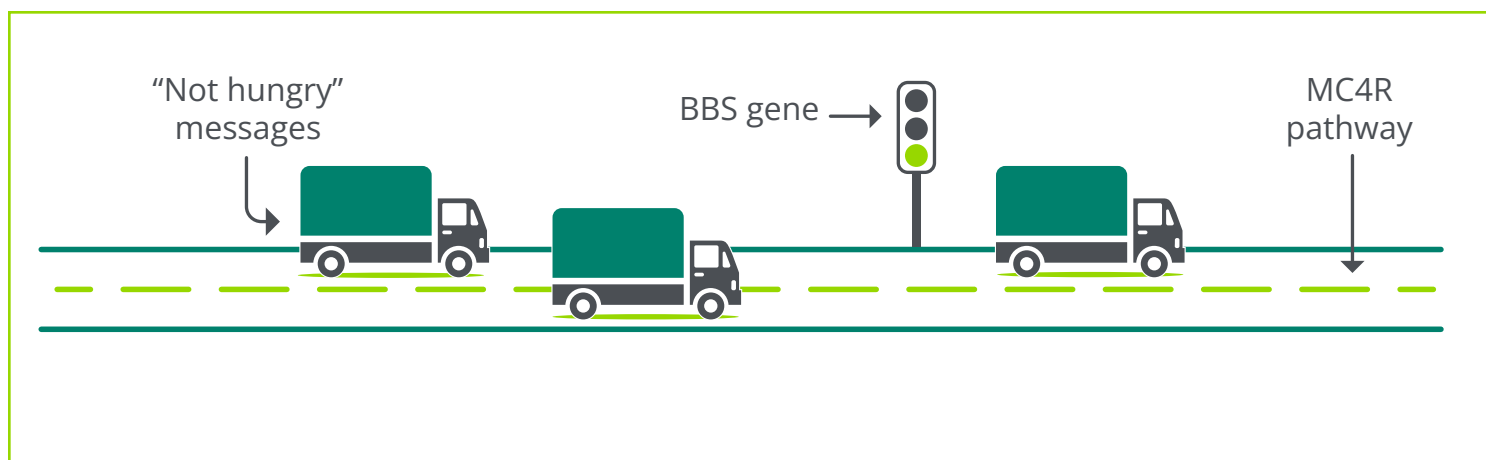
## Think of the hypothalamus as a neighborhood within the brain



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



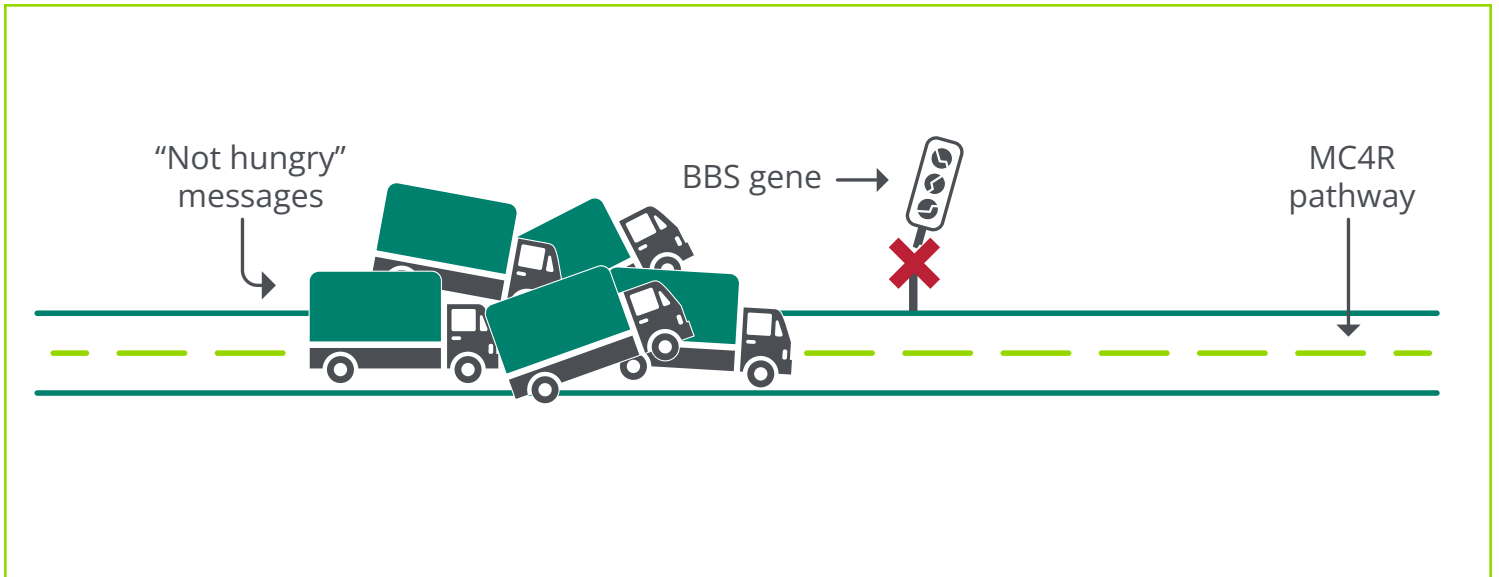
When BBS genes are normal, without a variant (or change), the traffic light works correctly. The road (MC4R pathway) is open, and the trucks can deliver messages to the brain that the body is satisfied and doesn't need more food.



# What causes hunger and obesity due to BBS?

**In people living with BBS, the signals that turn hunger “off” don’t work correctly in the brain**

When a BBS gene has a variant (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 brain believes that the body is still hungry.



# How does IMCIVREE work in obesity due to BBS?

**IMCIVREE is the first and only treatment that targets an impaired MC4R pathway in the brain, a root cause of obesity and hunger in people living with BBS**

IMCIVREE is designed to reestablish function to the road (MC4R pathway) so trucks can deliver messages to the brain that the body is satisfied and no longer 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 MC4R pathway function properly.



**IMCIVREE helps to reestablish MC4R pathway activity and supports long-term reductions in weight when used continuously.**

## 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.

**Please see Important Safety Information throughout, and full Prescribing Information and Patient Information.**

## How was IMCIVREE studied?

### IMCIVREE was studied in two first-ever year-long clinical trials dedicated to obesity and hunger reduction in people with BBS

#### The people studied in the trials included:


- 5 young children aged 2 to less than 6 years old with obesity due to BBS
- 31 children and adults who were 6 years and older with obesity due to BBS


#### People included in the clinical trials had to have a certain weight or body mass index (BMI). BMI is a measure of body fat based on height and weight

- Both young children aged 2 to less than 6 and children aged 6 to less than 18 had to have a weight in the 97th percentile or higher
- Adults aged 18 years and older had to have a BMI of 30 kg/m<sup>2</sup> or more

BMI Z-score was used to measure reductions in weight in both young children aged 2 to less than 6 and children aged 6 to less than 18. BMI Z-scores are reliable measures of weight in growing children because the score takes into account height, age, and gender.

### IMCIVREE reduced BMI over the course of both clinical trials

 **~10%**  
**average**  
**reduction in BMI**  
**in young children aged 2**  
**to less than 6 years**

 **~8%**  
**average**  
**reduction in BMI**  
**in people 6 years**  
**and older\***

\*People taking IMCIVREE had general improvements in other areas. Blood pressure, lipids, and waist size improved with IMCIVREE. Due to a limited number of people studied and the lack of a control group in the study, these treatment effects could not be accurately measured.

### Important Safety Information (cont'd)

#### What are the possible side effects of IMCIVREE?

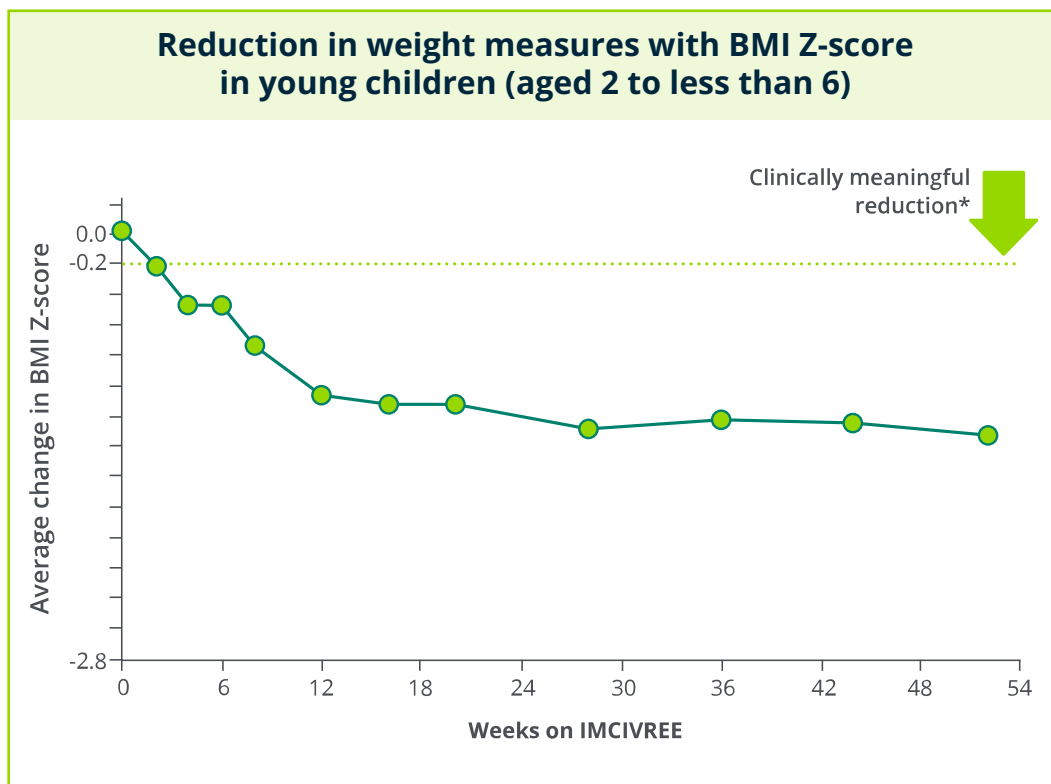
#### IMCIVREE may cause serious side effects, including:

- **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

**Please see Important Safety Information throughout, and full Prescribing Information and Patient Information.**

# How did IMCIVREE help reduce weight measures in young children?

IMCIVREE helped young children aged 2 to less than 6 years achieve early and clinically meaningful reduction in weight measures



## Early meaningful reduction in weight measures

- Young children saw an early meaningful reduction in weight measures\*

## Steady reduction in weight measures during year 1

- Young children continued to see a reduction in weight measures by BMI Z-score over the course of their first year on treatment

5 young children between the ages of 2 to less than 6 were evaluated as part of the study.

\*A clinically meaningful reduction is generally defined as a reduction of greater than or equal to 0.2 in BMI Z-score.

## Important Safety Information (cont'd)

### What are the possible side effects of IMCIVREE? (cont'd)

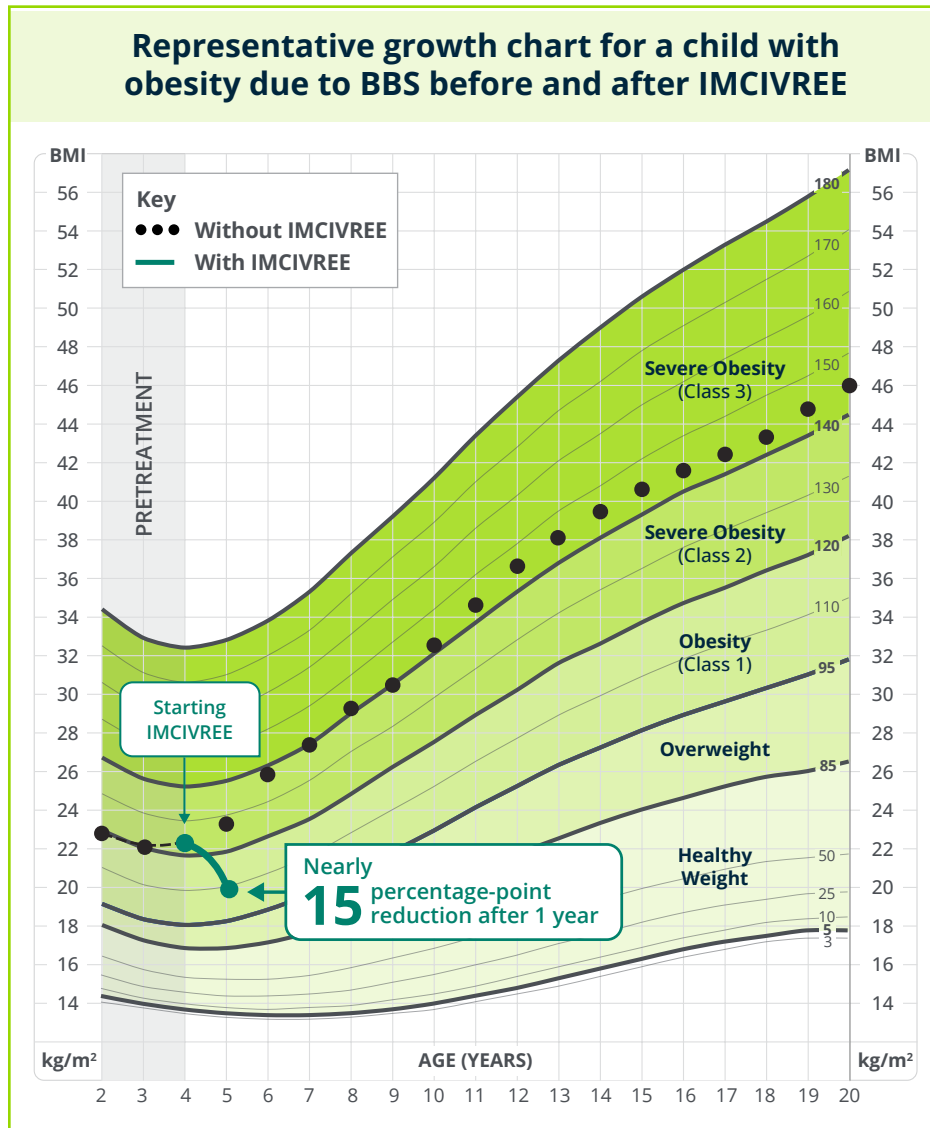
#### IMCIVREE may cause serious side effects, including:

- **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

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

# IMCIVREE reduced the severity of obesity in young children living with BBS

You may be more familiar with viewing a child's growth on a chart that compares how their height and weight match up with other children the same age. This is called a growth chart. The growth chart here shows a representation of a 4-year-old girl with obesity due to BBS. It demonstrates how IMCIVREE might help to lower her BMI after 1 year of treatment, based on results from the IMCIVREE clinical study.



After 1 year on IMCIVREE, she would see a **15 percentage-point reduction in BMI** as a percentage of the 95th percentile, dropping into the obesity (class 1) category.

Without IMCIVREE, her BMI may have continued to go up, leading to severe obesity (class 3) by age 7 and remaining in this category as she ages.

Not an actual patient. Growth chart is based on females 2 to 20 years of age and is for illustrative purposes only.

## Important Safety Information (cont'd)

### What are the possible side effects of IMCIVREE? (cont'd)

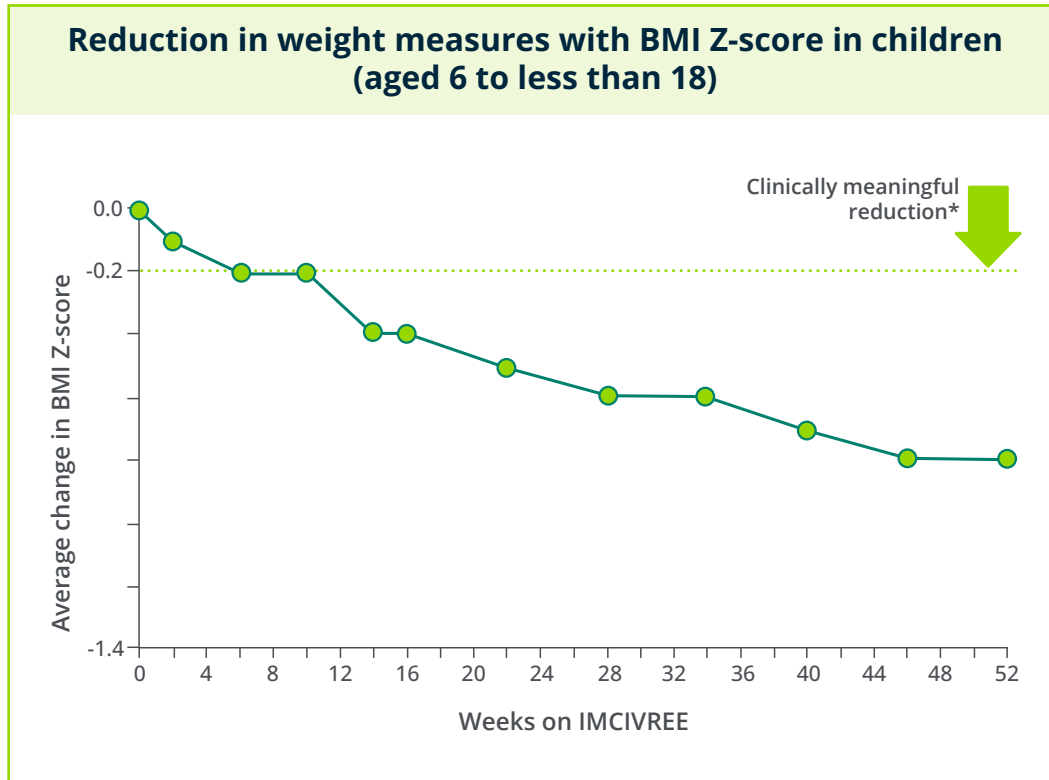
#### IMCIVREE may cause serious side effects, including:

- **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

Please see Important Safety Information throughout, and full Prescribing Information and Patient Information.

# How did IMCIVREE help reduce weight measures in children?

IMCIVREE helped children aged 6 to less than 18 years reach steady and long-lasting reduction in weight measures



## Early meaningful reduction in weight measures

- Children saw an early meaningful reduction in weight measures\*

## Steady reduction in weight measures during year 1

- Children continued to see a reduction in weight measures by BMI Z-score over the course of their first year of treatment

16 children between the ages of 6 to less than 18 years were evaluated as part of the study.

\*A clinically meaningful reduction is generally defined as a reduction of greater than or equal to 0.2 in BMI Z-score.

## Important Safety Information (cont'd)

**What are the possible side effects of IMCIVREE? (cont'd)**

**IMCIVREE may cause serious side effects, including:**

- **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

**Please see Important Safety Information throughout, and full Prescribing Information and Patient Information.**

# IMCIVREE is the first and only treatment to significantly reduce BMI Z-score in children with obesity due to BBS

Some people chose to continue taking IMCIVREE in a separate long-term clinical trial. After receiving 2 years of treatment, their results were analyzed.

 **86% of children had a meaningful reduction in BMI Z-score over 1 year**

 **100% of children had a meaningful reduction in BMI Z-score after 2 years**

- There was a 0.72 average reduction in BMI Z-score
- 12 children between the ages of 6 to less than 18 years were evaluated as part of the 2-year follow-up study

**No change to diet or exercise: In the clinical trial, people were not required to change their diet or exercise routine.**



*Actor portrayals*

## Important Safety Information (cont'd)

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.

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

# IMCIVREE reduced the severity of obesity in children living with BBS

You may be more familiar with viewing a child's growth on a chart that compares how their height and weight match up with other children the same age. This is called a growth chart. The growth chart here shows a representation of a 12-year-old girl with obesity due to BBS. It demonstrates how IMCIVREE might help to lower her BMI after 1 and 2 years of treatment, based on results from the IMCIVREE clinical study.



After 1 and 2 years on IMCIVREE, she would see a **17 percentage-point** and **30 percentage-point** reduction in BMI as a percentage of the 95th percentile, respectively.

With IMCIVREE, her weight-gain trajectory drops down to obesity (class 1). **Without IMCIVREE, she might be expected to remain in the severe obesity (class 3) category** as she ages.

**Long-term treatment with IMCIVREE helped children achieve and maintain a healthier BMI.**

Not an actual patient. Growth chart is based on females 2 to 20 years of age and is for illustrative purposes only.

## Important Safety Information (cont'd)

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.

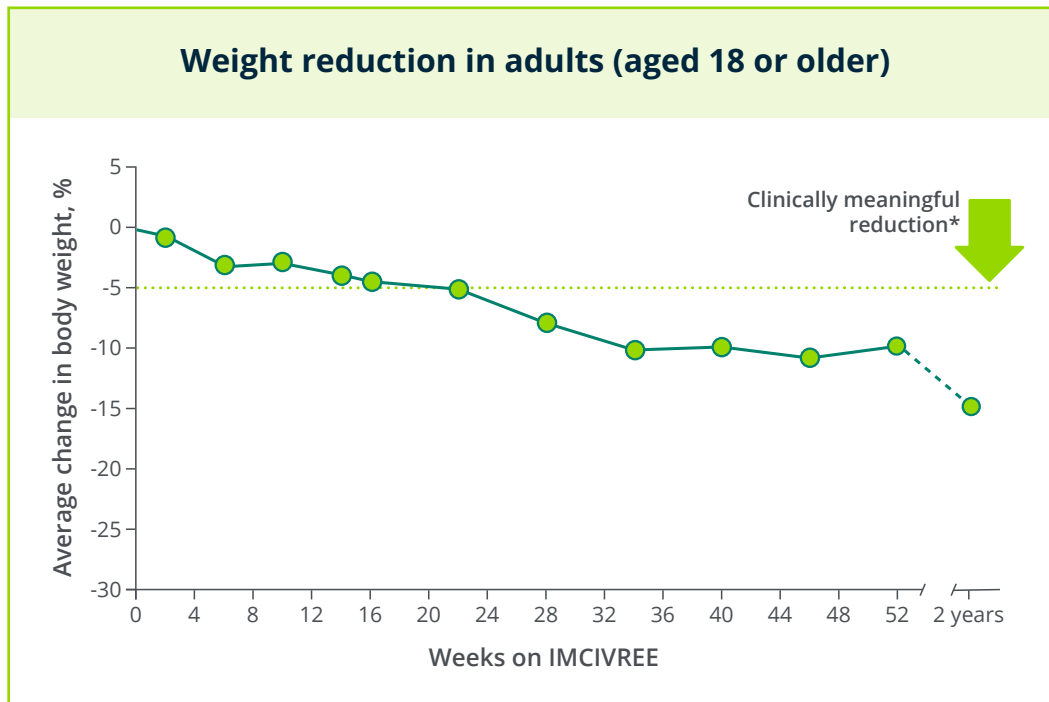
**Please see Important Safety Information throughout, and full Prescribing Information and Patient Information.**

# How did IMCIVREE help adults lose weight?

**IMCIVREE helped adults aged 18 and older reach steady and long-lasting weight reduction.**

## Gradual and continued weight loss over 2 years

For adults, weight loss was steady and meaningful during the first year and continued over 2 years in a long-term extension trial.



- IMCIVREE reduced body weight over the course of the 1-year clinical trial
- 15 adults aged 18 years or older were evaluated as part of the study

\*A clinically meaningful reduction is generally defined as a reduction of greater than or equal to 5% in BMI.

## Important Safety Information (cont'd)

**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.**

# IMCIVREE helped adults 18 years and older reach steady and long-lasting weight reduction

**At 14 weeks, people lost an average of 11 pounds**

 **4%**

average reductions in weight

**At 1 year, people lost an average of 20 pounds**

 **10%**

average reductions in weight

**At 2 years, people lost even more weight**

 **15%**

average reductions in weight

6 adults were part of the study at 24 months

At the end of the clinical trial for IMCIVREE, 19 people continued in a long-term study; 6 of those people were adults. People are being assessed every 3 months until the end of the study (up to 5 years or study withdrawal).

**No change in diet or exercise: In the clinical trial, people were not required to change their diet or exercise routine.**

“

**IMCIVREE has mainly helped me lose and control my weight. I know I couldn't have done it without this medication.**

— Adult patient enrolled in the IMCIVREE clinical trial

Individual results may vary.

## Important Safety Information (cont'd)

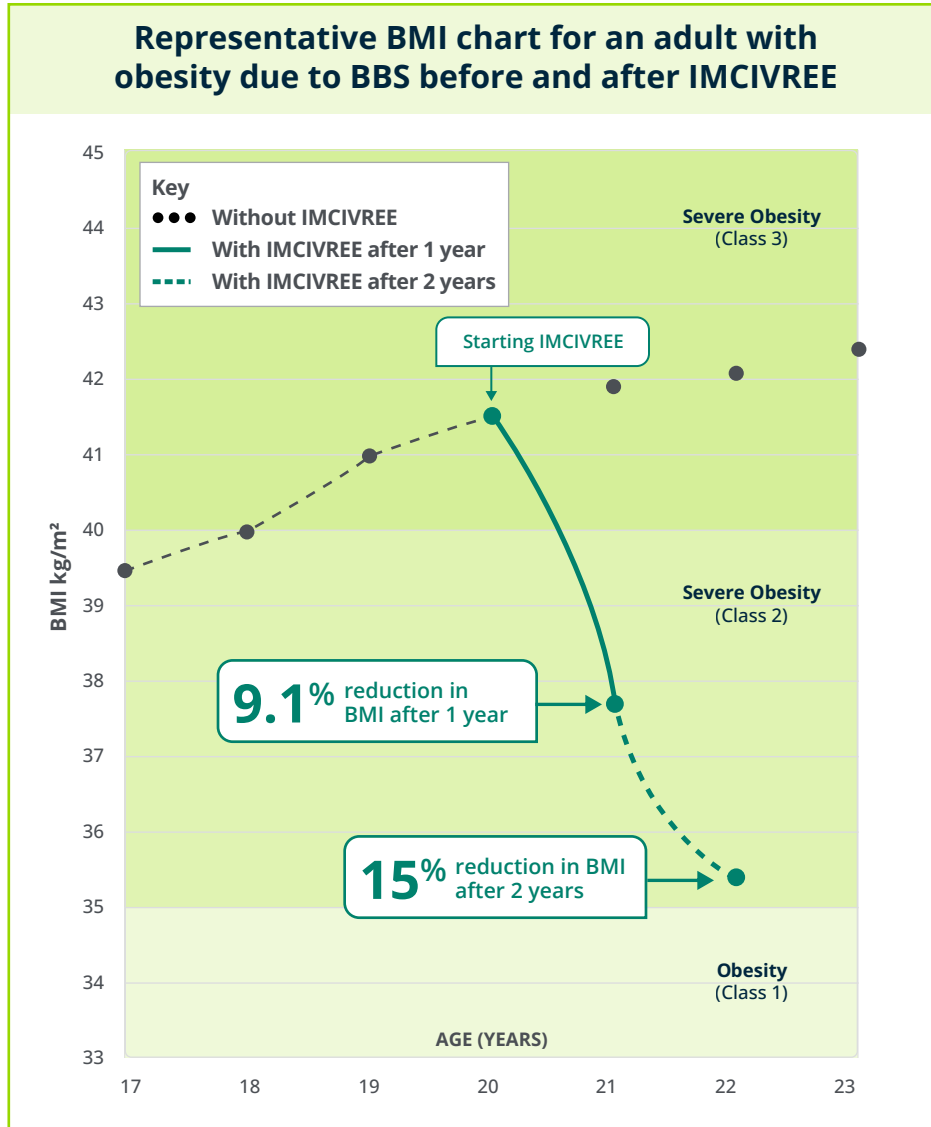
**Before you use IMCIVREE, tell your healthcare provider about all your medical conditions, including if you:**

- Have or have had areas of darkened skin, including skin discoloration (hyperpigmentation)

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

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

# IMCIVREE reduced the severity of obesity in adults living with BBS



The BMI chart here shows a representation of an adult female with obesity due to BBS. It demonstrates how IMCIVREE might help to lower her BMI after 1 and 2 years of treatment, based on results from the IMCIVREE clinical study. BMI at the start of IMCIVREE treatment and after 1 and 2 years with IMCIVREE are average values for adults 18 years and older in the Phase 3 trial.

## Important Safety Information (cont'd)

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

- 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](#).

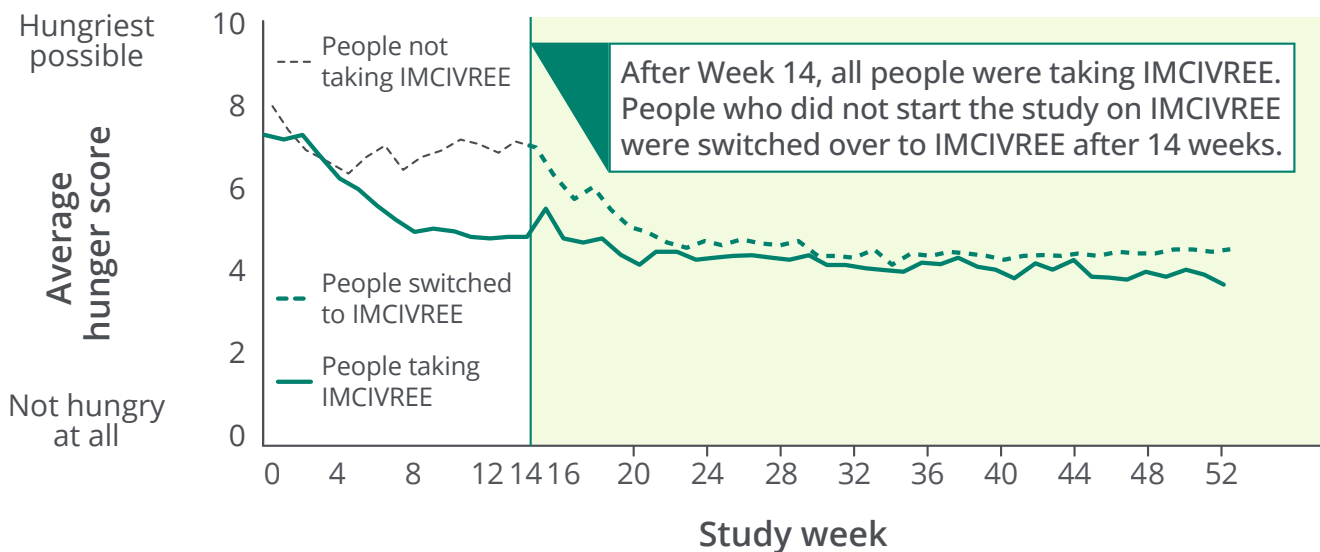
# How did IMCIVREE help with hunger reduction in people 12 years and older?

## IMCIVREE provided reduction in hunger scores early and continuously throughout treatment in people 12 years and older

The effect of IMCIVREE on reducing hunger was studied in 14 people 12 years and older living with BBS who could self-report their hunger.

- They completed a questionnaire every day for 1 year to determine changes in their hunger
- They scored their hunger on a daily basis using a scale from 0 to 10

### IMCIVREE reduced the most severe feelings of hunger in people 12 years and older



**A majority of people 12 years and older reported a reduction in hunger within weeks of starting IMCIVREE.**

### 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

**Please see Important Safety Information throughout, and full Prescribing Information and Patient Information.**

# How did children and adults with obesity due to BBS report changes to their health-related quality of life?

Quality of life is a measure of a person's day-to-day well-being at a point in time

As part of this study, people with BBS were asked to evaluate aspects of their quality of life

## For children, questions in the survey measured:

- Physical ability in daily activities
- Emotional state
- Social needs
- Ability to perform at school

## For adults, the questions in the survey measured:

- Physical ability in daily activities
- Self-esteem
- Sexual life
- Feelings of distress in public
- Ability to perform at work

Higher survey scores indicated improvement to daily life. Lower scores indicated a decrease.

On average, people reported higher scores after 1 year of taking IMCIVREE.

Although general improvements were measured, there were a limited number of people to make clear conclusions. The trial was also not set up to determine whether these changes were because of IMCIVREE.

“

Before IMCIVREE, I didn't realize how much time I spent focusing on food, and how much that was affecting my day-to-day and the other things I could be accomplishing.

— Kathryn, a person living with BBS

Individual results may vary.

## Important Safety Information (cont'd)

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

- 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](#).

# What are the most common side effects of IMCIVREE?

**IMCIVREE has a well-established safety and tolerability profile; most side effects were generally mild and improved over time**

**The most common side effects of IMCIVREE 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

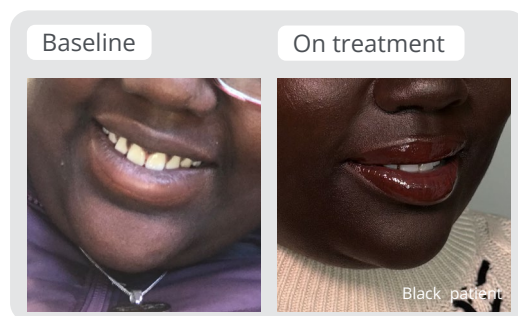
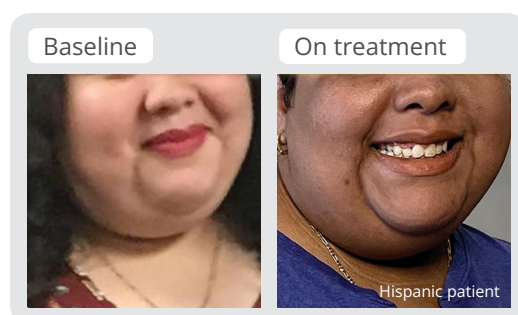
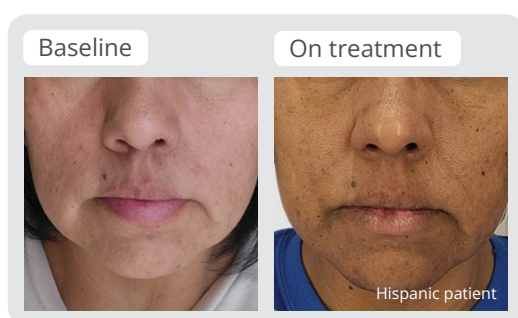
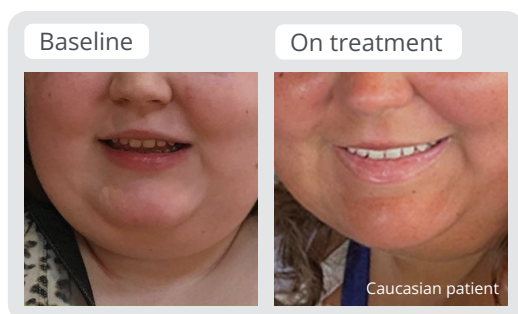
In clinical trials of IMCIVREE in people with obesity due to BBS, most nausea and vomiting events were mild, and none were severe. Nausea and vomiting were primarily reported within the first month of treatment and typically went away after a few days.

These are not all the possible side effects of IMCIVREE. Please see Important Safety Information continued within this brochure. Call your doctor for medical advice about side effects.

The safety of IMCIVREE has been evaluated in more than 700 people over 10+ years through clinical trials and real-world experience across multiple approved uses.

# What should I know about skin changes with IMCIVREE?

A general darkening of the skin (hyperpigmentation) is expected because of how IMCIVREE works



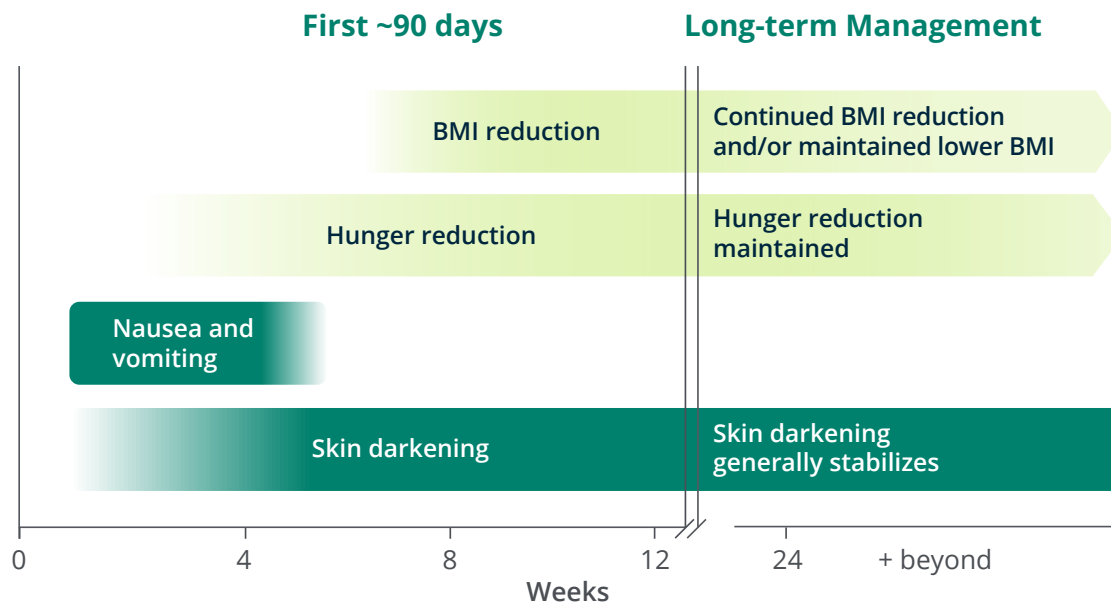
- Darkening of the skin and/or hair is expected, as IMCIVREE may lead to increased production of melanin (which gives color to your skin and hair)
- The degree of skin darkening can vary from person to person and can sometimes include darkening of existing skin growths (such as moles); the degree of darkening may depend on how much natural melanin a person has
- In the clinical trials, hyperpigmentation increased over the first several weeks of IMCIVREE use but generally leveled off in the initial months of treatment
- Darkening of the skin went away after people stopped using IMCIVREE
- **If hyperpigmentation is a concern, talk to your doctor and they will assess your response to treatment and work with you to create a plan to check for skin changes**

You should have a full-body skin exam before starting and during treatment with IMCIVREE to check for skin changes.

# How long does it take to notice results with IMCIVREE?

In clinical trials, it took some time for weight and hunger reductions to occur, while people experienced certain side effects soon after starting treatment.

This chart highlights some of the most common side effects, but it does not include all reported side effects.



**Staying on IMCIVREE is important to maintain long-term reductions in weight.**

## 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.

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

# Achieving the benefits of IMCIVREE may take time, but consistent treatment is key

## In clinical trials:

- **Meaningful weight reduction** as measured by BMI began within 6 to 8 weeks of beginning treatment and continued over time
- **Hunger reduction** began within weeks; measures of hunger increased quickly upon dose reduction or discontinuation of IMCIVREE
- **Nausea and vomiting** were primarily reported within the first 4 weeks of treatment and typically went away within a few days; nearly all events were mild, and none were serious
- **Skin darkening** generally appeared within the first month of starting IMCIVREE; it usually leveled off within the initial months, then remained stable over long-term treatment

Nausea and vomiting are some of the common side effects of IMCIVREE. There are other side effects reported with IMCIVREE that may occur within the first ~90 days of treatment or later. Talk to your doctor about any side effects you experience while on treatment with IMCIVREE.

**Tracking your progress and keeping your treatment goals in mind may help you see your results over time.**



*Actor portrayals*

## Important Safety Information (cont'd)

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.

Please see **Important Safety Information** throughout, and **full Prescribing Information** and **Patient Information**.

# How can I get started on IMCIVREE?

**Your doctor will decide whether IMCIVREE may be an appropriate treatment for you.**

## Deciding on IMCIVREE



If you and your doctor agree IMCIVREE is right for you, your doctor will submit a Start Form (prescription) along with your consent to enroll in Rhythm InTune.

Rhythm InTune is your dedicated source for personalized support, which includes helping you understand insurance coverage and exploring financial assistance options for eligible patients. For more information about Rhythm InTune, please turn to page 24.



### Learning to inject IMCIVREE

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



### Starting on IMCIVREE

IMCIVREE is only available through what is known as a specialty pharmacy. Rhythm InTune will coordinate delivery of IMCIVREE. You should start IMCIVREE at your starting dose, as directed by your doctor.



### Staying on IMCIVREE

Your doctor will monitor you for the first few weeks while you are on IMCIVREE. During this time, they may increase or decrease your dose, depending on how well you tolerate it, until you reach the maintenance dose.

## Important Safety Information (cont'd)

**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

**Please see Important Safety Information throughout, and full Prescribing Information and Patient Information.**

# Personalized support throughout your journey

## Rhythm InTune is here to support you



Whether you're learning about BBS, preparing for a visit, or managing daily routines, a Rhythm InTune Patient Education Manager (PEM)\* can provide resources, education, and information.

### Patient Education Managers can help you with:



#### Coverage and Financial Assistance:

Help investigate your insurance coverage and explain financial assistance options for eligible patients



#### Injection Training:

Provide virtual or live injection training and educational materials



#### Starting Treatment:

Provide education on what to expect when you start treatment and possible side effects



#### Accessing Educational Resources:

Provide a library of resources with information about BBS and treatment with IMCIVREE



#### Connecting With a Community:

Help connect you with individuals living with obesity due to BBS who may understand your experience

Access support at 1-855-206-0815 (M-F, 8am-6pm ET), or by emailing [patientsupport@rhythmtx.com](mailto:patientsupport@rhythmtx.com).



\*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.

### Important Safety Information (cont'd)

#### What are the possible side effects of IMCIVREE? (cont'd)

##### IMCIVREE may cause serious side effects, including:

- **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

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

# Helpful resources

Visit [BBS.IMCIVREE.com](https://BBS.IMCIVREE.com) to learn more about treatment with IMCIVREE

## Doctor Discussion Guide

A guide to help you speak to a doctor about obesity due to BBS and treatment with IMCIVREE.



Download  
the guide

## IMCIVREE Injection Guide

A step-by-step guide that includes important information about giving an IMCIVREE injection.



Download  
the guide

**NOTE:** A printed version of the IMCIVREE Injection Guide is also included with your first shipment of IMCIVREE.

## Rhythm InTune Brochure

A brochure detailing the personalized support, education, and resources that Rhythm InTune offers to people living with certain conditions that can cause obesity.



Download  
the brochure



*Actor portrayals*

## Important Safety Information (cont'd)

What are the possible side effects of IMCIVREE? (cont'd)

IMCIVREE may cause serious side effects, including:

- **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

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

# Use and Important Safety Information

## What is IMCIVREE?

IMCIVREE is a prescription medicine used in adults and children 2 years of age and older with obesity due to Bardet-Biedl syndrome (BBS) 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 BBS 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 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.

**Please see Important Safety Information continued and [full Prescribing Information](#).**

## Important Safety Information (cont'd)

### 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

**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.

Please see [full Prescribing Information](#), including [Patient Information](#).

# IMCIVREE<sup>®</sup>

(setmelanotide) injection

FDA approved for people 2 years and older with obesity due to Bardet-Biedl syndrome (BBS)

Discover what's possible when you  
**TARGET** the  
**SOURCE**



Actor portrayals

## Treat obesity due to BBS at the source with IMCIVREE



IMCIVREE is the first and only treatment to target an impaired MC4R pathway, a root cause of obesity and hunger in people living with BBS.



IMCIVREE has been shown to deliver significant reductions in weight measures at 1 year.



The safety of IMCIVREE has been evaluated in more than 700 people over 10+ years through clinical trials and real-world experience across multiple approved uses. Some of the most common side effects of IMCIVREE were nausea, vomiting, and hyperpigmentation. Please see additional Important Safety Information.



Whether you're learning about obesity due to BBS, preparing for a visit, or managing daily routines, a Rhythm InTune Patient Education Manager (PEM)\* can provide resources, education, and information.

\*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.



**Ask your doctor about IMCIVREE today.**

## Important Safety Information (cont'd)

**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](#).



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