



IMCIVREE[®]
(setmelanotide) injection

How to give IMCIVREE

A step-by-step guide

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.

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

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.

Your guide to giving IMCIVREE

Introducing a new treatment into your daily routine may take some getting used to. This guide includes everything you need to know about giving an IMCIVREE injection. Talk to your doctor or to Rhythm InTune about additional training on how to prepare and inject IMCIVREE.



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.*

Additional questions? Contact us at:



patientsupport@rhythmtx.com



1-855-206-0815

If you have questions about your treatment plan, ask your doctor.

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

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

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Important things to know

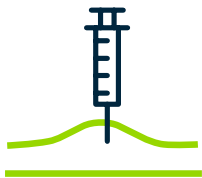
As you prepare to start treatment with IMCIVREE, here are a few important things to keep in mind:



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



Injection training can be given by your doctor or coordinated through Rhythm InTune.



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

- The IMCIVREE needle is half an inch long



Keep IMCIVREE, needles, syringes, and all medicines out of the reach of children.



For each injection:

- To prevent contamination, use only a new syringe with needle provided to you for use with IMCIVREE. Never reuse or share needles with others
- Immediately dispose of the used syringe with needle using the sharps container provided in your shipment of IMCIVREE. Never put used syringes or needles into the trash

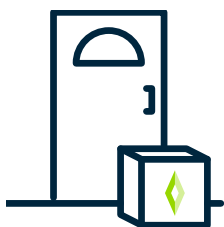
Please consult your healthcare provider if you have any questions.



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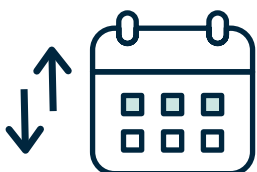
Understand IMCIVREE dosing

Starting treatment



When you or your loved one starts treatment, your doctor will determine the starting dose. Starting dose is typically determined by the age and/or weight of the person when they start IMCIVREE.

First few weeks



Over the first few weeks of treatment, your doctor will evaluate if the dose needs to change.

Ongoing treatment



After a certain time, you will reach a maintenance dose determined by your doctor based on weight and/or age. Once the maintenance dose is reached, your doctor will continue to monitor your progress.

Each vial contains multiple doses

The number of doses in each vial will depend on your or your loved one's 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 the 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 the injection.
Use one vial that contains enough medicine for the prescribed dose.

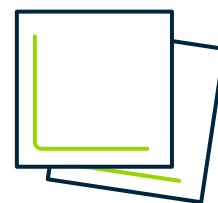
Supplies you'll need for each injection



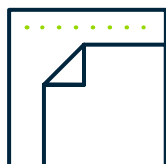
IMCIVREE vial



1-mL syringe with
28- or 29-gauge
(28G or 29G) needle



2 alcohol wipes



Gauze pad



Sharps container provided
in your shipment of
IMCIVREE and supplies

Please consult your healthcare provider if you have any questions.



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5 steps for injecting IMCIVREE

Training on how to prepare and inject IMCIVREE will also be provided by your doctor and/or by Rhythm InTune.

Here's an overview of what you'll need to do:

STEP 1 Gather supplies

STEP 2 Fill syringe with medicine

STEP 3 Choose injection site

STEP 4 Inject the medicine

STEP 5 Dispose of supplies



Watch the injection training video for further instruction.

STEP 1 Gather supplies

Before you inject IMCIVREE, you'll need to get your supplies ready (refer to page 11 for a list of supplies).

Remove IMCIVREE from the refrigerator and take the vial out of the carton until it reaches room temperature. Typically, this takes about 15 minutes.



You can also warm the vial by rolling it gently between the palms of your hands for about 1 minute.



Do not try to warm the vial using a heat source such as hot water or a microwave. Do not shake the vial.

STEP 1 Gather supplies (cont'd)

Inspect all the supplies before you start:

- Check the expiration date on the vial label; do not use if the date has passed
- Check the vial to be sure the liquid looks clear to almost clear and colorless to slightly yellow; do not use if the liquid looks cloudy or has particles floating in it
- For new vials, check the plastic cap; do not use if the cap is broken or missing



Please consult your healthcare provider if you have any questions.

STEP 2 Fill syringe with medicine

Prepare the vial

Wash your hands with soap and warm water.



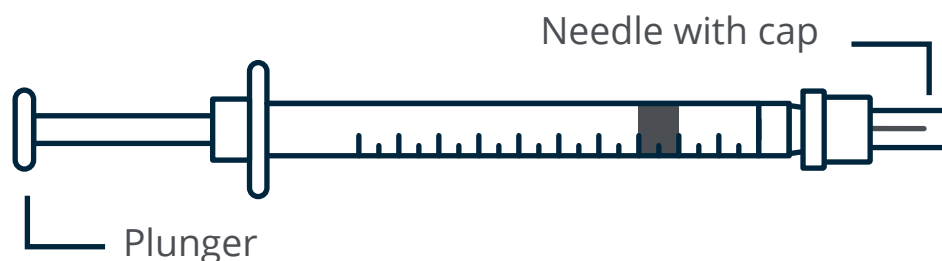
If you're using a new vial, take the plastic cap off and throw it in the trash. Do not put the plastic cap back on the vial. Do not remove the rubber stopper.

On both new and used vials, clean the rubber stopper with one of the alcohol wipes and throw the wipe away.

STEP 2 Fill syringe with medicine (cont'd)

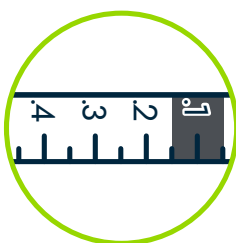
Measure the dose

- Read the markings on the syringe starting from the end closest to the black rubber stopper

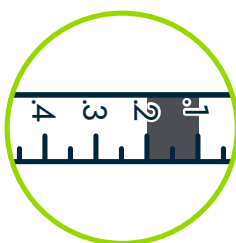


- Keep the needle cap on
- Before filling the syringe with medicine, you need to fill it with air. Slowly pull back the plunger and fill it with the same amount of air as the prescribed dose
 - Adding air into the syringe prior to use will help the medication be withdrawn more easily

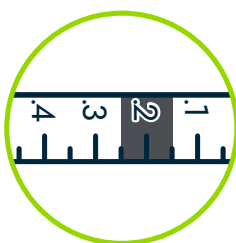
See examples below of what the syringe should look like when filled with air, based on the dose:



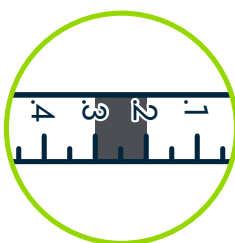
.5 mg (0.05 mL)



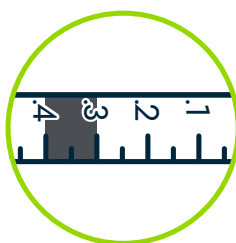
1 mg (0.1 mL)



1.5 mg (0.15 mL)



2 mg (0.2 mL)



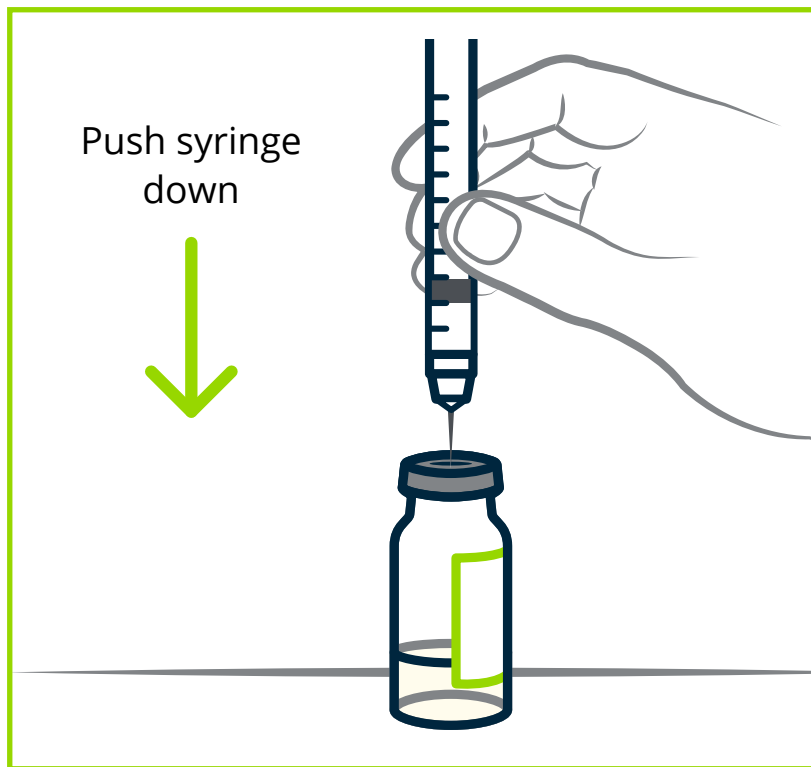
3 mg (0.3 mL)

If you need to, refer to the conversion card shipped with your or your loved one's IMCIVREE prescription.

- Pull the protective needle cap straight off and away from the body. Throw it in the trash

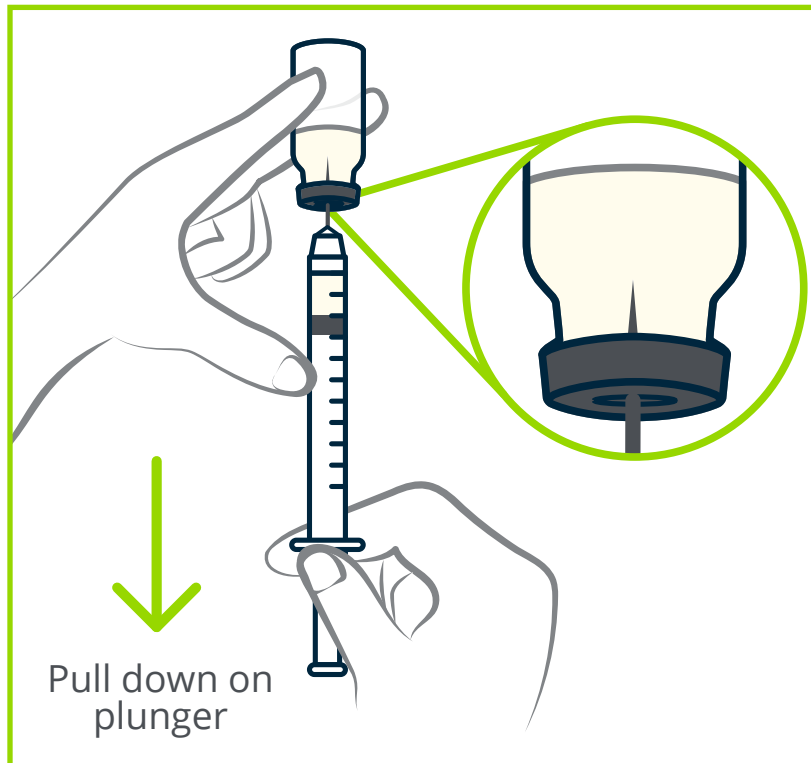
STEP 2 Fill syringe with medicine (cont'd)

Fill the syringe



- Place the vial on a clean, flat work surface
- Place the syringe directly over the vial. Then, insert the needle straight down into the center of the vial stopper and push the air from the syringe into the vial

STEP 2 Fill syringe with medicine (cont'd)

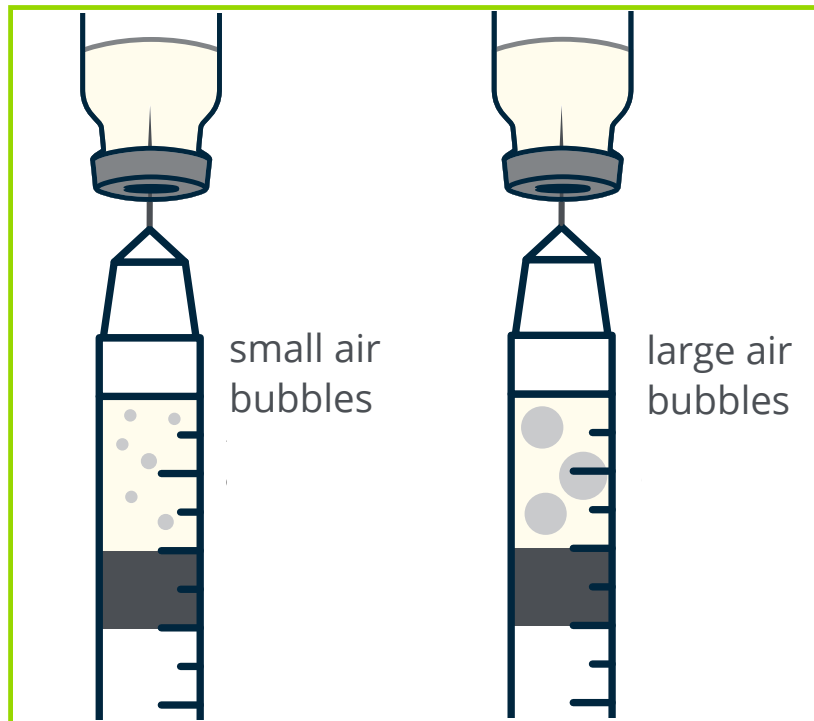


- Keeping the needle inside the vial, slowly turn the vial upside down. Make sure the tip of the needle stays fully covered by the medicine
- Slowly pull back the plunger to fill the syringe with the prescribed dose of IMCIVREE. Be careful not to pull the plunger out of the syringe



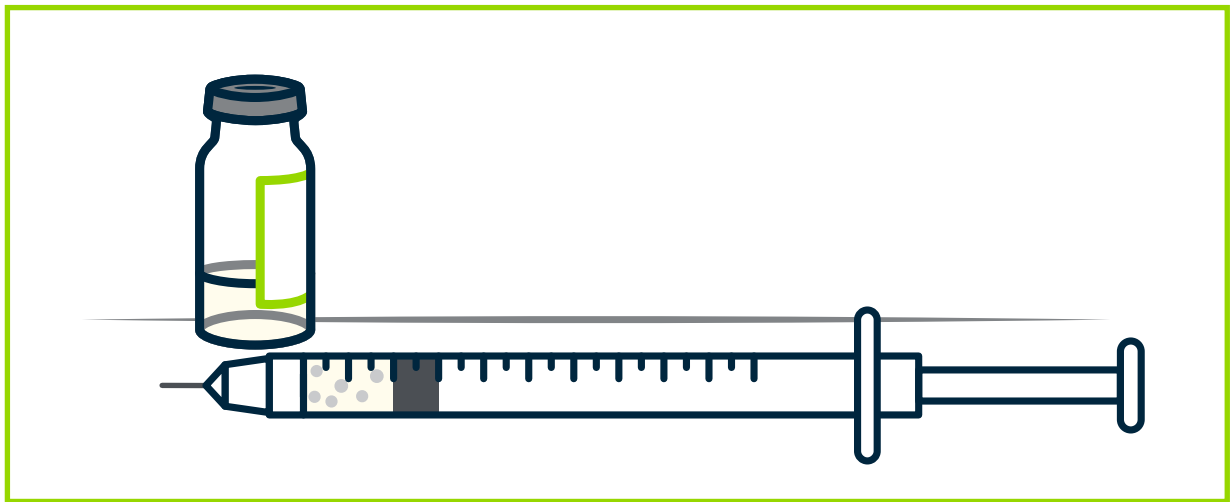
Reminder: Do not use more than 1 vial of IMCIVREE to give a single dose. Use a new vial that has enough medicine for the prescribed dose.

STEP 2 Fill syringe with medicine (cont'd)



- Once you have filled the syringe with the prescribed dose of IMCIVREE, keep the needle in the vial and check for large air bubbles. If there are large air bubbles, gently tap the side of the syringe to move the bubbles to the top. Move the tip of the needle above the medicine and slowly push the plunger up to push the large air bubbles back into the vial
 - Removing large air bubbles is important, as they can reduce the amount of medicine that is received
- After the large air bubbles are gone, move the tip of the needle into the medicine and pull back on the plunger again to fill the syringe with the prescribed dose

STEP 2 Fill syringe with medicine (cont'd)



- Once you have the correct dose, put the vial back down on the clean, flat work surface and gently pull the needle out of the vial, placing the syringe gently on its side on the clean, flat work surface. Be careful not to let the needle touch the work surface, and don't put the cap back on the needle

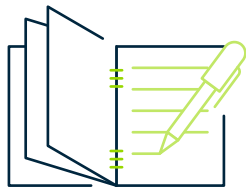
Please consult your healthcare provider if you have any questions.

STEP 3 Choose injection site

There are 3 recommended areas in which to inject IMCIVREE:

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

Be sure to rotate the injection site each day. You should always choose a site at least 1 inch away from the area you used for the previous injection.

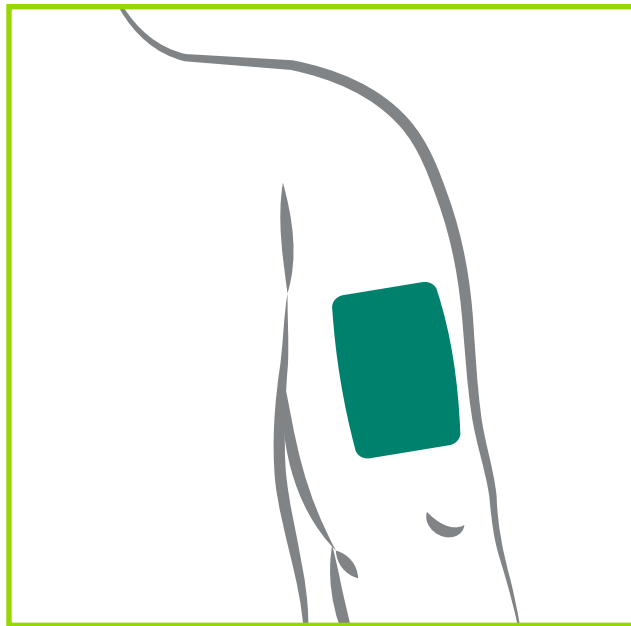


Use the **IMCIVREE Treatment Journal** or a planner, calendar, phone, or other method to record the location, date, and time for each injection.

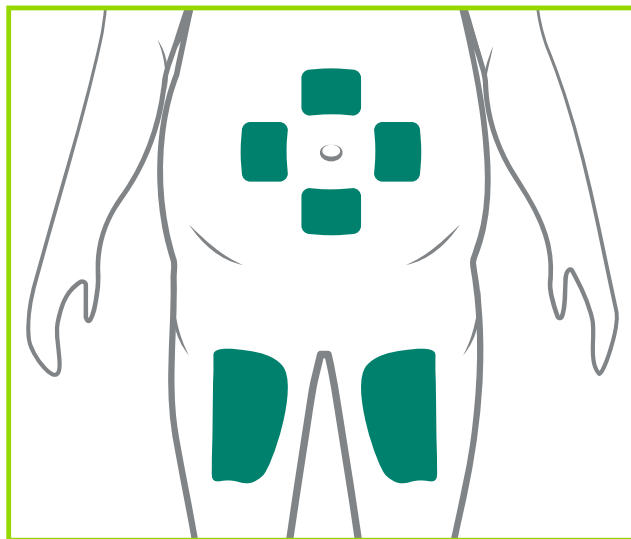


Do not inject IMCIVREE into the belly button, ribs, hip bones, or any scars or moles. Never inject in an area that is red, swollen, or irritated.

STEP 3 Choose injection site (cont'd)



Back of upper arms



Belly

Note: If you choose the belly, make sure to choose an area at least 2 inches from the belly button.

Front of the middle thighs

Please consult your healthcare provider if you have any questions.

STEP 4 Inject the medicine

Clean the area with the second alcohol wipe using a circular motion. Allow the skin to dry for 10 seconds. Don't touch, fan, or blow on the cleaned area.



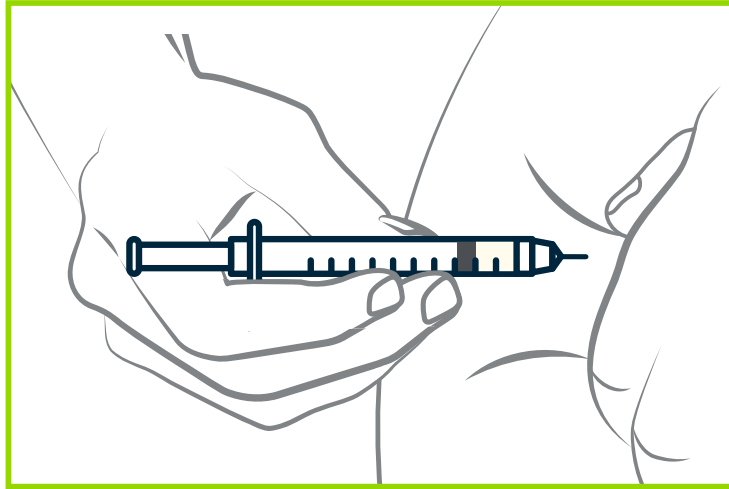
Position your hands. Grab and pinch about 2 inches of skin between your thumb and pointer finger at the injection site. This helps make sure the medicine will be injected into the tissue just below the skin, but not into any muscle. Using the other hand, hold the syringe with your thumb and pointer finger, like a pencil.



Always inject IMCIVREE directly into the tissue just under the skin (subcutaneous). Never inject IMCIVREE into a vein or muscle.

STEP 4 Inject the medicine (cont'd)

Inject IMCIVREE:



- Hold the middle section of the syringe (where the measurements are printed) at a 90-degree angle to the body. Do not hold or push on the plunger
- Insert the needle all the way into the skin
- Once the needle is in the skin, slowly push the plunger down to inject the medicine
- Count to 5 to make sure all the medicine is delivered
- Let go of the pinched skin and pull the needle out
- Use the gauze pad to gently apply pressure to the injection site, then throw away the gauze in the trash
- Do not recap the needle. Throw away the syringe with needle in the sharps container provided in the shipment of IMCIVREE

See helpful tips for giving IMCIVREE to a child on page 29.

Please consult your healthcare provider if you have any questions.

STEP 5 Dispose of used supplies



Always throw away used syringes with needles immediately after use in the sharps container provided in the shipment of IMCIVREE.

Other supplies, like alcohol wipes, used gauze pads, and vials, can go into your household trash.

Appropriately dispose of your sharps container when it is full. The website [fda.gov/safesharpsdisposal](https://www.fda.gov/safesharpsdisposal) may be helpful, as the rules for disposal can vary based on where you live.

Keep IMCIVREE, needles, syringes, and sharps disposal containers out of the reach of children and pets. To order another sharps container, contact Rhythm InTune at 1-855-206-0815.

Remember:

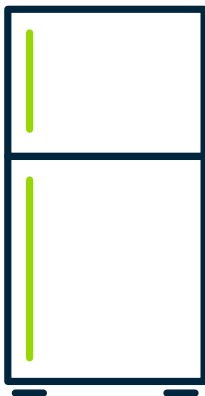
- Do not put syringes in the trash
- Do not reuse or share needles
- Do not recap the needle (as recapping can lead to needlestick injuries)

Please consult your healthcare provider if you have any questions.

Storing IMCIVREE

Store all vials of IMCIVREE, even those you have opened, in the original carton to protect them from light.

Write the date that you first opened the vial on the carton, and always refer back to that date to make sure the medicine is no more than 30 days old.



- Store all vials in the refrigerator at 36°F to 46°F (2°C to 8°C)
- If needed, you can remove the vials from the refrigerator and store them at temperatures ranging from 36°F to 77°F (2°C to 25°C) for up to 30 days (but never past the expiration date)
- You can also briefly store them at up to 86°F (30°C)
- Vials stored at room temperature can be returned to the refrigerator

Appropriately dispose of any IMCIVREE vials that:

- Are past their expiration date
- Have been stored at temperatures above 86°F (30°C)
- Have been out of the refrigerator for more than 30 days, even if it's before their expiration date
- Have been opened for 30 days, even if some medicine is left in the vial

Helpful tips for giving IMCIVREE

Keeping track of the injections



- Use the **IMCIVREE Treatment Journal** or a planner, calendar, phone, or other method to record the location, date, and time for each injection



- When you first open the vial, write the date on the IMCIVREE carton so you can be sure to dispose of any unused medicine after 30 days

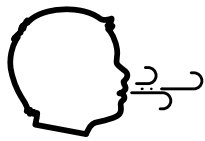


If you miss a dose of IMCIVREE, inject the next dose at the regularly scheduled time the next day.

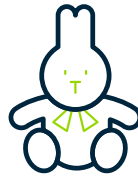
Assisting children

Distraction may help reduce fear when giving injections to children.

Have your child try:



- Deep (tummy) breathing



- Squeezing a stuffed animal



- Reading or looking at a book



- Listening to music



- Watching TV or a movie



- Playing a video game



Developing a routine and doing it the same way every day can help build your confidence and reassure your child.



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.*

Rhythm InTune can help you:



Access educational resources



Connect to
a community



Understand insurance
coverage



Get started on a
Rhythm treatment

If you have questions or need personalized support, you can email or call us at:



patientsupport@rhythmtx.com



1-855-206-0815

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