



IMCIVREE[®]
(setmelanotide) injection

HOW TO GIVE IMCIVREE

A step-by-step guide

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

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

Be sure to check out our support program, Rhythm InTune, for resources, education, and information that may be helpful to you during treatment.

Additional questions? Contact us at:



patientsupport@rhythmtx.com



1-855-206-0815

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

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

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Important things to know

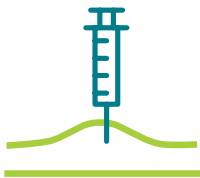
As you prepare to start treatment with IMCIVREE, here are a few important things to keep in mind:



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



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



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

- ◆ The IMCIVREE needle is half an inch long

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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



If you're low on injection supplies, contact Rhythm InTune at [1-855-206-0815](tel:1-855-206-0815) to order more.

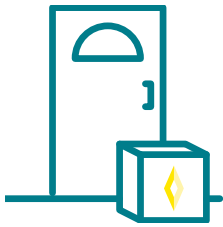


Understanding your dose

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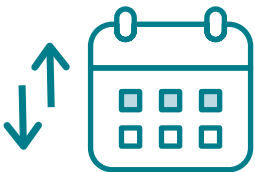
Starting treatment



When you start treatment, your doctor will determine the starting dose for you.

For most people 12 years and older, the starting dose is 2 mg per day. For people between the ages of 6 and 12 years, the starting dose is typically 1 mg per day.

First few weeks



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

If any side effects occur, your doctor may adjust your dose.

Ongoing treatment



Once you've reached the target dose of 3 mg (0.3 mL), your doctor will continue to check on your progress.

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 number of potential doses included in each vial based on different prescribed doses.

| Prescribed dose | Number of doses per vial |
|------------------------------|--------------------------|
| 1 mg (0.1 mL) | 10 |
| 2 mg (0.2 mL) | 5 |
| 3 mg (0.3 mL) Target dose | 3 |



10-mg/1-mL
multiple-dose vial

Only use the number of doses per vial as listed on 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.

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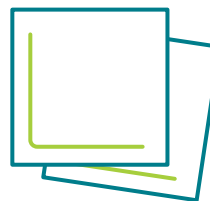
Supplies you'll need for each injection



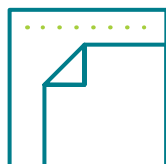
IMCIVREE vial



**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**

You should have received all of these supplies when you received your medicine. If you have questions about your supplies or how to obtain them, please contact Rhythm InTune at [1-855-206-0815](tel:1-855-206-0815).



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.

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

STEP 1 Gather your supplies

STEP 2 Fill your syringe with medicine

STEP 3 Choose your injection site

STEP 4 Inject the medicine

STEP 5 Dispose of your supplies



STEP 1 Gather your supplies

Before you inject IMCIVREE, you'll need to get your supplies ready (refer to page 9 for a list of supplies).

Remove your 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 by using a heat source such as hot water or a microwave. Do not shake the vial.

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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



STEP 2 Fill your syringe with medicine

Prepare the vial

Wash your hands with soap and warm water.

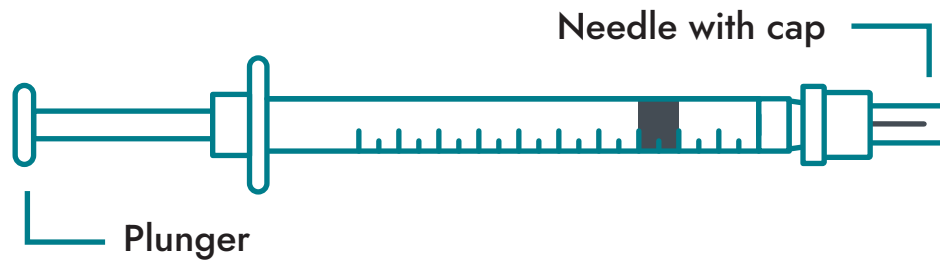


If you're using a new vial, take the plastic cap off and throw it in the trash. Do not put the plastic cap back on the vial. Do not remove the rubber stopper.

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

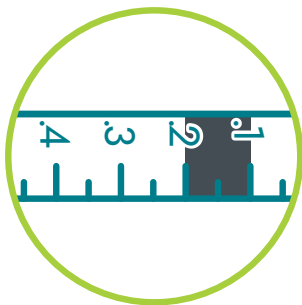
Measure your dose

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

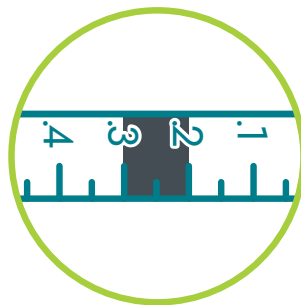


- ◆ Keep the needle cap on
- ◆ Before filling your syringe with medicine, you need to fill it with air. Slowly pull back the plunger and fill it with the same amount of air as your prescribed dose
 - Adding air into the syringe prior to use will help your medication be withdrawn more easily

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



1 mg (0.1 mL)



2 mg (0.2 mL)



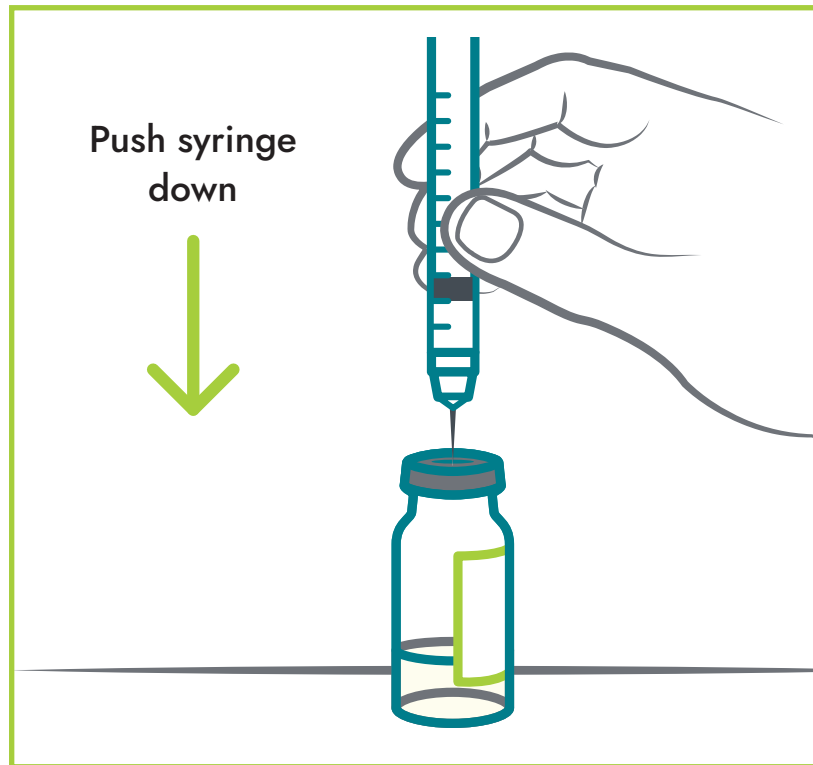
3 mg (0.3 mL)

If you need to, refer to the conversion card shipped with your IMCIVREE prescription.

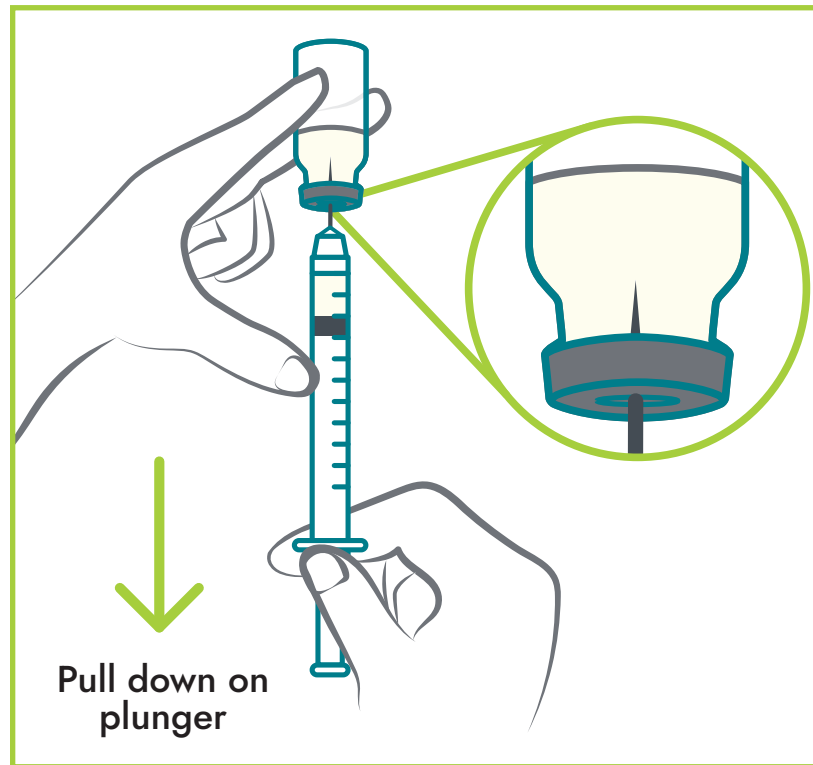
- ◆ Pull the protective needle cap straight off and away from your body. Throw it in the trash

STEP 2 Fill your 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

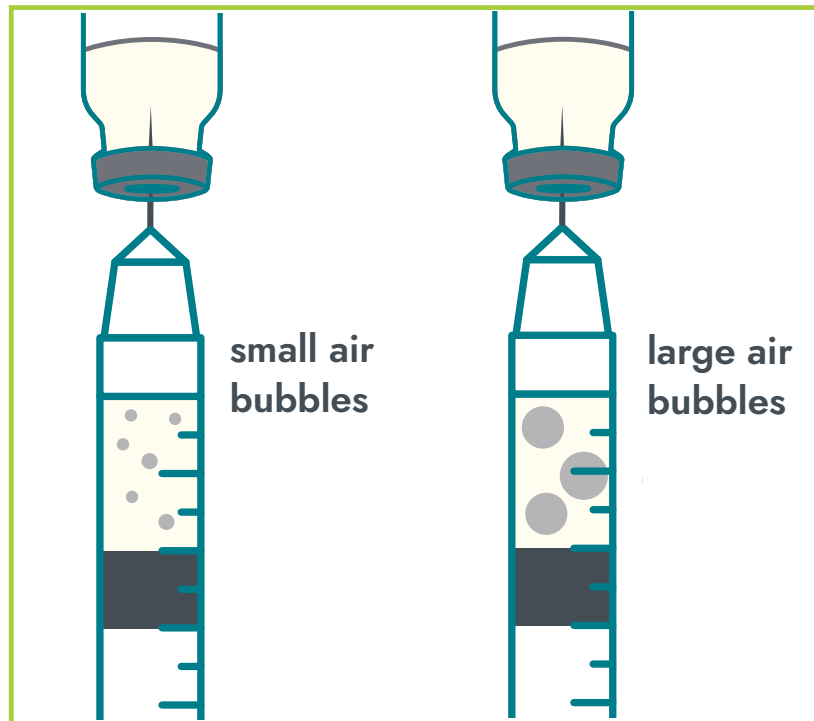


- ◆ Keeping the needle inside the vial, slowly turn the vial upside down. Make sure the tip of the needle stays fully covered by the medicine
- ◆ Slowly pull back the plunger to fill the syringe with your prescribed dose of IMCIVREE. Be careful not to pull the plunger out of the syringe



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

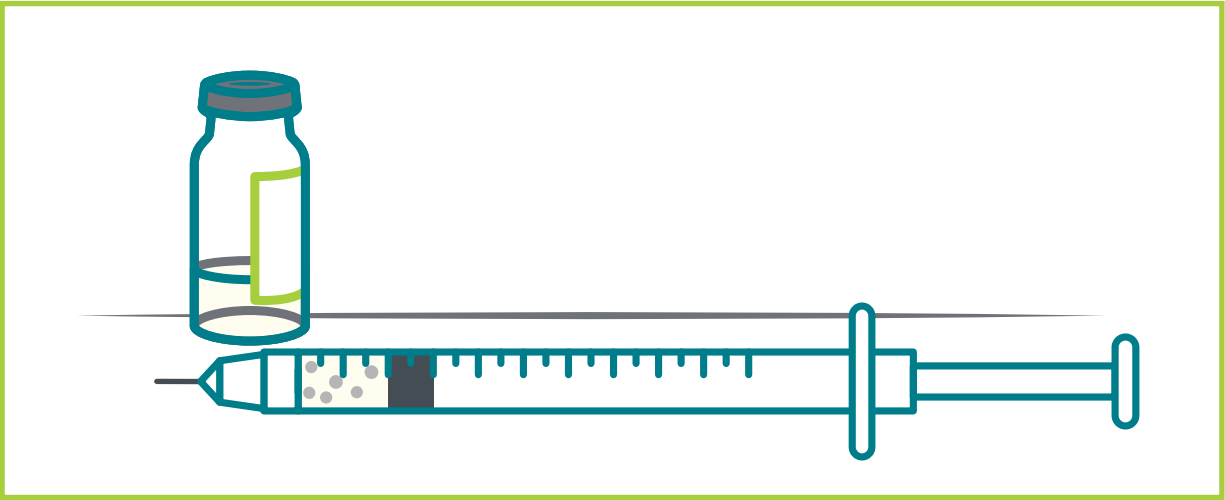
STEP 2 Fill your syringe with medicine (cont'd)



- ◆ Once you have filled the syringe with your 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 you receive
- ◆ 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

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- ◆ 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. Be careful not to let the needle touch the work surface, and don't put the cap back on the needle

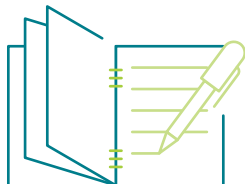


STEP 3 Choose your injection site

There are 3 recommended areas in which to inject IMCIVREE:

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

Be sure to rotate 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.



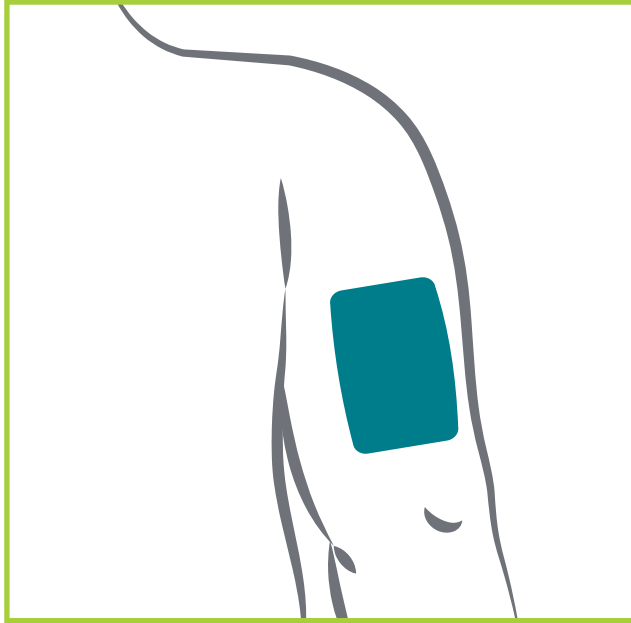
Use the **IMCIVREE Treatment Journal** or a planner, calendar, phone, or other method to record the location, date, and time for each injection.



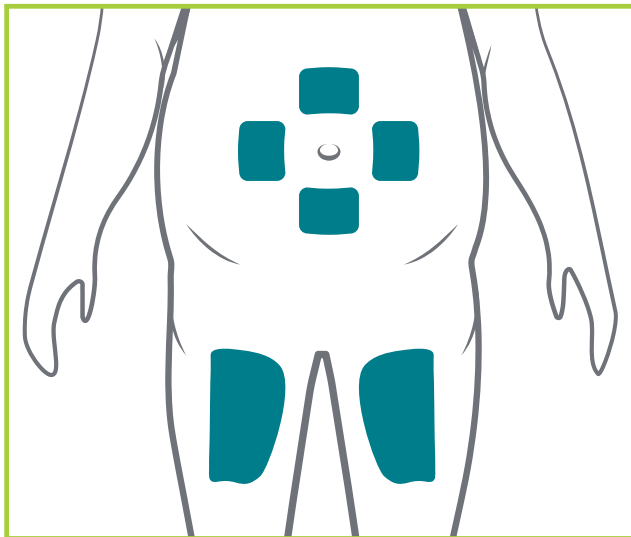
Do not inject IMCIVREE into your belly button, ribs, hip bones, or any scars or moles. Never inject in an area that is red, swollen, or irritated.

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Back of upper arms



Belly

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

Front of the middle thighs



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 your skin, but not into any muscle. Using the other hand, hold the syringe with your thumb and pointer finger, like a pencil.

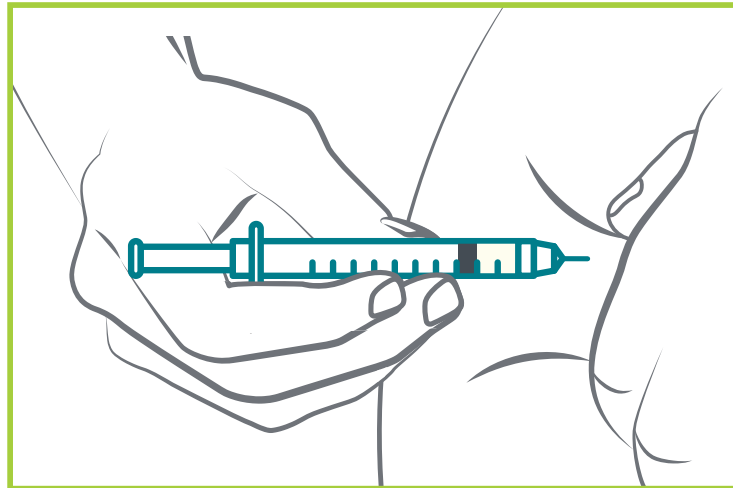


Always inject IMCIVREE directly into the tissue just under your skin (subcutaneous). Never inject IMCIVREE into a vein or muscle.

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Inject IMCIVREE:



- ◆ Hold the middle section of the syringe (where the measurements are printed) at a 90-degree angle to your body. Do not hold or push on the plunger
- ◆ Insert the needle all the way into your skin
- ◆ Once the needle is in your 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 your shipment of IMCIVREE

See helpful tips for giving IMCIVREE to a child on page 27.

STEP 5 Dispose of your supplies



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

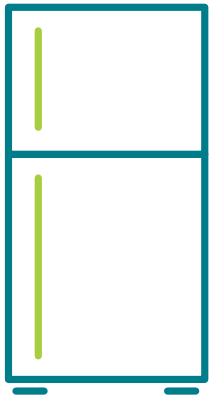
Remember:

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

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 your 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 your next dose at the regularly scheduled time the next day.

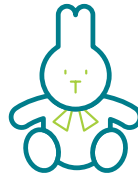
Assisting children

Distraction can often help reduce fear when giving injections to children.

Have your child try:



◆ Deep (tummy) breathing



◆ Squeezing a stuffed animal



◆ Reading



◆ Listening to music



◆ Watching TV or a movie



◆ Playing a video game





Your source for personalized support

Be sure to check out our support program, Rhythm InTune, for resources, education, and information that may be helpful to you during treatment.

Rhythm InTune can help you:



Access educational resources



Connect to a community



Understand your insurance coverage



Get started on a Rhythm treatment

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



patientsupport@rhythmtx.com



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