

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

Pr **IMCIVREE**[®]

Setmelanotide injection

Read this carefully before you start taking **IMCIVREE** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **IMCIVREE**.

What is IMCIVREE used for?

IMCIVREE is used to manage weight in adults and children 6 years of age or older with obesity due to one of the following inherited (genetic) conditions:

- Bardet-Biedl syndrome (BBS)
- Biallelic Pro-opiomelanocortin (POMC)
- Proprotein convertase subtilisin/kexin type 1 (PCSK1)
- Leptin receptor (LEPR) deficiency

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

How does IMCIVREE work?

Setmelanotide, the medicine in IMCIVREE is in a class of medicines called melanocortin 4 (MC4) receptor agonists. It works in the brain to promote weight loss.

What are the ingredients in IMCIVREE?

Medicinal ingredient: Setmelanotide (as setmelanotide acetate)

Non-medicinal ingredients: **Benzyl alcohol** (preservative), carboxymethylcellulose sodium, edetate disodium dihydrate (EDTA), mannitol, mPEG-2000-DSPE, nitrogen, phenol (preservative), water for injection. May contain hydrochloric acid and sodium hydroxide to adjust pH.

IMCIVREE comes in the following dosage forms:

solution: 10 mg/mL

Do not use IMCIVREE if:

- You are allergic to setmelanotide or any other ingredients in IMCIVREE.

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.

Other warnings you should know about:

IMCIVREE may cause serious side effects, including:

- **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 color. 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.
- See the Serious side effects and what to do about them table, below, for more information on these and other serious side effects.

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.

How to take IMCIVREE:

Before you use **IMCIVREE:**

- use IMCIVREE exactly as prescribed by your healthcare professional.
- children should have regular growth checks to monitor weight loss and growth.
- your healthcare professional will regularly check how well IMCIVREE is working and may adjust your dose if necessary.
- If you have POMC, PCSK1, or LEPR deficiency, your healthcare professional may tell you to stop using IMCIVREE if you have not lost a certain amount of weight after 12 to 16 weeks of treatment.

- If you have BBS, your healthcare professional may tell you to stop using IMCIVREE if you have not lost a certain amount of weight after 22 weeks of treatment.

How to inject IMCIVREE:

- see the detailed instructions for use below to learn how to prepare and inject IMCIVREE.
- IMCIVREE is for injection under the skin (subcutaneous injection)
- IMCIVREE may be given by your healthcare professional, yourself or your caregiver. If you will be giving yourself the shot, your healthcare professional will teach you how to prepare and inject your dose of IMCIVREE for the first time. **Do not** try to inject IMCIVREE unless you have been trained by a healthcare professional.
- inject IMCIVREE 1 time each day when you first wake up.
- inject IMCIVREE under the skin of your belly (stomach) area.
- change the site where you give the shot each day.
- give IMCIVREE with or without food.
- only use the syringes and needles recommended by your healthcare professional for use with IMCIVREE.
- always use a new syringe and needle for each injection to prevent contamination.
- throw away used syringes and needles in a puncture-resistant, disposable sharps container as soon as you finish giving the injection.
- **do not** reuse or share your needles with other people.
- **do not** recap the needle. Recapping the needle can lead to a needle stick injury.
- keep IMCIVREE, needles, syringes, and all medicines out of the reach of children.

Usual dose:

Your healthcare professional will advise you on the right dose to inject.

Overdose:

If you, or a person you are caring for, have taken or received too much IMCIVREE, you may experience the side effects described in the below section “**What are possible side effects from using IMCIVREE?**”.

If you think you, or a person you are caring for, have taken too much IMCIVREE, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

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

What are possible side effects from using IMCIVREE?

These are not all the possible side effects you may have when taking **IMCIVREE**. If you experience any side effects not listed here, tell your healthcare professional.

- injection site reaction (pain, redness, irritation, swelling or other problems where the shot was given)
- nausea, diarrhea, stomach (belly) pain, throwing up
- headache
- back pain
- fatigue
- weakness

- dizziness
- dry mouth

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
VERY COMMON			
Increased skin pigmentation or darkening of pre-existing skin lesions (mole)		X	
Depression (sad mood that won't go away) or suicidal thoughts or actions: difficulty sleeping or sleeping too much, feelings of worthlessness, guilt, helplessness or hopelessness, withdrawal from social situations, reduced libido (sex drive) and thoughts of harming or killing yourself or plan or try to do so			X
Erections lasting more than 4 hours			X
Unwanted sexual reaction (changes in sexual arousal that happen without any sexual activity)		X	

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:**unopened and opened vials of IMCIVREE:**

- keep out of reach and sight of children.
- **do not** use after the expiry date which is stated on the carton or the vial.
- keep vials in the original carton.
- store in the refrigerator between 2°C to 8°C. If needed, unopened and opened vials may be removed from the refrigerator and stored at temperatures ranging from refrigerated to room temperature (2°C to 30°C) for up to 30 days. unopened and opened vials may be returned to the refrigerator.
- throw away:
 - **opened** vials 30 days after first opening, even if some medicine is still left. Write the date on the carton when you first open the vial.
 - **unopened** vials of IMCIVREE if it has been more than 30 days since the vial was first removed from the refrigerator.

If you want more information about IMCIVREE:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer's website www.rhythmtx.ca, or by calling 1-833-789-6337.

This leaflet was prepared by Rhythm Pharmaceuticals Inc.

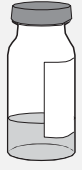
Last Revised May 4, 2023

Instructions For Use

Calculate the number of doses of IMCIVREE in each vial:

- Each unopened IMCIVREE vial contains 10 milligrams (mg) of medicine in 1 milliliter (mL) of solution.
- The vial will contain both medicine and air. Most of the vial will be filled with air.
- Your healthcare professional will determine your dose of medicine in milligrams (mg).
- The IMCIVREE vial may be used to give more than 1 dose of medicine (multiple-dose vial).
- Use [Table 11](#) to see how many times you may use each vial based on your prescribed dose.
- **Do not** use more doses from a single vial than listed in [Table 11](#).

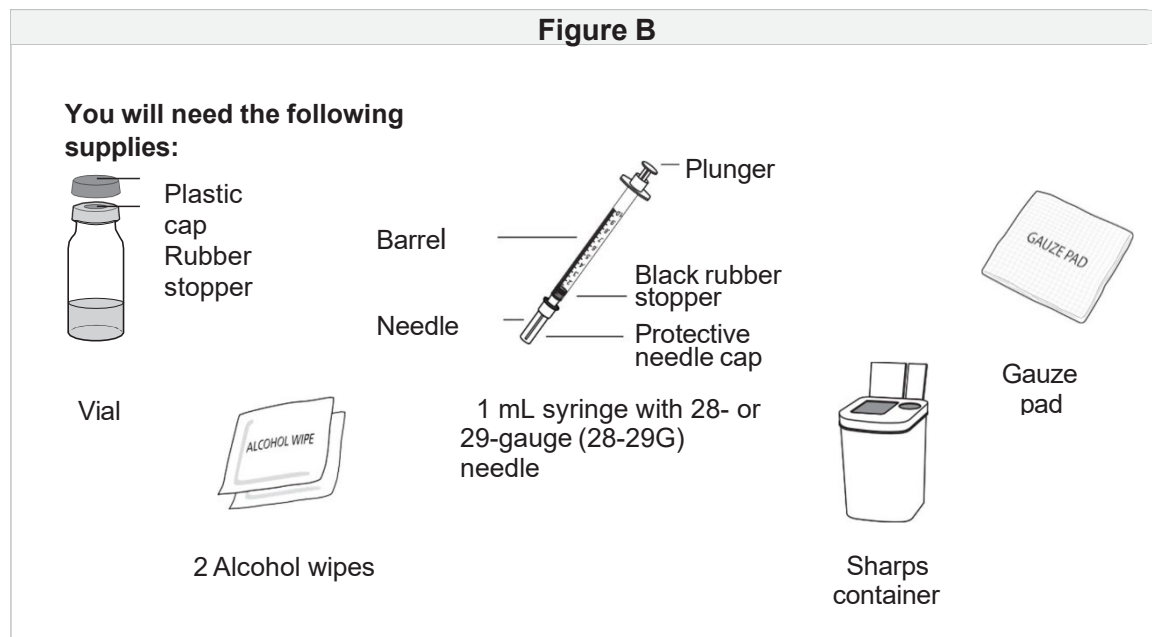
Table 11: Dose Calculation

 <p>Figure A</p>	<p>10 mg/mL multiple dose vial</p>	Prescribed dose (mg)	Prescribed dose (mL)	Number of doses per vial
		0.5 mg	0.05 mL	20
		1 mg	0.1 mL	10
		1.5 mg	0.15 mL	6
		2 mg	0.2 mL	5
		2.5 mg	0.25 mL	4
		3 mg	0.3 mL	3

Step 1

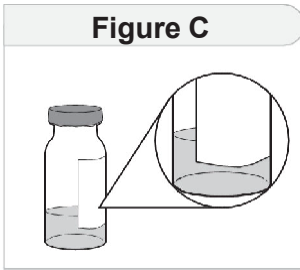
Gather Your Supplies

- Gather the supplies you will need for your injection (**Figure B**).
- Place your supplies on a clean, flat work surface.



Step 2

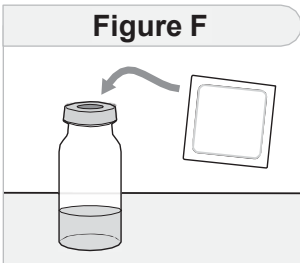
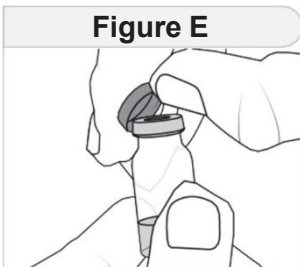
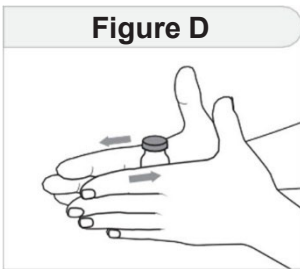
Check your IMCIVREE vial



- Check the expiration (Exp) date on the vial label (**Figure C**).
- Check the liquid. The liquid should look clear to almost clear and colorless to slightly yellow. The liquid should be free of particles.
- **Do not** use if:
 - The expiration (Exp) date has passed.
 - The liquid is cloudy.
 - There are particles floating in the vial.
 - The plastic cap on a new vial is broken or missing.

Step 3

Prepare your IMCIVREE vial



- Allow the vial to reach room temperature.
 - Remove the vial from the refrigerator 15 minutes before injection.
 - You can also warm the vial by rolling it gently between the palms of your hands for 60 seconds (**Figure D**).
- **Do not** try to warm the vial by using a heat source such as hot water or a microwave.
- **Do not** shake the vial.
- Wash your hands with soap and warm water.
- If using a new vial, remove the plastic cap (**Figure E**) and throw away this plastic cap in the trash. Do not put the plastic cap back on the vial.
- Clean the top of the vial rubber stopper with 1 alcohol wipe (**Figure F**). Throw away the alcohol wipe in the trash.
- **Do not** remove the vial rubber stopper.

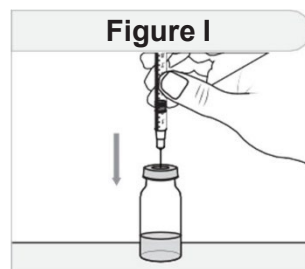
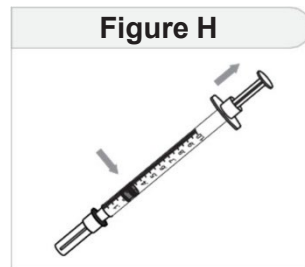
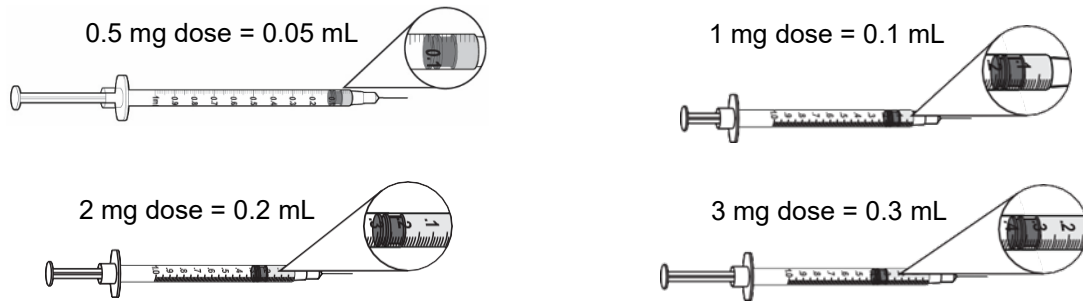
Step 4

Prepare the syringe

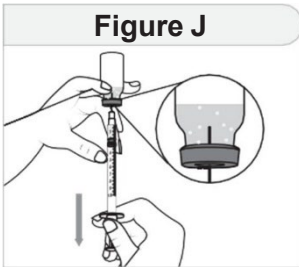
- When measuring your dose, be sure to read the markings starting from the end closest to the black rubber stopper (Figure G).

FIGURE G

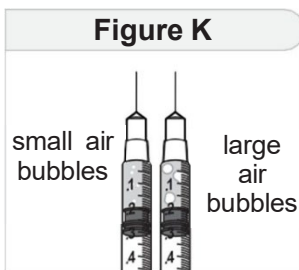
Use a 1 ml syringe with 0.01 ml dosing increments and a 28 to 29 gauge needle with a 6 to 13 mm needle length, suitable for injection under the skin.



- Fill the syringe with air.
 - Keep the protective needle cap on the syringe.
 - Pull back on the plunger until the end of the black rubber stopper stops at your dose. Read the units starting from the end closest to the black rubber stopper. Fill the syringe with air equal to the amount of the medicine to be given (Figure H).
- Remove the protective needle cap from the syringe.
 - Remove the protective needle cap by pulling it straight off and away from your body.
- Insert the needle.
 - Place the vial on the clean, flat work surface.
 - With the vial in the upright position, place the syringe directly over the vial and insert the needle straight down into the center of the vial rubber stopper (Figure I).
 - Push the air from the syringe into the vial.



- Fill the syringe with IMCIVREE.
 - Keep the needle in the vial and slowly turn the vial upside down.
 - Make sure to keep the tip of the needle in the medicine (**Figure J**).
- Slowly pull back on the plunger to fill the syringe with the amount of IMCIVREE needed for your prescribed dose.
- Be careful not to pull the plunger out of the syringe.
- **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.

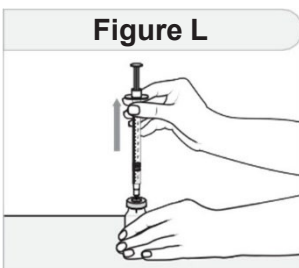


- Check for large air bubbles (**Figure K**).
 - Keep the needle in the vial and check the syringe for large air bubbles.

What to do if you see large air bubbles:

Large air bubbles can reduce the dose of medicine you receive. To remove large air bubbles:

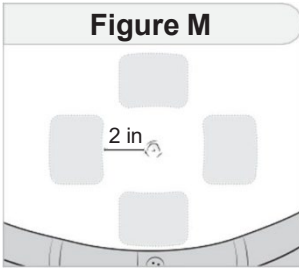
- Gently tap the side of the syringe with your finger to move the air bubbles to the top of the syringe.
- Move the tip of the needle above the medicine and slowly push the plunger up to push the large air bubbles back into the vial.
- After the large air bubbles are removed, pull back on the plunger again (more slowly this time) to fill the syringe with your prescribed dose of medicine.



- Withdraw the needle
 - Return the vial to an upright position and place it on the clean, flat work surface.
 - While holding the vial with 1 hand and the barrel of the syringe between the fingertips of your other hand, pull the needle straight out of the vial (**Figure L**).
 - Set the syringe down on the clean, flat work surface.
- Make sure the needle does not touch the surface.
- **Do not** recap the needle

Step 5

Prepare your injection site



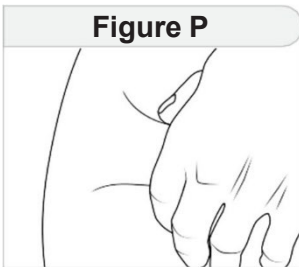
- Choose the area on the belly (abdomen) where you will give the injection (**Figure M**).
 - Be sure to choose an area on the belly (abdomen) at least 2 inches from the belly button.
 - **Do not** inject into the belly button, ribs, and hip bones, as well as scars or moles.
 - **Do not** inject in an area that is red, swollen, or irritated.
-
- Clean the injection site with the second alcohol wipe using a circular motion.
 - **Do not** touch, fan, or blow on the cleaned area.
 - Allow the skin to dry for about 10 seconds.

Rotate your injection site each day.

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. You may want to use a calendar or diary to record your injection sites.

Step 6

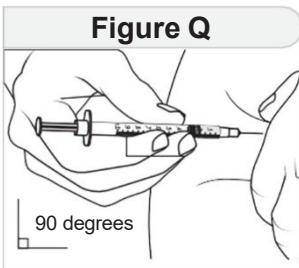
Place your hands for the injection



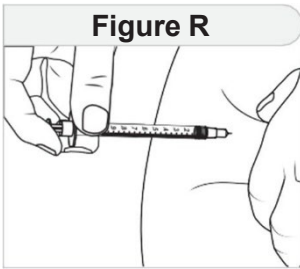
- With 1 hand, pinch about 2 inches of skin at the injection site between your thumb and index (pointer) finger (**Figure P**). Pinching the skin is important to help make sure that you inject the medicine under the skin (into fatty tissue) but not any deeper (into the muscle).

Step 7

Inject and release



- With your other hand, place the syringe between the thumb and index (pointer) finger.
- Hold the middle of the syringe (where the markings are printed) at a 90-degree angle to your body and push the needle straight into the injection site (**Figure Q**). Make sure that you push the needle all the way into the skin.
- **Do not** hold or push on the plunger while inserting the needle.



- Slowly push the plunger down to inject the medicine (**Figure R**)
- Keep the needle in your skin and count to 5 to make sure that all the medicine is given.
- Let go of the pinched skin and remove the needle.
- Use the gauze pad to gently apply pressure to the injection site.
- **Do not** recap the needle.

Tips for giving injections to children

When giving a child an injection, it can help to have the child do other things. Have the child:

- squeeze something soft like a ball or stuffed animal.
- slowly breathe in and out.
- sing a song, count, or name favorite colors or animals.

Last Revised May 4, 2023

CA-SET-2300004 05/2023