M120256AD

Package leaflet: Information for the user

IMCIVREE 10 mg/ml solution for injection
setmelanotide

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist, or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What IMCVIREE is and what it is used for

IMCIVREE contains the active substance setmelanotide. It is used in adults and children of 2 years and above, to treat obesity caused by certain genetic conditions that affect how your brain controls feelings of hunger.

The genetic conditions this medicine is used to treat are:
- Bardet-Biedl syndrome (BBS)
- POMC (pro-opiomelanocortin) deficiency obesity
- PCSK1 (proprotein convertase subtilisin/kexin type 1) deficiency obesity
- LEPR (leptin receptor) deficiency obesity.

People with these conditions lack certain natural substances involved in controlling appetite or these substances do not work properly. This increases hunger levels and leads to obesity. The medicine helps to restore control of appetite and reduces symptoms of the condition.

2. What you need to know before you use IMCIVREE

Do not use IMCIVREE
- if you are allergic to setmelanotide or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions
Talk to your doctor, pharmacist or nurse before using IMCIVREE.

Before you start and during treatment with this medicine your doctor should examine your skin for any markings or dark areas. Whilst you are using this medicine you may get more marks or dark patches on your skin. A check before you start treatment will help you identify any new marks that appear once you have used this medicine.

It is very common (may affect more than 1 in 10 people) for male patients to get spontaneous erections of the penis when using this medicine. If an erection lasts more than 4 hours, please see a doctor urgently. Prolonged erections (priapism) can reduce your ability to get erections in the future if not treated.

Children

Do not give this medicine to children under the age of 2 years since there is no information on use in children below this age.

Other medicines and IMCIVREE

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before using this medicine.

It is not recommended to use IMCIVREE when pregnant or while trying to get pregnant, as it has not been studied in pregnant women. Weight loss during pregnancy can harm the baby.

Talk to your doctor before using this medicine if you are breast-feeding. Your doctor will discuss with you the benefits and risks of using IMCIVREE during this time.

Driving and using machines
This medicine should not have any effect on your ability to drive or use machines.

IMCIVREE contains benzyl alcohol

This medicine contains 10 mg benzyl alcohol in each 1 ml which is equivalent to 1 mg for each mg of your dose.

Benzyl alcohol has been linked with the risk of severe side effects in young children (less than 3 years old). There is an increased possibility that benzyl alcohol could build-up in their body (called “metabolic acidosis”) leading to “gasping syndrome”. Children aged 2 years old should be monitored by their doctor for signs of this build-up (including rapid heartbeat, rapid breathing, or confusion).

Benzyl alcohol may cause allergic reactions.

Ask your doctor or pharmacist for advice if you are pregnant or breast-feeding. This is because benzyl alcohol can build-up in your body and may cause side effects (called “metabolic acidosis”).

Ask your doctor or pharmacist for advice if you have a liver or kidney disease. This is because benzyl alcohol can build-up in your body and may cause side effects (called “metabolic acidosis”).

IMCIVREE contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially “sodium-free”.

3. How to use IMCIVREE

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

IMCIVREE is given as an injection under the skin, once a day, at the start of the day. The medicine is for long-term use.

Your doctor will advise you on the right dose to inject.

Pro-opiomelanocortin deficiency obesity, proprotein convertase subtilisin/kexin type 1 deficiency obesity and leptin receptor deficiency obesity.

In **adults and children aged 12 years or more**, recommended doses are as follows:

Treatment week	Daily dose in mg	Volume to be injected
Weeks 1–2	1 mg once daily	0.1 ml once daily
Week 3 and onward	2 mg once daily	0.2 ml once daily
If dose is not enough and side effects are acceptable	2.5 mg once daily	0.25 ml once daily
If dose is not enough and side effects are acceptable	3 mg once daily	0.3 ml once daily

In **children aged 6 to <12 years**, recommended doses are as follows:

Treatment week	Daily dose in mg	Volume to be injected
Weeks 1–2	0.5 mg once daily	0.05 ml once daily
Weeks 3–4	1 mg once daily	0.1 ml once daily
Week 5 and onward	2 mg once daily	0.2 ml once daily
If dose is not enough and side effects are acceptable	2.5 mg once daily	0.25 ml once daily

In **children aged 2 to <6 years**, recommended doses are as follows:

Patient weight/treatment week	Daily dose	Volume to be injected
<20 kg		
Week 1 and onward	0.5 mg once daily	0.05 ml once daily
20-<30 kg		
Weeks 1-2	0.5 mg once daily	0.05 ml once daily
Week 3 and onward (if dose is not enough and side effects are acceptable)	1 mg once daily	0.1 ml once daily
30-<40 kg		
Weeks 1-2	0.5 mg once daily	0.05 ml once daily
Weeks 3-4 (if dose is not enough and side effects are acceptable)	1 mg once daily	0.1 ml once daily
Week 5 and onward (if dose is not enough and side effects are acceptable)	1.5 mg once daily	0.15 ml once daily
≥40 kg		
Weeks 1-2	0.5 mg once daily	0.05 ml once daily
Weeks 3-4 (if dose is not enough and side effects are acceptable)	1 mg once daily	0.1 ml once daily
Weeks 5-6 (if dose is not enough and side effects are acceptable)	1.5 mg once daily	0.15 ml once daily
Weeks 7-8 (if dose is not enough and side effects are acceptable)	2 mg once daily	0.2 ml once daily
Week 9 and onward (if dose is not enough and side effects are acceptable)	2.5 mg once daily	0.25 ml once daily

Following the starting dose, if side effects of a subsequent dose are not acceptable, the dose will be reduced to the previous dose level. If the side effects of the reduced dose are acceptable, the dose will continue to be increased.

In patients with mild or moderate kidney disease, no changes to the dosing regimen are needed.

For **adults and children 12 to 17 years of age** with severe renal impairment, recommended doses are as follows:

Treatment week	Daily dose in mg	Volume to be injected
Weeks 1–2	0.5 mg once daily	0.05 ml once daily
Week 3 and onward (if side effects are acceptable)	1 mg once daily	0.1 ml once daily
If dose is not enough and side effects are acceptable	2 mg once daily	0.2 ml once daily
If dose is not enough and side effects are acceptable	2.5 mg once daily	0.25 ml once daily
If dose is not enough and side effects are acceptable	3 mg once daily	0.3 ml once daily

If side effects of the 0.5 mg starting dose are not acceptable, it will be reduced to 0.25 mg (0.025 ml). If side effects of the 0.25 mg once daily dose are acceptable, the dose will continue to be increased.

Following the starting dose, if side effects of a subsequent dose are not acceptable, the dose will be reduced to the previous dose level. If the side effects of the reduced dose are acceptable, the dose will continue to be increased.

If side effects of the 3 mg dose are not acceptable, it will be reduced to 2.5 mg, and you will continue on this dose.

In **children aged 6 to less than 12 years** with severe renal impairment, recommended doses are as follows:

Treatment week	Daily dose in mg	Volume to be injected
Weeks 1–2	0.25 mg once daily	0.025 ml once daily
Weeks 3–4 (if side effects are acceptable)	0.5 mg once daily	0.05 ml once daily
Week 5 and onward (if side effects are acceptable)	1 mg once daily	0.1 ml once daily
If dose is not enough and side effects are acceptable	2 mg once daily	0.2 ml once daily

If side effects of the 0.25 mg starting dose are not acceptable, treatment should be discontinued.

Following the starting dose, if side effects of a subsequent dose are not acceptable, the dose will be reduced to the previous dose level. If the side effects of the reduced dose are acceptable, the dose will continue to be increased.

If side effects of the 2 mg dose are not acceptable, it will be reduced to 1 mg, and you will continue on this dose.

In **children aged 2 to less than 6 years** with severe renal impairment, recommended doses are as follows:

Patient weight/ treatment week	Daily dose	Volume to be injected
<20 kg		
Week 1 and onward	0.25 mg once daily	0.025 ml once daily
20-<30 kg		
Weeks 1-2	0.25 mg once daily	0.025 ml once daily
Week 3 and onward (if dose is not enough and side effects are acceptable)	0.5 mg once daily	0.05 ml once daily
30-<40 kg		
Weeks 1-2	0.25 mg once daily	0.025 ml once daily
Weeks 3-4 (if dose is not enough and side effects are acceptable)	0.5 mg once daily	0.05 ml once daily
Week 5 and onward (if dose is not enough and side effects are acceptable)	1 mg once daily	0.1 ml once daily
≥40 kg		
Weeks 1-2	0.25 mg once daily	0.025 ml once daily
Weeks 3-4 (if dose is not enough and side effects are acceptable)	0.5 mg once daily	0.05 ml once daily
Weeks 5-6 (if dose is not enough and side effects are acceptable)	1 mg once daily	0.1 ml once daily
Weeks 7 and onward (if dose is not enough and side effects are acceptable)	1.5 mg once daily	0.15 ml once daily

If side effects of the 0.25 mg starting dose are not acceptable, treatment should be discontinued.

Following the starting dose, if side effects of a subsequent dose are not acceptable, the dose will be reduced to the previous dose level. If the side effects of the reduced dose are acceptable, the dose will continue to be increased.

Bardet-Biedl Syndrome

In **adults and children aged 16 years or more**, recommended doses are as follows:

Treatment week	Daily dose in mg	Volume to be injected
Weeks 1–2	2 mg once daily	0.2 ml once daily
Week 3 and onward (if side effects are acceptable)	3 mg once daily	0.3 ml once daily

If side effects of the 2 mg starting dose are not acceptable, it will be reduced to 1 mg (0.1 ml). If side effects of the 1 mg once daily dose are acceptable, the dose will continue to be increased.

Following the starting dose, if side effects of a subsequent dose are not acceptable, the dose will be reduced to the previous dose level. If the side effects of the reduced dose are acceptable, the dose will continue to be increased.

If side effects of the 3 mg dose are not acceptable, it will be reduced to 2 mg, and you will continue on this dose.

In **children aged 6 to less than 16 years**, recommended doses are as follows:

Treatment week	Daily dose in mg	Volume to be injected
Week 1	1 mg once daily	0.1 ml once daily
Week 2 (if side effects are acceptable)	2 mg once daily	0.2 ml once daily
Week 3 and onward (if side effects are acceptable)	3 mg once daily	0.3 ml once daily

If side effects of the 1 mg starting dose are not acceptable, it will be reduced to 0.5 mg (0.05 ml). If side effects of the 0.5 mg dose are acceptable, the dose will continue to be increased.

Following the starting dose, if side effects of a subsequent dose are not acceptable, the dose will be reduced to the previous dose level.

If the side effects of the reduced dose are acceptable, the dose will continue to be increased.

If side effects of the 3 mg dose are not acceptable, it will be reduced to 2 mg, and you will continue on this dose.

In **children aged 2 to <6 years**, recommended doses are as follows:

Patient weight/ treatment week	Daily dose	Volume to be injected
<20 kg		
Week 1 and onward	0.5 mg once daily	0.05 ml once daily
20-<30 kg		
Weeks 1-2	0.5 mg once daily	0.05 ml once daily
Week 3 and onward (if dose is not enough and side effects are acceptable)	1 mg once daily	0.1 ml once daily
30-<40 kg		
Weeks 1-2	0.5 mg once daily	0.05 ml once daily
Weeks 3-4 (if dose is not enough and side effects are acceptable)	1 mg once daily	0.1 ml once daily
Week 5 and onward (if dose is not enough and side effects are acceptable)	1.5 mg once daily	0.15 ml once daily
≥40 kg		
Weeks 1-2	0.5 mg once daily	0.05 ml once daily
Weeks 3-4 (if dose is not enough and side effects are acceptable)	1 mg once daily	0.1 ml once daily
Weeks 5-6 (if dose is not enough and side effects are acceptable)	1.5 mg once daily	0.15 ml once daily
Weeks 7-8 (if dose is not enough and side effects are acceptable)	2 mg once daily	0.2 ml once daily
Week 9 and onward (if dose is not enough and side effects are acceptable)	2.5 mg once daily	0.25 ml once daily

Following the starting dose, if side effects of a subsequent dose are not acceptable, the dose will be reduced to the previous dose level. If the side effects of the reduced dose are acceptable, the dose will continue to be increased.

In patients with mild or moderate kidney disease, no changes to the dosing regimen are needed.

For **adults and children 16 to 17 years of age** with severe renal impairment, recommended doses are as follows:

Treatment week	Daily dose in mg	Volume to be injected
Weeks 1–2	0.5 mg once daily	0.05 ml once daily
Week 3 and onward (if side effects are acceptable)	1 mg once daily	0.1 ml once daily
If dose is not enough and side effects are acceptable	2 mg once daily	0.2 ml once daily
If dose is not enough and side effects are acceptable	2.5 mg once daily	0.25 ml once daily
If dose is not enough and side effects are acceptable	3 mg once daily	0.3 ml once daily

If side effects of the 0.5 mg starting dose are not acceptable, it will be reduced to 0.25 mg (0.025 ml). If side effects of the 0.25 mg once daily dose are acceptable, the dose will continue to be increased.

Following the starting dose, if side effects of a subsequent dose are not acceptable, the dose will be reduced to the previous dose level. If the side effects of the reduced dose are acceptable, the dose will continue to be increased.

If side effects of the 3 mg dose are not acceptable, it will be reduced to 2.5 mg, and you will continue on this dose.

In **children aged 6 to less than 16 years of age** with severe renal impairment, recommended doses are as follows:

Treatment week	Daily dose in mg	Volume to be injected
Weeks 1–2	0.25 mg once daily	0.025 ml once daily
Weeks 3–4 (if side effects are acceptable)	0.5 mg once daily	0.05 ml once daily
Week 5 and onward (if side effects are acceptable)	1 mg once daily	0.1 ml once daily
If dose is not enough and side effects are acceptable	2 mg once daily	0.2 ml once daily

If side effects of the 0.25 mg starting dose are not acceptable, treatment should be discontinued.

Following the starting dose, if side effects of a subsequent dose are not acceptable, the dose will be reduced to the previous dose level.

If the side effects of the reduced dose are acceptable, the dose will continue to be increased.

If side effects of the 2 mg dose are not acceptable, it will be reduced to 1 mg, and you will continue on this dose.

In **children aged 2 to less than 6 years** with severe renal impairment, recommended doses are as follows:

Patient weight/ treatment week	Daily dose	Volume to be injected
<20 kg		
Week 1 and onward	0.25 mg once daily	0.025 ml once daily
20-<30 kg		
Weeks 1-2	0.25 mg once daily	0.025 ml once daily
Week 3 and onward (if dose is not enough and side effects are acceptable)	0.5 mg once daily	0.05 ml once daily
30-<40 kg		
Weeks 1-2	0.25 mg once daily	0.025 ml once daily
Weeks 3-4 (if dose is not enough and side effects are acceptable)	0.5 mg once daily	0.05 ml once daily
Week 5 and onward (if dose is not enough and side effects are acceptable)	1 mg once daily	0.1 ml once daily
≥40 kg		
Weeks 1-2	0.25 mg once daily	0.025 ml once daily
Weeks 3-4 (if dose is not enough and side effects are acceptable)	0.5 mg once daily	0.05 ml once daily
Weeks 5-6 (if dose is not enough and side effects are acceptable)	1 mg once daily	0.1 ml once daily
Weeks 7 and onward (if dose is not enough and side effects are acceptable)	1.5 mg once daily	0.15 ml once daily

If side effects of the 0.25 mg starting dose are not acceptable, treatment should be discontinued.

Following the starting dose, if side effects of a subsequent dose are not acceptable, the dose will be reduced to the previous dose level. If the side effects of the reduced dose are acceptable, the dose will continue to be increased.

Your doctor should regularly check how well this medicine is working; the doctor may adjust the dose if necessary. In growing children and adolescents, the impact on weight loss and their growth and development should be monitored.

This medicine is intended for long-term use. Discontinuation or irregular use may lead to a return or worsening of your symptoms. Make sure to closely follow the dosing schedule as instructed by your doctor or pharmacist.

How to inject IMCIVREE

IMCIVREE is injected into the fatty layer under the skin, in the stomach. Your doctor, pharmacist or nurse will show you how to do this. Once you are comfortable injecting yourself or your child, you will be able to do this at home.

IMCIVREE should be injected at the start of your day to maximise hunger reduction when awake. IMCIVREE can be taken without regard to the timing of meals.

Before injecting IMCIVREE, please read the following instructions carefully.

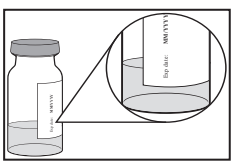
Step 1. Prepare for the injection

- Get the items you will need and place on a clean, flat surface.

You will need the following items that are supplied separately:

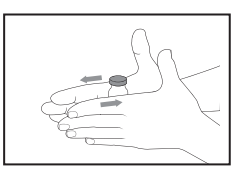
- Wash your hands with soap and warm water.
- Open the 2 alcohol wipes and the gauze pad.

Step 2 Examine the vial

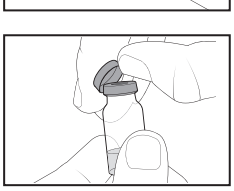


- Check the expiry date on the vial label, this is shown after 'EXP': MM/YYYY.
- The liquid should look clear to slightly yellow.
- Do not use if:
  - the expiry date has passed
  - the liquid is cloudy
  - there are particles floating in the vial
  - the plastic cap on a new vial is broken or missing
  - the vial has been stored at temperatures greater than 30°C.

Step 3. Prepare the vial

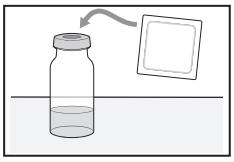


- Before use, let the vial reach room temperature. This can be done by removing the vial from the refrigerator 15 minutes before injection or by rolling the vial gently between the palms of your hands for 60 seconds.
  - Do not use warm water, a microwave or other appliance to heat the vial
  - Do not shake the vial



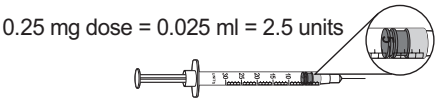
- If using a new vial, remove the plastic cap and throw it away in your household waste.

- Clean the top of the grey vial stopper with an alcohol wipe. Throw away the used alcohol wipe in your household waste.
  - Do not remove the vial stopper

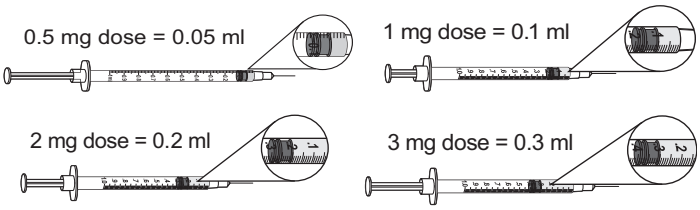


Step 4. Prepare the syringe

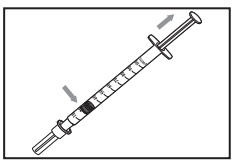
- For doses of 0.25 mg (0.025 ml or 2.5 units), use a 0.3 ml syringe with 0.5 (half) unit increments and a 29 to 31 size needle with a 6 to 13 mm needle length, suitable for injection under the skin.



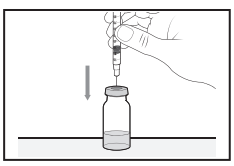
- For doses of 0.5 mg to 3 mg (0.05 ml to 0.3 ml), use a 1 ml syringe with 0.01 ml dosing increments and a 28 to 29 size needle with a 6 to 13 mm needle length, suitable for injection under the skin.



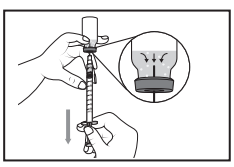
- Keep the protective needle cap on and pull back the plunger to fill the syringe with air equal to the amount of the medicine to be used.



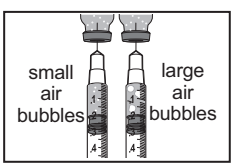
- Remove the needle cap from the syringe. Pull the cap straight off and away from your body.
- Place the vial upright on a flat surface. Hold the syringe and place it directly over the vial. Insert the needle straight down into the centre of the grey vial stopper.



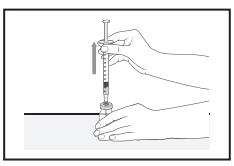
- Push the plunger down to inject the air from the syringe into the vial.
- Without removing the needle, gently turn the vial upside down.
  - Make sure the tip of the needle is fully in the medicine liquid and not in the air above the liquid



- Slowly pull back the plunger to fill the syringe with the amount medicine needed for your dose. When measuring your dose, be sure to read the units starting from the end closest to the black rubber stopper.
- Keep the needle in the vial and check for any large air bubbles in the syringe.
- If you see air bubbles these will need to be removed from the syringe. To remove:
  - Gently tap the side of the syringe with your finger to move the air bubble to the top of the syringe.
  - Empty the syringe back into the vial
  - Follow the above steps to fill your syringe again. Pull the plunger more slowly this time and make sure the tip of the needle is always fully in the liquid in the vial to reduce the chance of air bubbles.

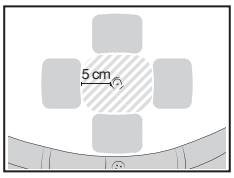


- Once there are no large air bubbles in the syringe, place the vial upright on a hard surface.
- Hold the vial with one hand and the barrel of the syringe between the fingertips of your other hand. Pull the needle straight up and out of the vial.
- Place the syringe on the hard surface, make sure the needle does not touch the surface. Do not recap the needle.



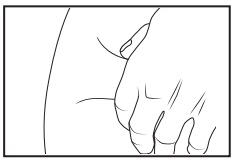
Step 5. Prepare the injection site

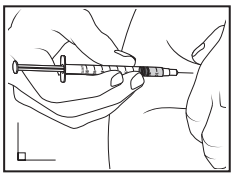
- Choose the area on your stomach for the injection.
  - Change your injection site each day.
  - Make sure the injection site is at least 5 cm away from the belly button.
  - Do not inject an area that is red, swollen, or irritated.

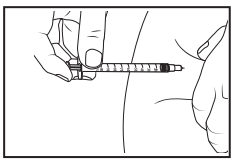


- Clean your chosen injection site with your second alcohol wipe using a circular motion.
- Allow the skin to dry for about 10 seconds.
- Do not touch, fan, or blow on the cleaned area

Step 6. Injecting IMCIVREE







- Place the syringe between your thumb and index finger of the hand you write with.
- With your other hand, gently pinch about 5 cm of skin between your thumb and index finger. Make sure you hold the skin fold until the injection is complete.
- Hold the middle of the syringe at a 90° angle to your skin and push the needle straight into the injection site, making sure the needle goes in all the way
- Do not hold or push on the plunger while inserting the needle
- Holding the barrel of the syringe between your thumb and middle finger, use your index finger to slowly push the plunger to inject the medicine.
- Count to 5 after injecting IMCIVREE to make sure all the medicine has left the syringe.
- Let go of the pinched skin and pull the out the needle.
- Use a gauze pad to gently apply pressure to the injection site, then throw gauze pad into your household waste.
- Place your used syringe in the sharps bin. Do not throw away in your household waste.
- If you still have medicine left in your vial, place the vial back in the carton and store either in your refrigerator or in a safe place at a temperature of less than 30°C until it is time for your next dose.

If you use more IMCIVREE than you should

If you or your child use more IMCIVREE than you should, contact your doctor.

If you forget to use IMCIVREE

If you forget to inject the medicine, skip the dose and inject your next dose at the usual time. Do not use a double dose to make up for a forgotten dose.

If you stop using IMCIVREE

If you stop using this medicine your hunger may return and your weight loss may stop.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Very common (may affect more than 1 in 10 people)
- Dark areas or patches on your skin
- Pain, bruising or inflammation (redness and/or swelling) at the site of injection
- Feeling or being sick (vomiting)
- Headache
- Spontaneous penile erections
- Feeling thirsty or drinking more water

Common (may affect up to 1 in 10 people)
- Dry, red or itchy skin
- Pain
- Increased sweating
- Discoloured areas or patches on your skin
- Lesions on your skin
- Hair loss
- Feeling tired
- Feeling weak
- Dry mouth
- Indigestion
- Diarrhoea
- Feeling constipated
- Stomach pain
- Feeling dizzy
- Increased penile erections
- Trouble sleeping
- Feeling depressed
- Change in sexual arousal
- Increased sexual desire
- Skin neoplasm
- Back pain
- Muscle cramps
- Pain in arms or legs
- Hot flush
- Vertigo

Uncommon (may affect up to 1 in 100 people)
- Brown spots or freckles on your skin
- Redness of the skin
- Rash
- Lines or streaks on your skin
- Change in hair colour
- Bump on the skin
- Inflammation of the skin
- Nail colour changes or ridges
- Chest pain
- Sensitivity to hot or cold
- Itching around the site of injection
- Chills
- Feeling cold
- Feeling hot
- Discoloured gums
- Stomach bloating
- Increase in saliva
- Flatulence
- Heartburn
- Drowsiness
- Increase in sensitivity to sight, sound, touch, smell
- Migraine headache
- Loss or change in sense of smell
- Taste disorders
- Anxiety
- Change in mood
- Ejaculation disorder
- Female inability to achieve or maintain sexual arousal
- Genital discomfort or sensitivity
- Decreased sexual desire
- Female genital disorder
- Depressed mood
- Sleep disorder
- Eye neoplasm
- Nightmares
- Flat, coloured mole on your skin
- Joint aches
- Yawning
- Cough
- Runny nose
- Pain in the muscles or bones of the chest
- Discolouration of the white part of the eyes
- Yellowing of eyes

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist, or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via Yellow Card Scheme, Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store IMCIVREE

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and vial. The expiry date refers to the last day of that month.

IMCIVREE should be stored in a refrigerator at 2°C to 8°C until the expiry date on the carton. Alternatively, IMCIVREE may be kept at room temperature, no warmer than 30°C, for up to 30 days or until the expiry date, whichever is sooner. Store all vials (even those you have opened) in the original carton to protect them from light. After you first use a vial, discard after 28 days.

Do not freeze this medicine.

If IMCIVREE is exposed to temperatures above 30°C do not use and discard according to local guidelines. Do not use this medicine if you notice floating particles or cloudiness.

Always use a new syringe for each injection.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What IMCIVREE contains
- The active substance is setmelanotide. Each multidose vial contains 10 mg of setmelanotide in 1 ml of solution.

The other ingredients are:
- benzyl alcohol (see section 2 What you need to know before you use IMCIVREE)
- N-(carbonyl-methoxypolyethylene glycol 2000)-1,2-distearoyl- glycero-3-phosphoethanolamine sodium salt (mPEG-2000-DSPE)
- Carmellose sodium (see section 2 What you need to know before you use IMCIVREE)
- Mannitol
- Phenol
- Disodium edetate (see section 2 What you need to know before you use IMCIVREE)
- Water for injections
- Hydrochloric acid (for pH-adjustment)
- Sodium hydroxide (for pH-adjustment)

What IMCIVREE looks like and contents of the pack
IMCIVREE is a clear colourless to slightly coloured solution.
This medicine comes in clear glass vials with a stopper and cap, containing 1 ml of solution for injection.

Marketing Authorisation Holder and Manufacturer
Rhythm Pharmaceuticals Netherlands B.V.
Radarweg 29,
1043NX Amsterdam,
Netherlands

This leaflet was last revised in September 2024