PATIENT & CAREGIVER EDUCATION

Setmelanotide

This information from UpToDate® Lexidrug™ explains what you need to know about this medication, including what it's used for, how to take it, its side effects, and when to call your healthcare provider.

Brand Names: US

Imcivree

Brand Names: Canada

Imcivree

What is this drug used for?

- It is used to help with weight loss and keep the weight off in certain people.

What do I need to tell the doctor BEFORE my child takes this drug?

- If your child is allergic to this drug; any part of this drug; or any other drugs, foods, or substances. Tell the doctor about the allergy and what signs your child had.
- If your child has kidney problems.

If your child is breast-feeding a baby:

- Be sure your child does not breast-feed a baby while taking this drug.

This is not a list of all drugs or health problems that interact with this drug.

Tell the doctor and pharmacist about all of your child's drugs (prescription or OTC, natural products, vitamins) and health problems. You must check to make sure that it is safe to give this drug with all of your child's other drugs and health problems. Do not start, stop, or change the dose of any drug your child takes without checking with the doctor.

What are some things I need to know or do while my child takes this drug?

- Tell all of your child's health care providers that your child is taking this drug. This includes your child's doctors, nurses, pharmacists, and dentists.
- Severe allergic reactions have happened with this drug. This usually happened within minutes to hours after taking this drug. Get medical help right away if your child has any signs that are not normal after getting this drug.
- Have your child's skin checked as you have been told by the doctor.

- Weight loss may affect growth in children. Children need regular growth checks.
- If the patient is a newborn or infant. This drug has benzyl alcohol in it. If possible, avoid products with benzyl alcohol in newborns or infants. Serious side effects can happen in these children with some doses of benzyl alcohol, including if given with other drugs that have benzyl alcohol.

If your child is pregnant:

- Tell the doctor if your child is pregnant or becomes pregnant. You will need to talk about the benefits and risks of your child using this drug while pregnant.

What are some side effects that I need to call my child's doctor about right away?

WARNING/CAUTION: Even though it may be rare, some people may have very bad and sometimes deadly side effects when taking a drug. Tell your child's doctor or get medical help right away if your child has any of the following signs or symptoms that may be related to a very bad side effect:

- Signs of an allergic reaction, like rash; hives; itching; red, swollen, blistered, or peeling skin with or without fever; wheezing; tightness in the chest or throat; trouble breathing, swallowing, or talking; unusual hoarseness; or

swelling of the mouth, face, lips, tongue, or throat.

- A fast heartbeat.
- Severe dizziness or passing out.
- New or worse behavior or mood changes like depression or thoughts of suicide.
- Falls.
- Fever.
- Ear pain.
- Some people have had sexual problems when taking this drug. Males have had erections (hard penis) that happened without sexual activity. Females have had more interest in sex without any sexual activity. Call the doctor if your child has sexual problems. Seek medical care right away if your child is a male and has an erection that lasts more than 4 hours.
- Patients with hypothalamic obesity (HO) and a weak adrenal gland may have worse adrenal gland problems with this drug. Tell the doctor right away if your child has signs of a weak adrenal gland like a severe upset stomach or throwing up, severe dizziness or passing out, muscle weakness, feeling very tired, mood changes, decreased appetite, or weight loss.
- Patients with hypothalamic obesity (HO) and diabetes

insipidus (DI) may have high or low sodium levels with this drug. Tell the doctor right away if your child has a change in fluid intake or may be dehydrated. Tell the doctor right away if your child has signs of high or low sodium levels like headache, trouble focusing, memory problems, feeling confused, tiredness or weakness, passing out, twitching, seizures, or change in balance.

What are some other side effects of this drug?

All drugs may cause side effects. However, many people have no side effects or only have minor side effects. Call your child's doctor or get medical help if any of these side effects or any other side effects bother your child or do not go away:

- Change in skin color, darkening of moles, and new moles. These changes will go away when this drug is stopped.
- Change in color of hair.
- Pain, redness, swelling, or other reaction where the injection was given.
- Constipation, diarrhea, stomach pain, upset stomach, throwing up, or decreased appetite.
- Headache.
- Back pain.

- Feeling dizzy, tired, or weak.
- Joint pain.
- Mouth or throat pain or irritation.
- Dry mouth.
- Dry skin.
- Trouble sleeping.
- Hair loss.
- Signs of a common cold.
- Flu-like signs.
- Chills.
- Cough.
- Muscle spasm.
- Pain in arms or legs.

These are not all of the side effects that may occur. If you have questions about side effects, call your child's doctor. Call your child's doctor for medical advice about side effects.

You may report side effects to your national health agency.

How is this drug best given?

Give this drug as ordered by your child's doctor. Read all information given to you. Follow all instructions closely.

- It is given as a shot into the fatty part of the skin on the top of the thigh, belly area, or upper arm.
- If you will be giving your child the shot, your child's doctor or nurse will teach you how to give the shot.
- Give this drug when your child first wakes up.
- Give this drug with or without food.
- Wash your hands before and after use.
- Move the site where you give the shot with each shot.
- If stored in a refrigerator, let this drug come to room temperature before using it. To do this, leave it at room temperature for about 15 minutes. Do not heat this drug. You may also warm the drug by rolling it in the palms of your hands for about 1 minute.
- Do not use if the solution is cloudy, leaking, or has particles.
- This drug is colorless to a faint yellow. Do not use if the solution changes color.
- Do not shake the solution.
- Do not give into skin within 2 inches (5 cm) of the belly button.

- Do not give into the belly button, ribs, or hip bones.
- Do not give into a mole.
- Do not give into skin that is red, swollen, scarred, or irritated.
- Throw away needles in a needle/sharp disposal box. Do not reuse needles or other items. When the box is full, follow all local rules for getting rid of it. Talk with a doctor or pharmacist if you have any questions.

What do I do if my child misses a dose?

- Skip the missed dose and go back to your child's normal time.
- Do not give 2 doses at the same time or extra doses.

How do I store and/or throw out this drug?

- Store unopened vials in a refrigerator. Do not freeze.
- If needed, you may store at room temperature for up to 30 days. Write down the date you take this drug out of the refrigerator. If stored at room temperature and not used within 30 days, throw this drug away.
- Store in the outer carton to protect from light.
- Protect from heat.
- Throw away drug if stored at a temperature above 86°F (30°C).

- You may store opened vials at room temperature or in a refrigerator.
- After opening, throw away any part not used after 30 days.
- Keep all drugs in a safe place. Keep all drugs out of the reach of children and pets.
- Throw away unused or expired drugs. Do not flush down a toilet or pour down a drain unless you are told to do so. Check with your pharmacist if you have questions about the best way to throw out drugs. There may be drug take-back programs in your area.

General drug facts

- If your child's symptoms or health problems do not get better or if they become worse, call your child's doctor.
- Do not share your child's drug with others and do not give anyone else's drug to your child.
- Some drugs may have another patient information leaflet. If you have any questions about this drug, please talk with your child's doctor, nurse, pharmacist, or other health care provider.
- If you think there has been an overdose, call your poison control center or get medical care right away. Be ready to tell or show what was taken, how much, and when it

happened.

Consumer Information Use and Disclaimer

This generalized information is a limited summary of diagnosis, treatment, and/or medication information. It is not meant to be comprehensive and should be used as a tool to help the user understand and/or assess potential diagnostic and treatment options. It does NOT include all information about conditions, treatments, medications, side effects, or risks that may apply to a specific patient. It is not intended to be medical advice or a substitute for the medical advice, diagnosis, or treatment of a health care provider based on the health care provider's examination and assessment of a patient's specific and unique circumstances. Patients must speak with a health care provider for complete information about their health, medical questions, and treatment options, including any risks or benefits regarding use of medications. This information does not endorse any treatments or medications as safe, effective, or approved for treating a specific patient. UpToDate, Inc. and its affiliates disclaim any warranty or liability relating to this information or the use thereof. The use of this information is governed by the Terms of Use, available at https://www.wolterskluwer.com/en/know/clinical-effectiveness-terms.

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If you have questions or concerns, contact your healthcare provider. A member of your care team will answer Monday through Friday from 9 a.m. to 5 p.m. Outside those hours, you can leave a message or talk with another MSK provider. There is always a doctor or nurse on call. If you're not sure how to reach your healthcare provider, call 212-639-2000.

For more resources, visit www.mskcc.org/pe to search our virtual library.

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