

THE OMNITROPE ADMINISTRATION GUIDE:

How to use the Omnitrope pen or vial & syringe



Omnitrope® (somatropin) injection is a laboratory-created human growth hormone. It is indicated for children with growth failure due to growth hormone deficiency (GHD), Prader-Willi Syndrome, Small for Gestational Age, Turner Syndrome, and Idiopathic Short Stature. It is also indicated for adults with growth hormone deficiency.

Omnitrope is available in 5 mg and 10 mg injection pens as well as in a 5.8 mg vial.

Please see accompanying full Prescribing Information and Important Safety Information starting on page 22.

HOW TO USE YOUR OMNITROPE PEN 5

For full instructions, please refer to the [Instructions For Use](#) supplied with each Pen 5.

Please see attached full Prescribing Information and Indications and Important Safety Information.

Read these Instructions for Use before you start using Omnitrope Pen 5 and each time you get a refill as there may be new information. Please note that this information does not take the place of talking to the healthcare provider about the medical condition or the treatment.

OMNITROPE PEN 5, CARTRIDGE CONTAINING OMNITROPE, NEEDLE, ALCOHOL SWAB, AND STORAGE CASE:

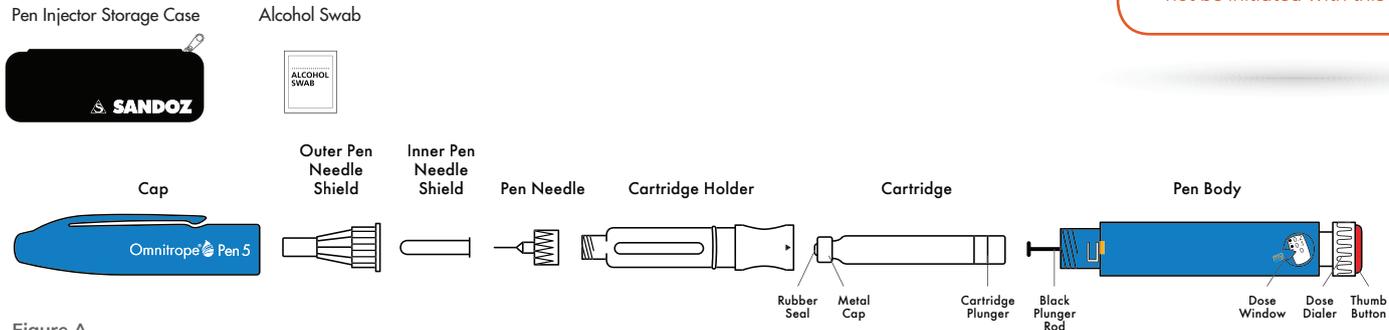


Figure A

NOTE:

- Omnitrope is for use under the skin only (subcutaneous)
- **Do not** share your Omnitrope Pen or needles with anyone else. You may give an infection to them or get an infection from them
- The “Start use by no later than” date, presented in year and month on the outer carton, indicates the date after which therapy should not be initiated with this pen

STEP 1. PLACING THE CARTRIDGE IN THE OMNITROPE PEN 5

- Take an Omnitrope cartridge out of the refrigerator and leave at room temperature for about 30 minutes. Wash and dry your hands while you wait
- Assemble all of the supplies needed on a flat surface. Remove the Pen and cartridge from their cartons if you are preparing the injection for the first time
- Hold the body of the Pen with 1 hand and pull off the Pen cap with the other hand. **See Figure B**
- Hold the body of the Pen with 1 hand and unscrew the cartridge holder in a clockwise direction until the Pen and cartridge holder are completely separated. **See Figure C**
- Hold the cartridge in 1 hand with the metal cap end pointing down. Insert the cartridge into the cartridge holder. **See Figure D**
- Lower the Pen body onto the cartridge holder so that the black rod presses against the cartridge plunger. Screw the cartridge holder onto the Pen body in a counterclockwise direction until the cartridge holder will not turn anymore. One of the blue arrows on the cartridge holder must line up with the yellow line mark on the Pen body. Do not over tighten the cartridge holder. **See Figure E**

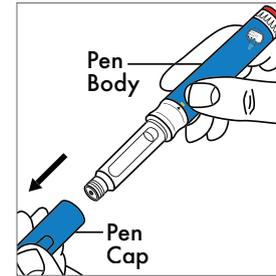


Figure B

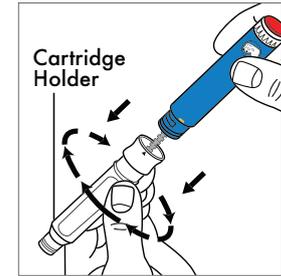


Figure C

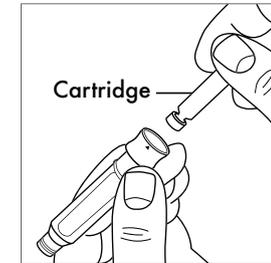


Figure D

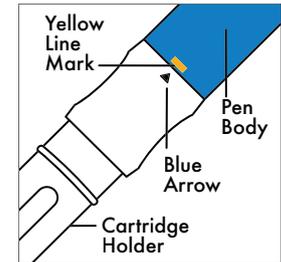
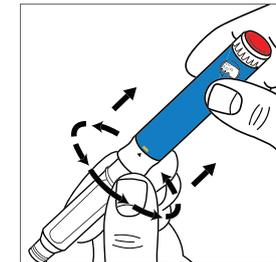


Figure E

STEP 2. ATTACHING THE NEEDLE TO THE OMNITROPE PEN 5

- Take a new disposable needle and tear off the paper tab. Do not touch the needle or lay it on a surface. **See Figure F**
- Holding the cartridge holder with 1 hand, firmly press the needle onto the cartridge holder end of the Pen. **See Figure G**. Screw the threaded hub of the needle onto the cartridge holder in a counterclockwise direction until the needle will not turn anymore. **See Figure H**
- Gently pull off the outer needle shield and put it on a flat surface. You will use the outer needle shield later to remove the needle from the Pen after the injection is finished. **See Figure I**

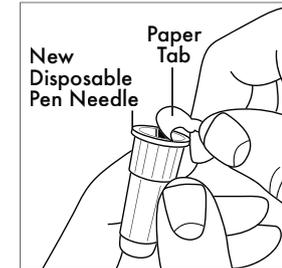


Figure F

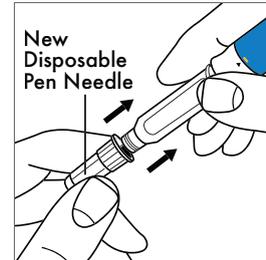


Figure G

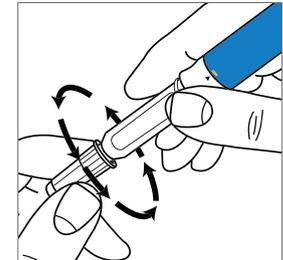


Figure H

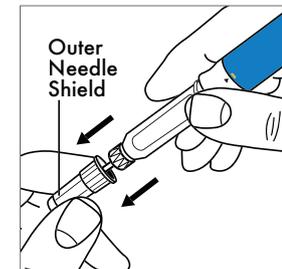


Figure I

NOTE:

Check that the cartridge holder is attached to the Pen body before each injection. One of the blue arrows on the cartridge holder should be lined up with the yellow mark on the Pen body. After you attach the needle, you may see a few drops of medicine at the tip of the needle.

STEP 3. PRIMING A NEW CARTRIDGE

- Priming is not needed for a cartridge you have used before. If the cartridge has already been primed, go to Step 4
- Before you use a new cartridge you must first prepare it for use. Hold the Pen with the needle pointing upwards. Gently tap the cartridge holder with your finger to help air bubbles rise to the top of the cartridge. See Figure J
- Hold the pen with the needle pointing up and the dose window facing you and you will see the numbers in the dose window at the bottom of the Pen body. Using the dose knob on the bottom of the Pen, slowly turn the dose knob in a clockwise direction as shown in Figure K until you hear 1 “click”. The arrow on the Pen body will then be lined up with the small line between “0” and “0.1” (0.05 mg). See Figure K
- Remove the inner needle shield. See Figure L
- With the needle pointing up, firmly turn the dose knob in a counterclockwise direction and back to the “0” position

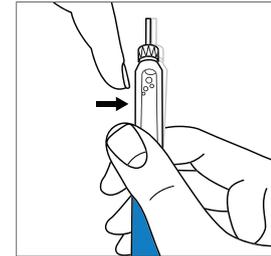


Figure J

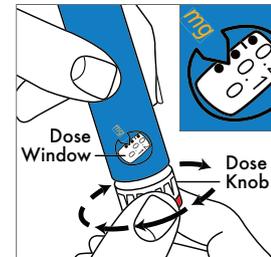


Figure K

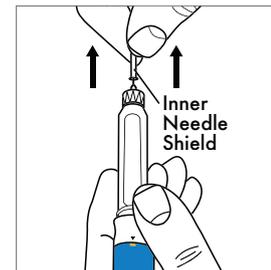


Figure L

- At least 2 drops of medicine must flow out of the needle for the Pen to be properly primed. **See Figure M**
- If at least 2 drops of medicine **do not** flow out, set the dose to 0.05 mg and repeat this step until at least 2 drops of medicine appear at the tip of the needle
- When you see 2 drops of medicine flow out of the needle, the Pen is correctly primed and ready to use

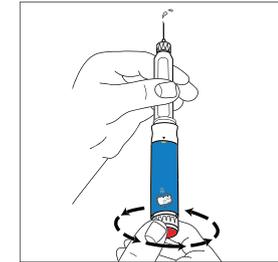


Figure M

STEP 4. SELECTING THE CORRECT DOSE OF OMNITROPE

- Hold the pen with the needle pointing up and the dose window facing you and turn (dial) the dose knob in a clockwise direction until you see the number of mgs for the prescribed dose in the middle of the dose window. The dose should be lined up with the arrow on the Pen body. You will hear 1 click for every single unit you dial. **See Figure N**

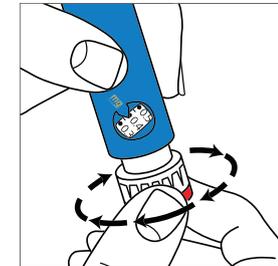


Figure N

Do not count the clicks to measure the correct dose of medicine.

- **If you turn the dose knob past the correct dose, do not dial counterclockwise**

Instead, hold the Pen body with the needle pointing up and turn the dose knob in a clockwise direction until you will see a bent arrow (↷) in the dose dialing window. **See Figure O.** Now continue to turn the dose knob in a clockwise direction until you hear a click and the entire Pen body is fully extended.

The injection button can now be fully pressed, resetting the dial to “0” without giving medicine. The correct dose can now be redialed.

- Check that the cartridge holder is still attached to the Pen body, with the blue arrow lined up with the yellow mark on the Pen body

STEP 5. SELECTING THE INJECTION SITE AND INJECTING THE DOSE OF OMNITROPE

Change the injection site every day. **See Figure P.**

- Select the injection site and wipe the skin with an alcohol pad as your healthcare provider showed you
- Insert the needle under the skin as your healthcare provider showed you. **See Figure Q**
- After inserting the needle into the skin, push the injection button as far in as it will go and press the button firmly. A clicking sound will be heard while the dose is being injected. Continue to press firmly on the injection button for **5 seconds** before you remove the needle from the skin. **See Figure R**

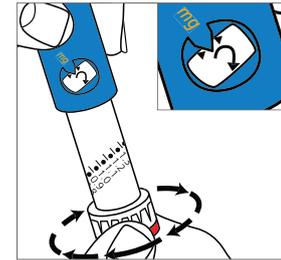


Figure O

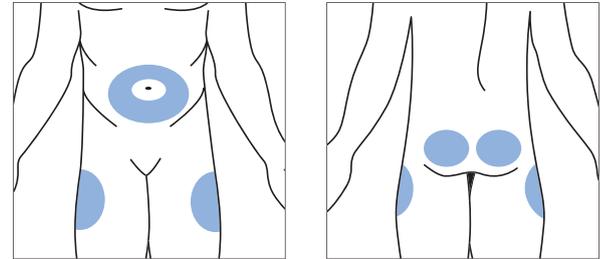


Figure P

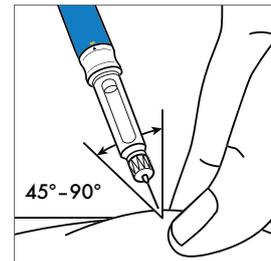


Figure Q

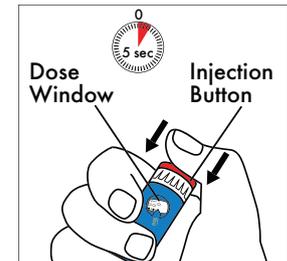


Figure R

- Stop pressing the injection button before you carefully remove the needle from the skin
- If the injection button cannot be pushed in completely or stops during the injection, and cartridge is empty, then the full dose has not been given. The dose indicator window will show the amount of medicine still needed. Reset the dose knob to “0” as described in Step 4. Remove the needle as described in Step 6. Replace the empty cartridge with a new cartridge as described in Step 1. Prime the new cartridge as described in Step 3. Set the dose, which you noted, and inject. This completes your dose

STEP 6. REMOVING AND THROWING AWAY THE NEEDLE AND EMPTY CARTRIDGE

- Carefully replace the outer needle shield. See Figure S
- Hold the Pen by the cartridge holder and carefully remove the needle from the Pen by turning the needle in a clockwise direction. See Figure T. Recap the pen

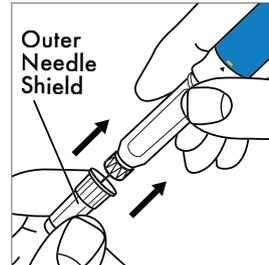


Figure S

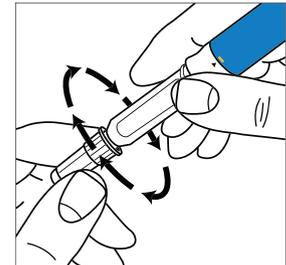


Figure T

- Put your used needles and cartridges in a FDA-cleared sharps disposal container right away after use. **Do not throw away (dispose of) loose needles and cartridges in your household trash**
- If you do not have a FDA-cleared sharps disposal container, you may use a household container that is:
 - made of a heavy-duty plastic,
 - can be closed with a tight-fitting, puncture-resistant lid, without sharps being able to come out,
 - upright and stable during use,
 - leak-resistant, and
 - properly labeled to warn of hazardous waste inside the container
- When your sharps disposal container is almost full, you will need to follow your community guidelines for the right way to dispose of your sharps disposal container. There may be state or local laws about how you should throw away used needles and cartridges. For more information about safe sharps disposal, and for specific information about sharps disposal in the state that you live in, go to the FDA's website at: <http://www.fda.gov/safesharpsdisposal>
- Do not dispose of your used sharps disposal container in your household trash unless your community guidelines permit this. Do not recycle your used sharps disposal container

HOW SHOULD I STORE OMNITROPE PEN 5?

- Store Omnitrope cartridges in the refrigerator between 36°F and 46°F (2°C and 8°C)
- When the Omnitrope Pen 5 contains a cartridge, do not remove the cartridge from the Pen in between injections. Store the Pen containing the cartridge in the storage case provided and place in the refrigerator
- When the Pen does not contain a cartridge, you may store the Pen at room temperature
- Do not freeze Omnitrope cartridges
- Protect the Omnitrope Pen 5 and cartridge from light by storing in their cartons or the storage case
- The Omnitrope cartridge must be thrown away 28 days after the first injection. The Omnitrope Pen 5 can be reloaded with a new cartridge and can be used multiple times

HOW TO USE YOUR OMNITROPE PEN 10

For full instructions, please refer to the [Instructions For Use](#) supplied with each Pen 10.

Please see attached full Prescribing Information and Indications and Important Safety Information.

Read these Instructions for Use before you start using Omnitrope Pen 10 and each time you get a refill as there may be new information. Please note that this information does not take the place of talking to the healthcare provider about the medical condition or the treatment.

OMNITROPE PEN 10, CARTRIDGE CONTAINING OMNITROPE, NEEDLE, ALCOHOL SWAB, AND STORAGE CASE:

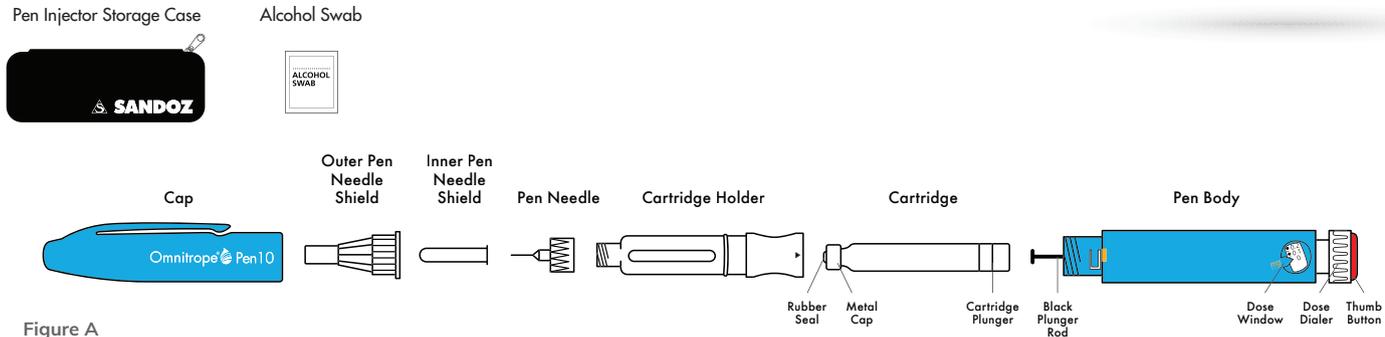


Figure A

NOTE:

- Omnitrope is for use under the skin only (subcutaneous)
- **Do not** share your Omnitrope Pen or needles with anyone else. You may give an infection to them or get an infection from them
- The “Start use by no later than” date, presented in year and month on the outer carton, indicates the date after which therapy should not be initiated with this pen

STEP 1. PLACING THE CARTRIDGE IN THE OMNITROPE PEN 10

- Take an Omnitrope cartridge out of the refrigerator and leave at room temperature for about 30 minutes. Wash and dry your hands while you wait
- Assemble all of the supplies needed on a flat surface. Remove the Pen and cartridge from their cartons if you are preparing the injection for the first time
- Hold the body of the Pen with 1 hand and pull off the Pen cap with the other hand. **See Figure B**
- Hold the body of the Pen with 1 hand and unscrew the cartridge holder in a clockwise direction until the Pen and cartridge holder are completely separated. **See Figure C**
- Hold the cartridge in 1 hand with the metal cap end pointing down. Insert the cartridge into the cartridge holder. **See Figure D**
- Lower the Pen body onto the cartridge holder so that the black rod presses against the cartridge plunger. Screw the cartridge holder onto the Pen body in a counterclockwise direction until the cartridge holder will not turn anymore. One of the blue arrows on the cartridge holder must line up with the white line mark on the Pen body. Do not over tighten the cartridge holder. **See Figure E**

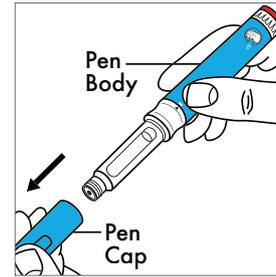


Figure B

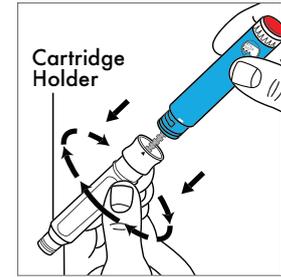


Figure C

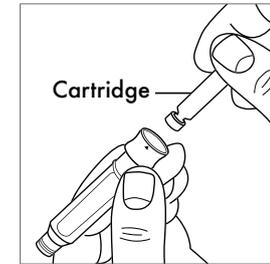


Figure D

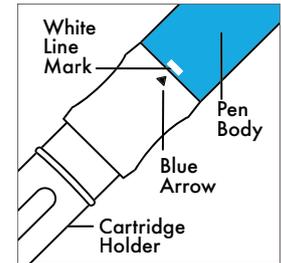
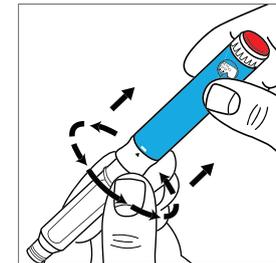


Figure E

STEP 2. ATTACHING THE NEEDLE TO THE OMNITROPE PEN 10

- Take a new disposable needle and tear off the paper tab. Do not touch the needle or lay it on a surface. **See Figure F**
- Holding the cartridge holder with 1 hand, firmly press the needle onto the cartridge holder end of the Pen. **See Figure G**. Screw the threaded hub of the needle onto the cartridge holder in a counterclockwise direction until the needle will not turn anymore. **See Figure H**
- Gently pull off the outer needle shield and put it on a flat surface. You will use the outer needle shield later to remove the needle from the Pen after the injection is finished. **See Figure I**

NOTE:

Check that the cartridge holder is attached to the Pen body before each injection. One of the blue arrows on the cartridge should be lined up with the white mark on the Pen body. After you attach the needle, you may see a few drops of medicine at the tip of the needle.

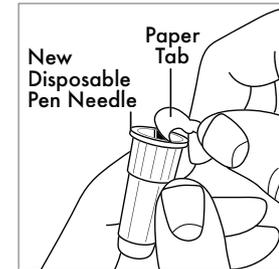


Figure F

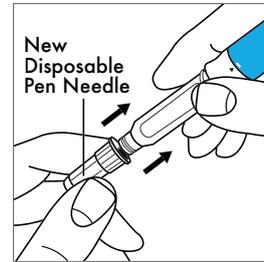


Figure G

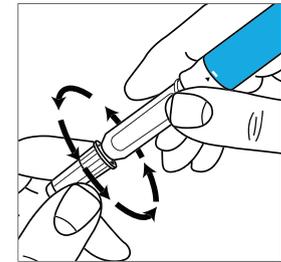


Figure H

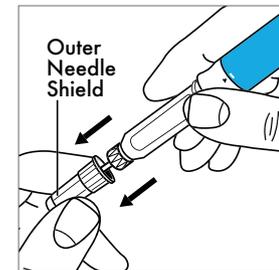


Figure I

STEP 3. PRIMING A NEW CARTRIDGE

- Priming is not needed for a cartridge you have used before. If the cartridge has already been primed, go to Step 4
- Before you use a new cartridge you must first prepare it for use. Hold the Pen with the needle pointing upwards. Gently tap the cartridge holder with your finger to help air bubbles rise to the top of the cartridge. See Figure J
- Hold the pen with the needle pointing up and the dose window facing you and you will see the numbers in the dose window at the bottom of the Pen body. Using the dose knob on the bottom of the Pen, slowly turn the dose knob in a clockwise direction as shown in Figure K until you hear 1 “click”. The arrow on the Pen body will then be lined up with the small line between “0” and “0.2” (0.1 mg). See Figure K
- Remove the inner needle shield. See Figure L
- With the needle pointing up, firmly turn the dose knob in a counterclockwise direction and back to the “0” position

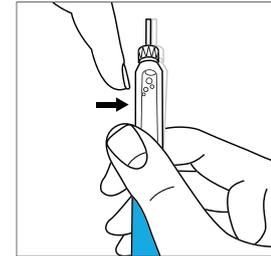


Figure J

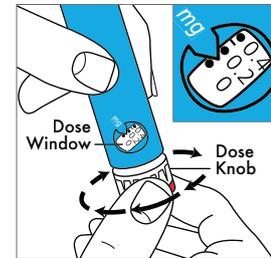


Figure K

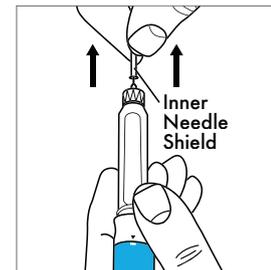


Figure L

- At least 2 drops of medicine must flow out of the needle for the Pen to be properly primed. **See Figure M**
- If at least 2 drops of medicine **do not** flow out, set the dose to 0.1 mg and repeat this step until at least 2 drops of medicine appear at the tip of the needle
- When you see 2 drops of medicine flow out of the needle, the Pen is correctly primed and ready to use

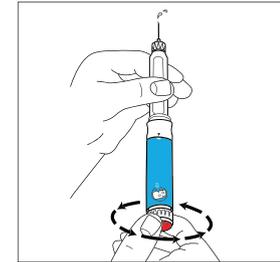


Figure M

STEP 4. SELECTING THE CORRECT DOSE OF OMNITROPE

- Hold the pen with the needle pointing up and the dose window facing you and turn (dial) the dose knob in a clockwise direction until you see the number of mgs for the prescribed dose in the middle of the dose window. The dose should be lined up with the arrow on the Pen body. You will hear 1 click for every single unit you dial. **See Figure N**

Do not count the clicks to measure the correct dose of medicine.

- **If you turn the dose knob past the correct dose, do not dial counterclockwise**

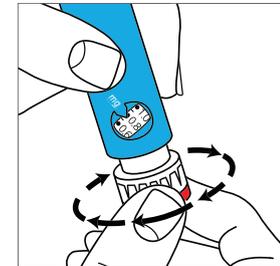


Figure N

Instead, hold the Pen body with the needle pointing up and turn the dose knob in a clockwise direction until you will see a bent arrow (↷) in the dose dialing window. **See Figure O.** Now continue to turn the dose knob in a clockwise direction until you hear a click and the entire Pen body is fully extended.

The injection button can now be fully pressed, resetting the dial to “0” without giving medicine. The correct dose can now be redialed.

- Check that the cartridge holder is still attached to the Pen body, with the blue arrow lined up with the white mark on the Pen body

STEP 5. SELECTING THE INJECTION SITE AND INJECTING THE DOSE OF OMNITROPE

Change the injection site every day. **See Figure P.**

- Select the injection site and wipe the skin with an alcohol pad as your healthcare provider showed you
- Insert the needle under the skin as your healthcare provider showed you. **See Figure Q**

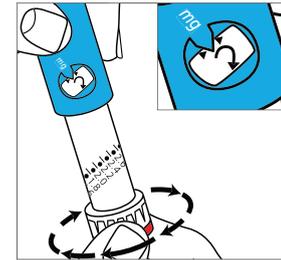


Figure O

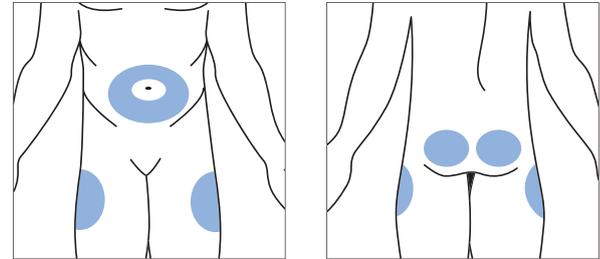


Figure P

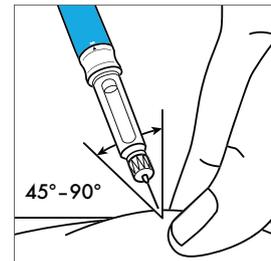


Figure Q

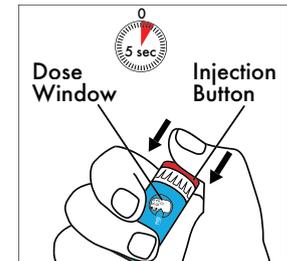


Figure R

- After inserting the needle into the skin, push the injection button as far in as it will go and press the button firmly. A clicking sound will be heard while the dose is being injected. Continue to press firmly on the injection button for **5 seconds** before you remove the needle from the skin. **See Figure R** Stop pressing the injection button before you carefully remove the needle from the skin
- If the injection button cannot be pushed in completely or stops during the injection, and cartridge is empty, then the full dose has not been given. The dose indicator window will show the amount of medicine still needed. Reset the dose knob to “0” as described in Step 4. Remove the needle as described in Step 6. Replace the empty cartridge with a new cartridge as described in Step 1. Prime the new cartridge as described in Step 3. Set the dose, which you noted, and inject. This completes your dose

STEP 6. REMOVING AND THROWING AWAY THE NEEDLE AND EMPTY CARTRIDGE

- Carefully replace the outer needle shield. **See Figure S**
- Hold the Pen by the cartridge holder and carefully remove the needle from the Pen by turning the needle in a clockwise direction. **See Figure T.** Recap the pen

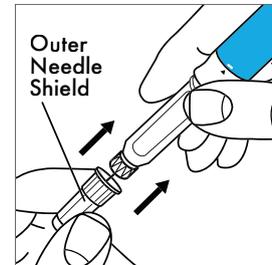


Figure S

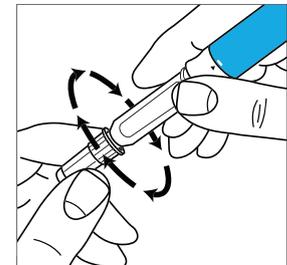


Figure T

- Put your used needles and cartridges in a FDA-cleared sharps disposal container right away after use. **Do not throw away (dispose of) loose needles and cartridges in your household trash**
- If you do not have a FDA-cleared sharps disposal container, you may use a household container that is:
 - made of a heavy-duty plastic,
 - can be closed with a tight-fitting, puncture-resistant lid, without sharps being able to come out,
 - upright and stable during use,
 - leak-resistant, and
 - properly labeled to warn of hazardous waste inside the container
- When your sharps disposal container is almost full, you will need to follow your community guidelines for the right way to dispose of your sharps disposal container. There may be state or local laws about how you should throw away used needles and cartridges. For more information about safe sharps disposal, and for specific information about sharps disposal in the state that you live in, go to the FDA's website at: <http://www.fda.gov/safesharpsdisposal>
- Do not dispose of your used sharps disposal container in your household trash unless your community guidelines permit this. Do not recycle your used sharps disposal container

HOW SHOULD I STORE OMNITROPE PEN 10?

- Store Omnitrope cartridges in the refrigerator between 36°F and 46°F (2°C and 8°C)
- When the Omnitrope Pen 10 contains a cartridge, do not remove the cartridge from the Pen in between injections. Store the Pen containing the cartridge in the storage case provided and place in the refrigerator
- When the Pen does not contain a cartridge, you may store the Pen at room temperature.
- Do not freeze Omnitrope cartridges
- Protect the Omnitrope Pen 10 and cartridge from light by storing in their cartons or the storage case
- The Omnitrope cartridge must be thrown away 28 days after the first injection. The Omnitrope Pen 10 can be reloaded with a new cartridge and can be used multiple times

HOW TO USE YOUR OMNITROPE VIAL



For full instructions, please refer to the **Instructions For Use** supplied with each vial.

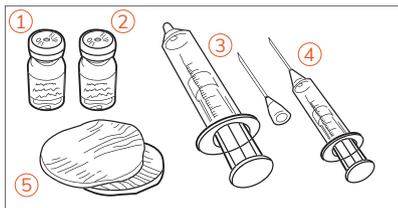
Please see attached full Prescribing Information and Indications and Important Safety Information.

The following instructions explain how to inject Omnitrope 5.8 mg. Do not inject Omnitrope yourself until your healthcare provider has taught you and you understand the instructions. Ask your healthcare provider or pharmacist if you have any questions about injecting Omnitrope.

- Omnitrope 5.8 mg is for multiple uses
- The concentration of Omnitrope after mixing is 5 mg/mL
- After mixing, Omnitrope 5.8 mg contains a preservative and should not be used in newborns

PREPARATION

- Collect necessary items before you begin:

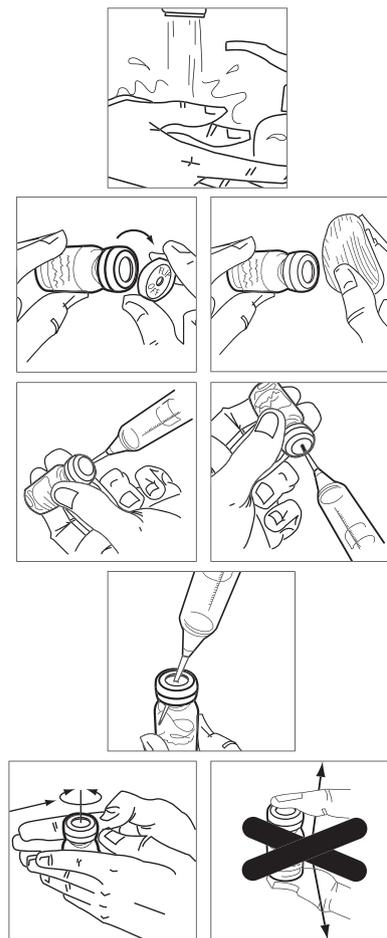


1. a vial with Omnitrope 5.8 mg
2. a vial with diluent (mixing liquid - Bacteriostatic Water for Injection containing benzyl alcohol as preservative) for Omnitrope 5.8 mg
3. a sterile, disposable 3 mL syringe and needle for withdrawing the diluent from the vial (not supplied in the pack)
4. sterile disposable syringe of appropriate size (eg, a 1 mL syringe) and needle for under the skin (subcutaneous) injection (not supplied in the pack)
5. 2 alcohol swabs (not supplied in the pack)

Wash your hands before you start with the next steps.

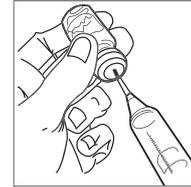
MIXING OMNITROPE 5.8 MG

- Remove the protective caps from the two vials. With one alcohol swab, clean both the rubber top of the vial that contains the powder and the rubber top of the vial that contains diluent
- Use next the sterile diluent vial, the disposal 3 mL syringe and a needle
- Attach the needle to the syringe (if not attached already). Pull back the syringe plunger and fill the syringe with air. Push the needle fitted to the syringe through the rubber top of the diluent vial, push all the air from the syringe into the vial, turn the vial upside down, and withdraw all the diluent from the vial into the syringe. Remove the syringe and needle
- Next take the syringe with the diluent in it and push the needle through the rubber stopper of the vial that contains the white powder. Inject the diluent slowly. Aim the stream of liquid against the glass wall in order to avoid foam. Remove the syringe and needle and dispose of them
- Gently swirl the vial until the content is completely dissolved. **Do not shake**
- If the medicine is cloudy or contains particles, it should not be used. The medicine must be clear and colorless after mixing
- **After mixing the medicine, the medicine in the vial must be used within 3 weeks. Store the vial in a refrigerator at 2°C to 8°C (36°F to 46°F) after mixing and using it each time**



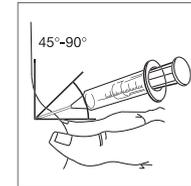
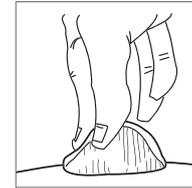
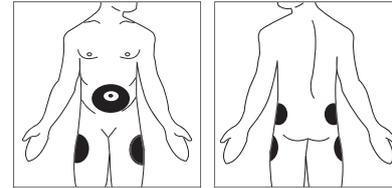
MEASURING THE DOSE OF OMNITROPE 5.8 MG TO BE INJECTED

- Next use the sterile, disposable 1 mL (or similar) syringe and needle for subcutaneous injection. Push the needle through the rubber top of the vial that contains the medicine that you have just mixed
- Turn the vial and the syringe upside down
- Be sure the tip of the syringe is in the Omnitrope mixed medicine
- Pull back on the plunger slowly and withdraw the dose prescribed by your doctor into the syringe
- Hold the syringe with the needle in the vial pointing up and remove the syringe from the vial
- Check for air bubbles in the syringe. If you see any bubbles, pull the plunger slightly back; tap the syringe gently, with the needle pointing upwards, until the bubble disappears. Push the plunger slowly back up to the correct dose. If there is not enough medicine in the syringe after removing the air bubbles, draw more medicine into the syringe from the mixed medicine vial and repeat checking for bubbles
- Look at the mixed medicine in the syringe before using. Do not use if discolored or particles are present. You are now ready to inject the dose



INJECTING OMNITROPE 5.8 MG

- Choose the site of injection on your body. The best sites for injection are tissues with a layer of fat between skin and muscle such as the upper leg (thigh), buttocks, or stomach area (abdomen) as in the picture shown below. **Do not inject near your belly button (navel) or waistline**
- Make sure you rotate the injection sites on your body. Inject at least 1/2 inch from the last injection. Change the places on your body where you inject, as you have been taught
- Before you make an injection, clean your skin well with an alcohol swab. Wait for the area to air dry
- With one hand, pinch a fold of loose skin at the injection site. With your other hand, hold the syringe as you would a pencil. Insert the needle into the pinched skin straight in or at a slight angle (an angle of 45° to 90°). After the needle is in, remove the hand used to pinch the skin and use it to hold the syringe barrel. Pull back the plunger very slightly with one hand. If blood comes into the syringe, the needle has entered a blood vessel. Do not inject into this site; withdraw the needle and repeat the procedure at a different site. If no blood comes into the syringe, inject the solution by pushing the plunger all the way down gently
- Pull the needle straight out of the skin. After injection, press the injection site with a small bandage or sterile gauze if needed for bleeding, for several seconds. Do not massage or rub the injection site



AFTER INJECTING OMNITROPE 5.8 MG

- Discard the injection materials
- Dispose the syringes safely in a closed container. You can ask your healthcare provider or pharmacist for a “sharps” container. A sharps container is a special container to put used needles and syringes in. You can return a full sharps container to your pharmacist or healthcare provider for disposal
- The vial of mixed medicine must be stored in the refrigerator in its carton at 2°C to 8°C (36°F to 46°F) and used within 3 weeks
- The solution should be clear after removal from the refrigerator. If the solution is cloudy or contains particles, **discard the vial. Do not inject the medicine from this vial.** Start over with a new vial of Omnitrope 5.8 mg. Call your pharmacist if you need a replacement
- Before each use disinfect the rubber top of the reconstituted vial with an alcohol swab. You **must** use a new disposable 1 mL syringe and needle for each injection

INDICATIONS

OMNITROPE IS A RECOMBINANT HUMAN GROWTH HORMONE INDICATED FOR:

- **Pediatric:** Treatment of children with growth failure due to growth hormone deficiency (GHD), Prader-Willi Syndrome, Small for Gestational Age, Turner Syndrome, and Idiopathic Short Stature
- **Adult:** Treatment of adults with either adult onset or childhood onset GHD

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

- **Acute Critical Illness:** Somatropin should not be used to treat patients with acute critical illness due to complications following open heart surgery, abdominal surgery or multiple accidental trauma, or those with acute respiratory failure
- **Prader-Willi Syndrome in Children:** Somatropin should not be used in patients with Prader-Willi syndrome who are severely obese, have a history of upper airway obstruction or sleep apnea, or have severe respiratory impairment. There have been reports of sudden death when somatropin was used in such patients
- **Active Malignancy:** Somatropin is contraindicated in patients with any evidence of active malignancy. Growth hormone deficiency may be an early sign of a pituitary tumor or other intracranial tumor; the presence of such a tumor should be excluded before initiation of somatropin treatment
- **Hypersensitivity:** Omnitrope® is contraindicated in patients with a known hypersensitivity to somatropin or any of its excipients. Systemic hypersensitivity reactions have been reported with postmarketing use of somatropin products
- **Diabetic Retinopathy:** Somatropin is contraindicated in patients with active proliferative or severe non-proliferative diabetic retinopathy
- **Closed Epiphyses:** Somatropin should not be used for growth promotion in pediatric patients with closed epiphyses

WARNINGS AND PRECAUTIONS

- **Acute Critical Illness:** Increased mortality in patients with acute critical illness due to complications following open heart surgery, abdominal surgery or multiple accidental trauma, or those with acute respiratory failure has been reported after treatment with pharmacologic doses of somatropin
- **Prader-Willi Syndrome in Children:** There have been reports of fatalities after initiating therapy with somatropin in pediatric patients with Prader-Willi syndrome who had one or more of the following risk factors: severe obesity, history of upper airway obstruction or sleep apnea, or unidentified respiratory infection. Male patients with one or more of these factors may be at greater risk than females. Patients with Prader-Willi syndrome should be evaluated for signs of upper airway obstruction and sleep apnea before initiation of treatment with somatropin. If, during treatment with somatropin, patients show signs of upper airway obstruction (including onset of or increased snoring) and/or new onset sleep apnea, treatment should be interrupted
- **Neoplasms:** An increased risk of a second neoplasm has been reported for childhood cancer survivors treated with somatropin for GH deficiency that developed following radiation to the brain/head. Intracranial tumors, in particular meningiomas, were the most common of these. The relationship between

somatropin therapy and CNS tumor recurrence in adults is unknown. Monitor for progression or recurrence in patients receiving somatropin therapy who have a history of GH deficiency secondary to an intracranial neoplasm. Thoroughly consider the risks and benefits of starting somatropin in children at increased risk for developing malignancies due to certain rare genetic causes of short stature. These patients should be carefully monitored for development of neoplasms. Any pre-existing nevi should be monitored carefully for increased growth or potential malignant changes

- **Impaired Glucose Intolerance and Diabetes Mellitus:** Previously undiagnosed impaired glucose tolerance and overt diabetes mellitus may be unmasked during somatropin treatment. New-onset type 2 diabetes mellitus has been reported. As a result, blood glucose concentrations should be monitored periodically in all patients taking somatropin, especially in those with risk factors for diabetes mellitus. Patients with pre-existing type 1 or type 2 diabetes mellitus or impaired glucose tolerance should be monitored closely during somatropin treatment
- **Intracranial Hypertension:** Intracranial hypertension with papilledema, visual changes, headache, nausea, and/or vomiting have been reported in a small number of patients treated with somatropin. Fundoscopic examination is recommended at the initiation of and periodically during therapy. If papilledema is observed

by funduscopy during treatment with somatropin, treatment should be stopped and the patient's condition should be reassessed before treatment is resumed. Patients with Turner syndrome and Prader-Willi Syndrome may be at increased risk for the development of intracranial hypertension

- **Hypersensitivity:** Serious systemic hypersensitivity reactions including anaphylactic reactions and angioedema have been reported with postmarketing use of somatropin products. Patients and caregivers should be informed that such reactions are possible and that prompt medical attention should be sought if an allergic reaction occurs
- **Fluid Retention:** Transient and dose-dependent fluid retention during somatropin replacement in adults may frequently occur
- **Hypoadrenalism:** Monitor patients for reduced serum cortisol levels and/or need for glucocorticoid dose increases in those with known hypoadrenalism
- **Hypothyroidism:** Patients treated with somatropin should have periodic thyroid function tests, and thyroid hormone replacement therapy should be initiated or appropriately adjusted in cases of unmasked or worsening hypothyroidism
- **Slipped Capital Femoral Epiphysis in Pediatric Patients:** Slipped capital femoral epiphysis may occur more frequently in patients with endocrine disorders and in patients undergoing rapid growth. Any pediatric patient with the onset of a limp or complaints of hip or knee pain during somatropin therapy should be carefully evaluated
- **Progression of Scoliosis in Pediatric Patients:** Progression of scoliosis can occur in patients who experience rapid growth. Because somatropin increases growth rate, patients with a history of scoliosis who are treated with somatropin should be monitored for progression of scoliosis. However, somatropin has not been shown to increase the occurrence of scoliosis
- **Confirmation of Childhood Onset Adult GHD:** Patients with epiphyseal closure who were treated with somatropin replacement therapy in childhood should be reevaluated before continuation of somatropin therapy at the reduced dose level recommended for GH deficient adults
- **Otitis Media and Cardiovascular Disorders in Patients with Turner Syndrome:** Patients with Turner Syndrome should be evaluated carefully for otitis media and other ear disorders as somatropin treatment may increase the occurrence of otitis media in these susceptible patients. In addition, patients with Turner Syndrome should be monitored closely for cardiovascular disorders (e.g., stroke, aortic aneurysm or dissection, hypertension) as they are at increased risk for these conditions

- **Lipoatrophy:** Injection site should be rotated to avoid tissue atrophy
- **Laboratory Tests:** Serum levels of inorganic phosphorus, alkaline phosphatase, parathyroid hormone and IGF-I may increase after somatropin therapy
- **Pancreatitis:** Cases of pancreatitis have been reported rarely in children and adults receiving somatropin. Pancreatitis should be considered in any somatropin-treated patient, especially a child, who develops persistent severe abdominal pain. Girls who have Turner Syndrome may be at greater risk than other somatropin-treated children
- **Benzyl Alcohol:** Benzyl alcohol, an ingredient in Omnitrope Cartridge 5 mg/1.5 mL and the diluent for Omnitrope for injection 5.8 mg/vial, has been associated with serious adverse events and death, particularly in pediatric patients and should not be used in premature babies or neonates. Consider the combined daily metabolic load of benzyl alcohol from all sources
- **Pregnancy/Nursing Mothers:** Somatropin should be used during pregnancy only if clearly needed and with caution in nursing mothers because it is not known whether somatropin is excreted in human milk
- **Special Populations:** The safety and effectiveness of somatropin in patients aged 65 years and over have not been evaluated in clinical studies. Elderly patients may be more sensitive to the action of somatropin and may be more prone to adverse reactions
- **Potential Drug Interactions:**
 - Somatropin inhibits 11 β -hydroxysteroid dehydrogenase type 1 (11 β HSD-1) in adipose/hepatic tissue and may significantly impact the conversion of cortisone to its active metabolite cortisol. As a consequence, in patients treated with somatropin, previously undiagnosed central (secondary) hypoadrenalism may be unmasked, requiring glucocorticoid replacement therapy
 - Careful monitoring is advisable when growth hormone is administered in combination with insulin and/or other hypoglycemic agents, other drugs metabolized by CYP450 liver enzymes (e.g., hydrocortisone or other corticosteroids, sex steroids, anticonvulsants, cyclosporine), or other hormone replacement therapy

ADVERSE REACTIONS

- Common adverse reactions reported in adult and pediatric patients taking somatropin include injection site reactions/rashes and lipoatrophy and headaches. Additional common adverse reactions include edema, arthralgia, myalgia, carpal tunnel syndrome, paresthesias, and hypothyroidism

Please see full Prescribing Information for Omnitrope.

You are encouraged to report negative side effects of prescription drugs to the FDA.

Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

To report SUSPECTED ADVERSE REACTIONS, contact Sandoz Inc. at 1-800-525-8747 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch

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S-OMN-1345026 6/17

 **Omnitrope**[®]
(somatropin) injection

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Division