



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

OMNITROPE[®] ADMINISTRATION GUIDE

How to use the Pen 5, Pen 10, or vial and 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 Important Safety Information starting on page 24
and accompanying full Prescribing Information.

SANDOZ A Novartis
Division

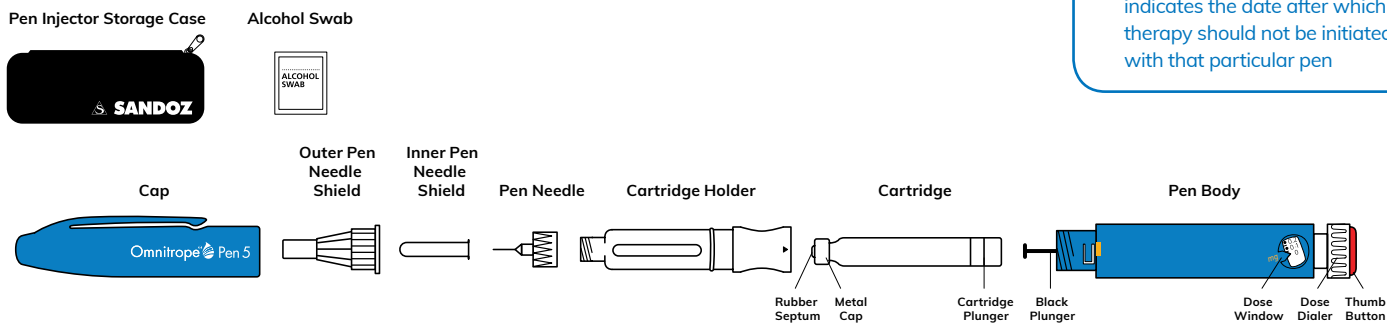
HOW TO USE YOUR OMNITROPE® PEN 5

Read the Instructions for Use supplied with each Omnitrope Pen 5 and its refills, as new or updated information about Omnitrope may have been added. Please note that this information does not take the place of talking to your healthcare provider about your medical condition or your treatment.

REMINDERS

- Omnitrope is intended to be injected under the skin (subcutaneously), not into the muscle
- 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, shown on the outer carton, indicates the date after which therapy should not be initiated with that particular pen

With your Omnitrope Pen 5 prescription, you will receive:

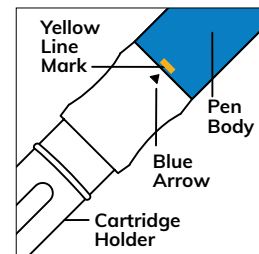
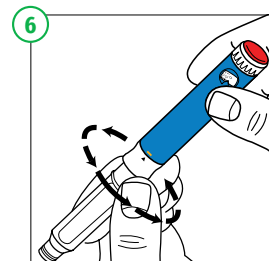
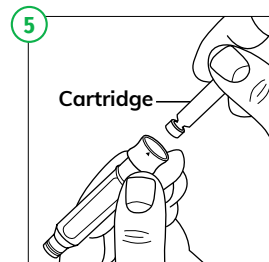
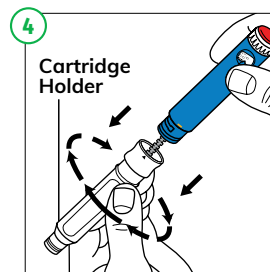
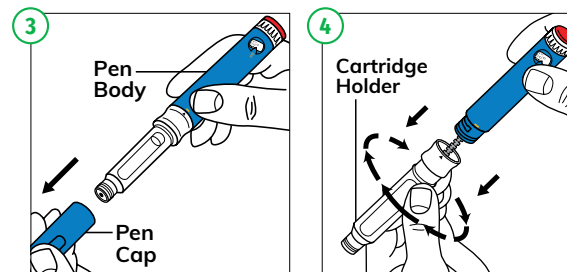


For full instructions, please refer to the **Instructions for Use** supplied with each Omnitrope Pen 5.

Please see Important Safety Information starting on page 24 and accompanying full Prescribing Information.

PLACING THE CARTRIDGE IN THE OMNITROPE PEN 5

- 1 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.
- 2 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.
- 3 Hold the body of the Pen with one hand and pull off the Pen cap with the other hand.
- 4 Hold the body of the Pen with one hand and unscrew the cartridge holder in a clockwise direction until the Pen and cartridge holder are completely separated.
- 5 Hold the cartridge in one hand with the metal cap end pointing down. Insert the cartridge into the cartridge holder.
- 6 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 overtighten the cartridge holder.



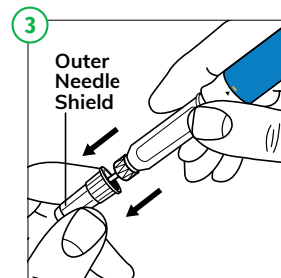
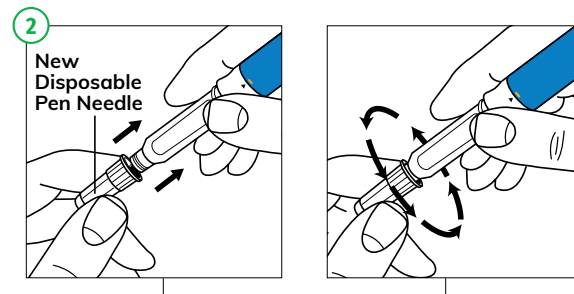
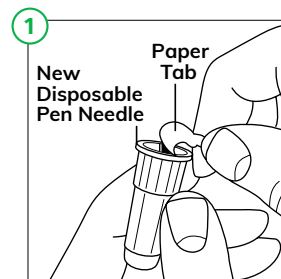
Please see Important Safety Information starting on page 24 and accompanying full Prescribing Information.

ATTACHING THE NEEDLE TO THE OMNITROPE PEN 5

- 1 Take a new disposable needle and tear off the paper tab. Do not touch the needle or lay it on any surface.
- 2 Holding the cartridge holder with one hand, firmly press the needle onto the cartridge-holder end of the Pen. Screw the threaded hub of the needle onto the cartridge holder in a counterclockwise direction until the needle will not turn anymore.
- 3 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.

NOTE

Check that the cartridge holder is attached to the Pen body before each injection. After you attach the needle, you may see a few drops of medicine at the tip of the needle.



Please see Important Safety Information starting on page 24 and accompanying full Prescribing Information.

PRIMING A NEW CARTRIDGE

Before starting a new cartridge, you must first prime it for use. Priming is not needed for a cartridge you have used before. If the cartridge has already been primed, go to step 1 of the Selecting the Correct Dose of Omnitrope section on the following page.

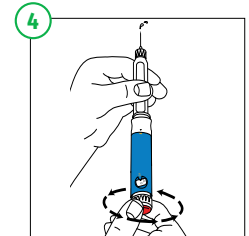
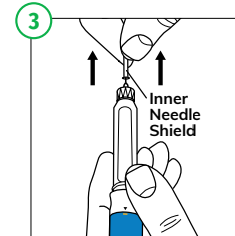
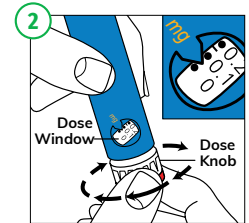
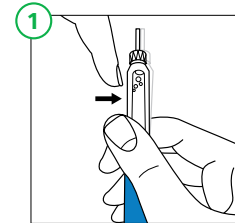
IMPORTANT: To ensure no accidental leakage of medicine, hold the Pen with the needle pointing up until ready to make the injection.

- 1 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.
- 2 Hold the Pen with the dose window facing you to see the numbers at the bottom of the Pen body. Slowly turn the dose knob at the bottom of the Pen in a clockwise direction until you hear a click. The arrow on the Pen body will then be lined up with the small line between "0" and "0.1" (0.05 mg).
- 3 After removing the inner needle shield with the needle pointing up, firmly turn the dose knob in a counterclockwise direction and back to the "0" position.
- 4 At least 2 drops of medicine must flow out of the needle for the Pen to be properly primed.

If you **do not** see at least 2 drops of medicine flow out, set the dose to 0.05 mg and repeat this step until you see at least 2 drops of medicine appear at the tip of the needle. The Pen is properly primed and ready for use **only** when these drops have flowed from the needle.

NOTE

Do not worry if more than 2 drops flow out of the needle. There is enough medicine in each Pen to accommodate the priming process.



Please see Important Safety Information starting on page 24 and accompanying full Prescribing Information.

SELECTING THE CORRECT DOSE OF OMNITROPE

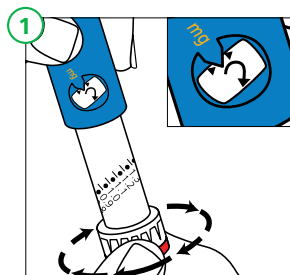
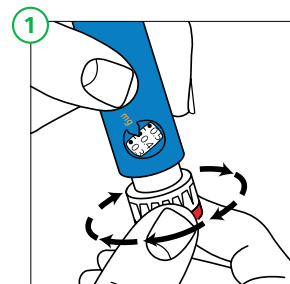
- 1 Hold the Pen with the needle pointing up and the dose window facing you and turn (dial) the dose knob in a clockwise direction until you see the number of milligrams for the prescribed dose in the middle of the dose window. The dose should be lined up with the arrow on the Pen body. You will hear a click for each dose increment you dial.

Do not rely on counting these clicks to measure the correct dose of medicine.

CORRECTING FOR THE RIGHT DOSE

If you turn the dose knob past the correct dose, do not dial backwards.

- 1 **Instead**, hold the Pen body with the needle pointing up and turn the dose knob in a clockwise direction until you see a bent arrow (↷) in the dose dialing window. Now continue to turn the dose knob in a clockwise direction until you hear a click and the entire Pen body is fully extended.
- 2 The injection button can now be fully pressed, resetting the dial to "0" without giving medicine. The correct dose can now be redialed.
- 3 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.



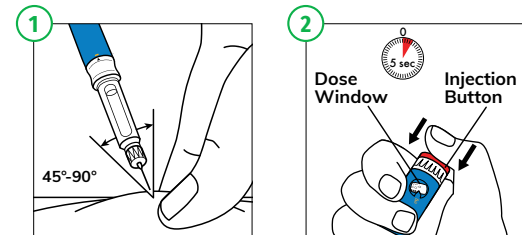
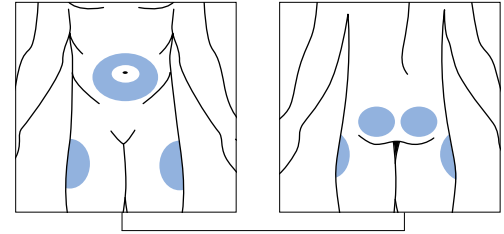
Please see Important Safety Information starting on page 24 and accompanying full Prescribing Information.

GIVING AN INJECTION WITH OMNITROPE PEN 5

Change the injection site every day. The best sites are tissues with a layer of fat between skin and muscle, such as the upper leg (thigh), buttocks, or stomach area (abdomen). Make sure to rotate injection sites and inject at least half an inch from the last injection site.

Do not inject near your belly button (navel) or waistline.

- 1 When an injection site has been chosen, wipe the skin with an alcohol pad and insert the needle under the skin, as your healthcare provider has instructed you.
- 2 After inserting the needle into the skin, push the injection button as far in as it will go and press firmly. You will hear a clicking sound 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.



Please see Important Safety Information starting on page 24 and accompanying full Prescribing Information.

GIVING AN INJECTION WITH OMNITROPE PEN 5

- 3 Stop pressing the injection button before you carefully remove the needle from the skin.

NOTE

If the injection button cannot be pushed in completely or stops during the injection and the cartridge is empty, then the full dose has NOT been given. The dose indicator window will show the amount of medicine that still needs to be administered.

To complete your dose:

- Reset the dose knob to “0” as described in the *Selecting the Correct Dose of Omnitrope* section (page 6)
- Remove the needle as described in the section below
- Replace the empty cartridge with a new cartridge as described in the *Placing the Cartridge in the Omnitrope Pen 5* section (page 3)
- Prime the new cartridge as described in the *Priming a New Cartridge* section (page 5)
- Set the remainder of the dose, noted from previous dose indicator window and inject

Please see Important Safety Information starting on page 24 and accompanying full Prescribing Information.

REMOVING AN EMPTY CARTRIDGE AND DISPOSING OF THE OMNITROPE PEN 5 NEEDLE

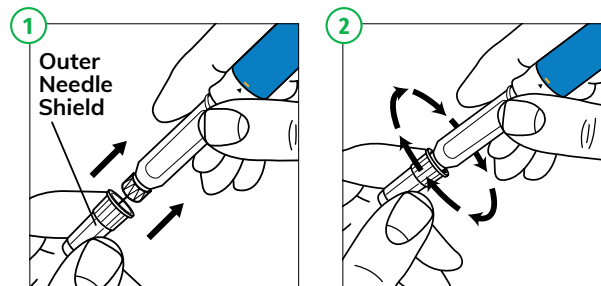
- 1 Carefully replace the outer needle shield.
- 2 Hold the Pen by the cartridge holder and unscrew the Pen needle from the cartridge holder by turning the needle in a clockwise direction. Recap the Pen.
- 3 Put your used needles and cartridges in an FDA-cleared sharps disposal container right away after use. **Do not throw away (dispose of) loose needles and cartridges in your household trash, and do not recycle a used sharps disposal container.**

When your sharps disposal container is almost full, you will need to follow your community guidelines for the right way to dispose of it. There may be state or local laws about how you should throw away used needles and cartridges. For information about your state's guidelines for safe sharps disposal, go to the FDA's website at: <http://www.fda.gov/safesharpsdisposal>.

NOTE

If you do not have an 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 that does not allow the needles to fall out
- Upright and stable during use
- Leak resistant
- Properly labeled to warn of the hazardous waste that is inside the 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 them 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

FDA=Food and Drug Administration.

Please see Important Safety Information starting on page 24 and accompanying full Prescribing Information.

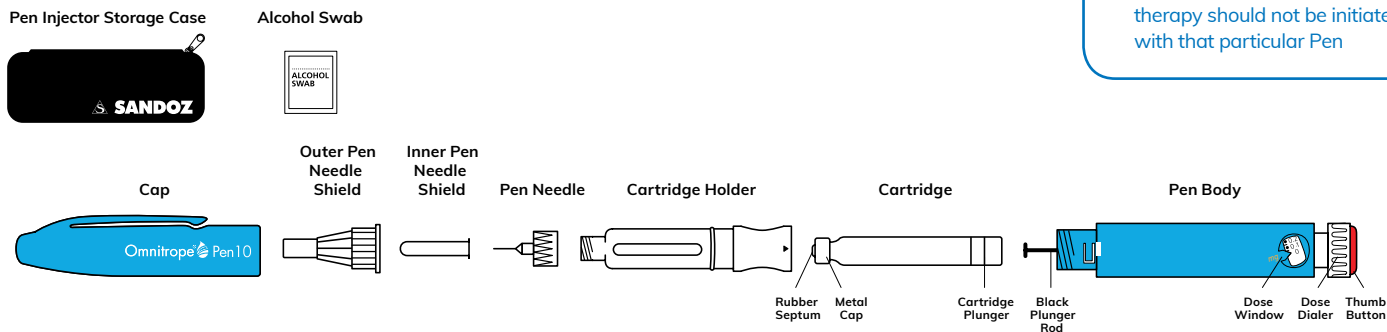
HOW TO USE YOUR OMNITROPE® PEN 10

Read the Instructions for Use supplied with each Omnitrope Pen 10 and its refills, as new or updated information about Omnitrope may have been added. Please note that this information does not take the place of talking to your healthcare provider about your medical condition or your treatment.

REMINDERS

- Omnitrope is intended to be injected under the skin (subcutaneously), not into the muscle
- 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, shown on the outer carton, indicates the date after which therapy should not be initiated with that particular Pen

With your Omnitrope Pen 10 prescription, you will receive:

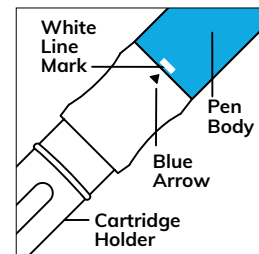
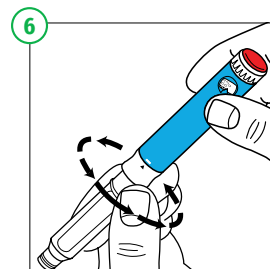
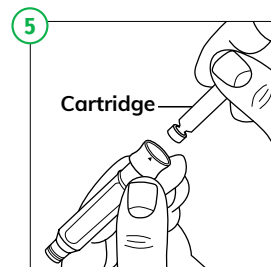
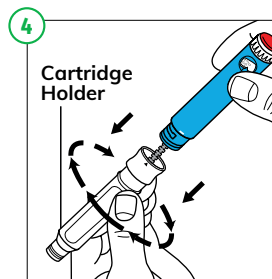
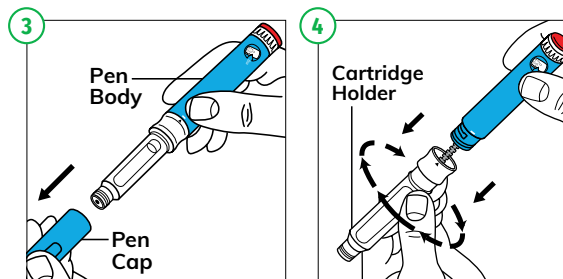


For full instructions, please refer to the **Instructions for Use** supplied with each Omnitrope Pen 10.

Please see Important Safety Information starting on page 24 and accompanying full Prescribing Information.

PLACING THE CARTRIDGE IN THE OMNITROPE PEN 10

- 1 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.
- 2 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.
- 3 Hold the body of the Pen with one hand and pull off the Pen cap with the other hand.
- 4 Hold the body of the Pen with one hand and unscrew the cartridge holder in a clockwise direction until the Pen and cartridge holder are completely separated.
- 5 Hold the cartridge in one hand with the metal cap end pointing down. Insert the cartridge into the cartridge holder.
- 6 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 overtighten the cartridge holder.



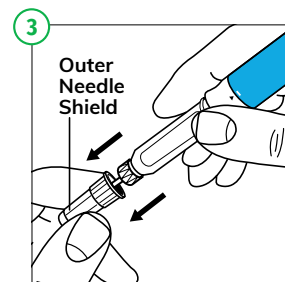
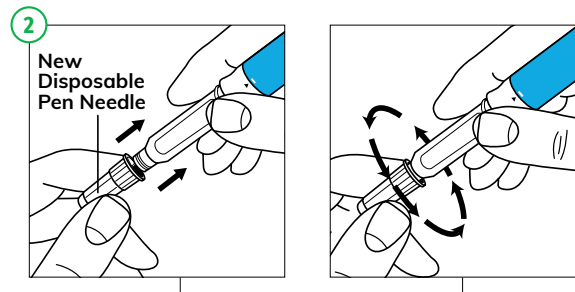
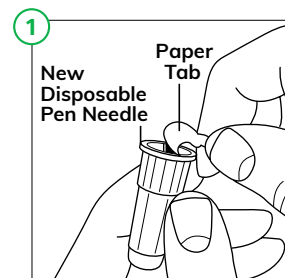
Please see Important Safety Information starting on page 24 and accompanying full Prescribing Information.

ATTACHING THE NEEDLE TO THE OMNITROPE PEN 10

- 1 Take a new disposable needle and tear off the paper tab. Do not touch the needle or lay it on any surface.
- 2 Holding the cartridge holder with one hand, firmly press the needle onto the cartridge-holder end of the Pen. Screw the threaded hub of the needle onto the cartridge holder in a counterclockwise direction until the needle will not turn anymore.
- 3 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.

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 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.



Please see Important Safety Information starting on page 24 and accompanying full Prescribing Information.

PRIMING A NEW CARTRIDGE

Before starting a new cartridge, you must first prime it for use. Priming is not needed for a cartridge you have used before. If the cartridge has already been primed, go to step 1 of the *Selecting the Correct Dose of Omnitrope* section on following page.

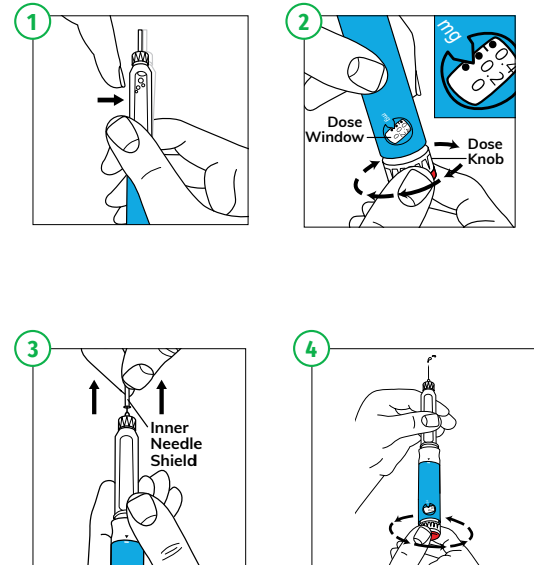
IMPORTANT: To ensure no accidental leakage of medicine, hold the Pen with the needle pointing up until ready to make the injection.

- 1 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.
- 2 Hold the Pen with the dose window facing you to see the numbers at the bottom of the Pen body. Slowly turn the dose knob at the bottom of the Pen in a clockwise direction until you hear a click. The arrow on the Pen body will then be lined up with the small line between “0” and “0.2” (0.1 mg).
- 3 After removing the inner needle shield with the needle pointing up, firmly turn the dose knob in a counterclockwise direction and back to the “0” position.
- 4 At least 2 drops of medicine must flow out of the needle for the Pen to be properly primed.

If you **do not** see at least 2 drops of medicine flow out, set the dose to 0.1 mg and repeat this step until you see at least 2 drops of medicine appear at the tip of the needle. The Pen is properly primed and ready for use only when these drops have flowed from the needle.

NOTE

Do not worry if more than 2 drops flow out of the needle. There is enough medicine in each Pen to accommodate the priming process.

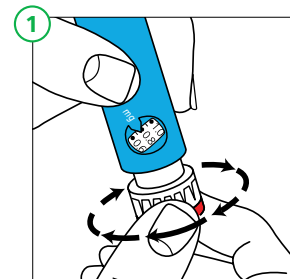


Please see Important Safety Information starting on page 24 and accompanying full Prescribing Information.

SELECTING THE CORRECT DOSE OF OMNITROPE

- 1 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 milligrams 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 a click for each dose increment you dial.

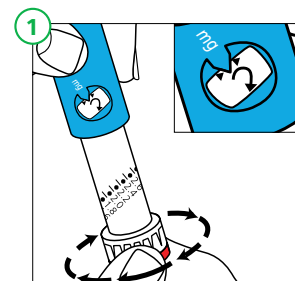
Do not rely on counting these clicks to measure the correct dose of medicine.



CORRECTING FOR THE RIGHT DOSE

If you turn the dose knob past the correct dose, do not dial backwards.

- 1 Instead, hold the Pen body with the needle pointing up and turn the dose knob in a clockwise direction until you see a bent arrow (↻) in the dose dialing window. Now continue to turn the dose knob in a clockwise direction until you hear a click and the entire Pen body is fully extended.
- 2 The injection button can now be fully pressed, resetting the dial to "0" without giving medicine. The correct dose can now be redialed.
- 3 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.



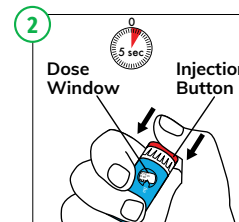
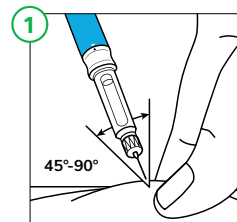
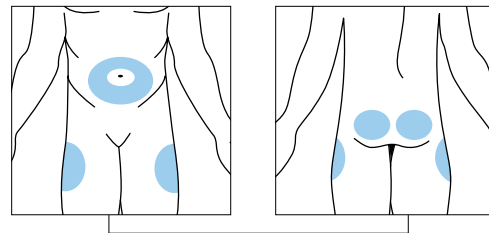
Please see Important Safety Information starting on page 24 and accompanying full Prescribing Information.

GIVING AN INJECTION WITH OMNITROPE PEN 10

Change the injection site every day. The best sites are tissues with a layer of fat between skin and muscle, such as the upper leg (thigh), buttocks, or stomach area (abdomen). Make sure to rotate injection sites and inject at least half an inch from the last injection site.

Do not inject near your belly button (navel) or waistline.

- 1 When an injection site has been chosen, wipe the skin with an alcohol pad and insert the needle under the skin, as your healthcare provider has instructed you.
- 2 After inserting the needle into the skin, push the injection button as far in as it will go and press firmly. You will hear a clicking sound 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.



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GIVING AN INJECTION WITH OMNITROPE PEN 10

- 3 Stop pressing the injection button before you carefully remove the needle from the skin.

NOTE

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 that still needs to be administered.

To complete your dose:

- Reset the dose knob to "0" as described in the *Selecting the Correct Dose of Omnitrope* section (page 14)
- Remove the needle as described in the section below
- Replace the empty cartridge with a new cartridge as described in the *Placing the Cartridge in the Omnitrope Pen 10* section (page 11)
- Prime the new cartridge as described in the *Priming a New Cartridge* section (page 13)
- Set the remainder of the dose, noted from previous dose indicator window and inject

Please see Important Safety Information starting on page 24 and accompanying full Prescribing Information.

REMOVING AN EMPTY CARTRIDGE AND DISPOSING OF THE OMNITROPE PEN 10 NEEDLE

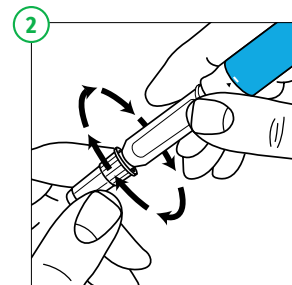
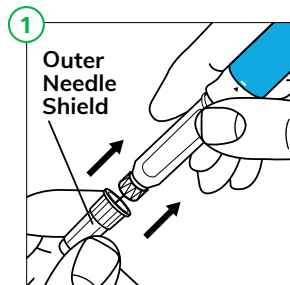
- 1 Carefully replace the outer needle shield.
- 2 Hold the Pen by the cartridge holder and unscrew the pen needle from the cartridge holder by turning it in a clockwise manner. Recap the pen.
- 3 Put your used needles and cartridges in an FDA-cleared sharps disposal container right away after use. **Do not throw away (dispose of) loose needles and cartridges in your household trash, and do not recycle a used sharps disposal container.**

When your sharps disposal container is almost full, you will need to follow your community guidelines for the right way to dispose of it. There may be state or local laws about how you should throw away used needles and cartridges. For information about your state's guidelines for safe sharps disposal, go to the FDA's website at: <http://www.fda.gov/safesharpsdisposal>.

NOTE

If you do not have an 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 that does not allow the needles to fall out
- Upright and stable during use
- Leak resistant
- Properly labeled to warn of the hazardous waste that is inside the 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 them 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

FDA=Food and Drug Administration.

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HOW TO USE YOUR OMNITROPE® VIAL

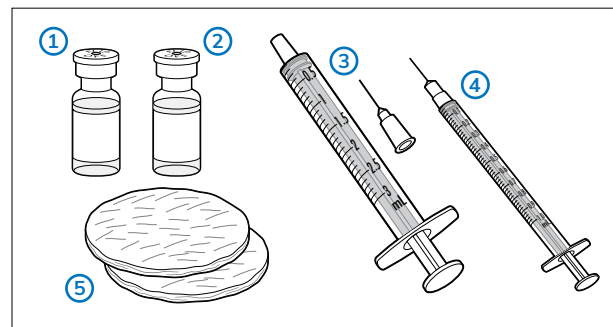
The following instructions explain how to inject Omnitrope 5.8 mg. Do not inject Omnitrope yourself until your healthcare provider has taught you how and you understand the instructions. Ask your healthcare provider or pharmacist if you have any questions about injecting Omnitrope.

- 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 1 mL syringes and needles for under the skin (subcutaneous) injection (not supplied in the pack)
- ⑤ 2 alcohol swabs (not supplied in the pack)



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

Please see Important Safety Information starting on page 24 and accompanying full Prescribing Information.

MIXING OMNITROPE 5.8 MG

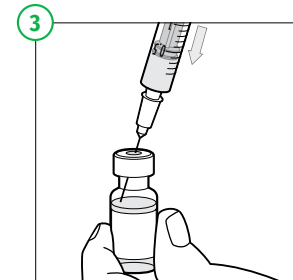
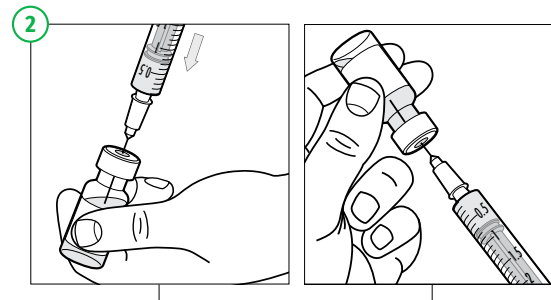
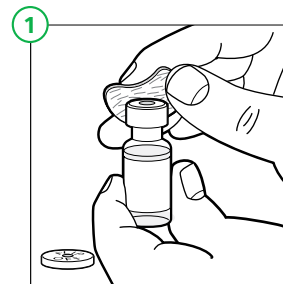
Wash your hands before you start the next steps.

- 1 Remove the protective caps from the 2 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.
- 2 Attach the needle to the syringe (if it is not attached already). Pull back the syringe plunger and fill the syringe with air. Push the syringe's needle through the rubber top of the diluent vial. Once inserted, press the plunger to push all the air into the vial. Turn the syringe and vial upside down and pull the plunger back once again to withdraw all the diluent into the syringe. Pull needle from vial.
- 3 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 making foam. Remove the syringe and needle and dispose of them.
- 4 Gently swirl the vial until the content is completely dissolved. **Do not shake.**

NOTE

The medicine in the vial must be clear and colorless after mixing. Do not use if it is cloudy or contains particles.

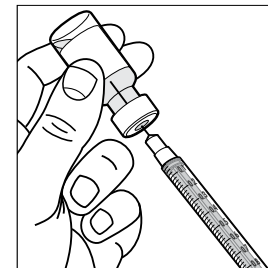
After mixing the medicine, the medicine in the vial must be used within 3 weeks. Store the vial in a refrigerator at 2°C to 8°C (36°F to 46°F) after mixing and using it each time



Please see Important Safety Information starting on page 24 and accompanying full Prescribing Information.

MEASURING THE CORRECT DOSE OF OMNITROPE 5.8 MG

- 1 Using a sterilized disposable 1 mL (or similar gauge) syringe and needle for subcutaneous injection, push the needle through the rubber top of the vial that contains the medicine that you have mixed.
- 2 Turn the vial and the syringe upside down.
- 3 Be sure the tip of the syringe is in the Omnitrope mixed medicine.
- 4 Pull back on the plunger slowly and withdraw the dose prescribed by your doctor into the syringe.
- 5 Hold the syringe with the needle in the vial pointing up and remove the syringe from the vial.
- 6 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 bubbles disappear. 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.
- 7 Look at the mixed medicine in the syringe before using. Do not use if the medicine is discolored or particles are present. You are now ready to inject the dose.



IMPORTANT: To ensure no accidental leakage of medicine, hold the syringe with the needle pointing up until ready to make the injection.

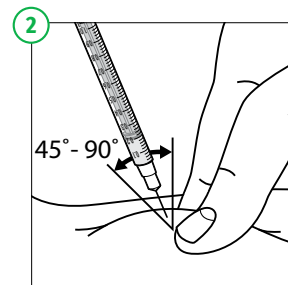
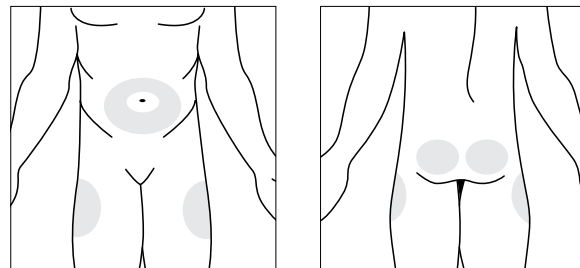
Please see Important Safety Information starting on page 24 and accompanying full Prescribing Information.

GIVING AN INJECTION WITH OMNITROPE 5.8 MG

Change the injection site every day. The best sites are tissues with a layer of fat between skin and muscle, such as the upper leg (thigh), buttocks, or stomach area (abdomen). Make sure to rotate the injection site and inject at least half an inch from the last injection site.

Do not inject near your belly button (navel) or waistline.

- 1 Before you make an injection, clean your skin well with an alcohol swab and let air-dry.
- 2 With one hand, pinch a fold of loose skin at injection site. With your other hand, hold the syringe like you would a pencil. To give the injection:
 - Insert the needle into the pinched skin straight or at a slight angle (45° to 90°)
 - When needle is in, use the hand that had pinched the skin 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 procedure at a different site
 - If no blood enters the syringe, inject the Omnitrope solution by pushing the plunger all the way down gently
 - Once the medicine has been injected, pull the needle straight out of the skin
- 3 After the injection, press the injection site with a small bandage or sterile gauze pad for several seconds, if needed for bleeding. Do not massage or rub the injection site.



Please see Important Safety Information starting on page 24 and accompanying full Prescribing Information.

DISPOSING OF THE OMNITROPE 5.8 MG SYRINGE AND NEEDLE

- 1 Put your used needles and syringes in an FDA-cleared sharps disposal container right away after use. **Do not throw away (dispose of) loose needles and syringes in your household trash, and do not recycle a used sharps disposal container.**

When your sharps disposal container is almost full, you will need to follow your community guidelines for the right way to dispose of it. There may be state or local laws about how you should throw away used needles and syringes. For information about your state's guidelines for safe sharps disposal, go to the FDA's website at: <http://www.fda.gov/safesharpsdisposal>.

NOTE

If you do not have an 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 that does not allow the needles to fall out
- Upright and stable during use
- Leak resistant
- Properly labeled to warn of the hazardous waste that is inside the container

HOW SHOULD I STORE OMNITROPE VIALS?

- 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 in 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**

FDA=Food and Drug Administration.

Please see Important Safety Information starting on page 24 and accompanying full Prescribing Information.



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

Who should not take Omnitrope?

Omnitrope should not be used in children and adults with any of the following medical conditions because serious side effects, including death, can occur:

- a critical illness caused by certain types of heart or stomach surgery, serious injury or a sudden and severe breathing problem (respiratory failure)
- Prader-Willi syndrome who are severely overweight or have a history of breathing problems including sleep apnea
- cancer or other tumors
- allergies to growth hormone or any of the ingredients in the medicine
- certain types of eye problems caused by diabetes

Omnitrope should also not be used in children who have completed growth

What should patients tell their doctor before taking Omnitrope?

Patients should tell their doctor about their medical and family history, treatment use and past and existing medical conditions, such as but not limited to the following:

- cancer or any tumor
- diabetes
- use of prescription and non-prescription medicines, steroids, vitamins, and herbal supplements
- pregnancy
- nursing

What are the most common side effects of Omnitrope?

- local reactions at the injection site (such as pain, numbness, redness and swelling)
- headaches
- swelling associated with fluid retention
- pain in joints and muscle pain
- carpal tunnel syndrome
- tingling and numbness
- high blood sugar (hyperglycemia/diabetes) and sugar in your urine (glucosuria)
- unusual skin sensations
- low levels of thyroid hormone (hypothyroidism)

Please see accompanying full Prescription Information.

IMPORTANT SAFETY INFORMATION (continued)

Other possible side effects of Omnitrope are:

- return of tumor or cancerous growths
- headaches, changes in vision, nausea or vomiting (these may be symptoms of raised pressure in the brain which requires immediate medical attention)
- hip and knee pain or a limp in children, that can be a sign of slipped capital femoral epiphysis
- worsening of pre-existing curvature of the spine in children (scoliosis)
- increased ear infections and ear disorders in children with Turner syndrome; check for cardiovascular disorders (hypertension, stroke)
- intense pain and tenderness in the abdomen as consequence of an inflammation of the pancreas (pancreatitis)
- gasping syndrome (decreased rate of breathing) in children from high levels of benzyl alcohol (an inactive ingredient)
- increased mortality in patients with Prader-Willi and acute illness

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

SANDOZ A Novartis
Division