

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.

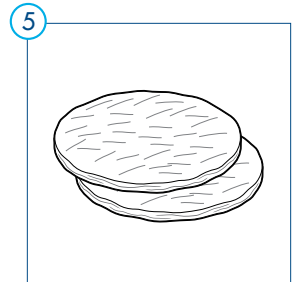
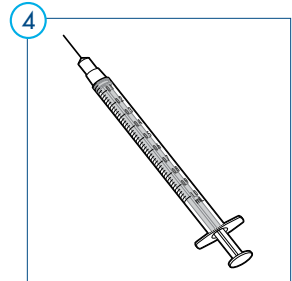
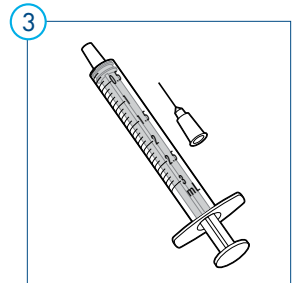
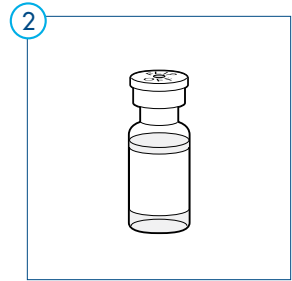
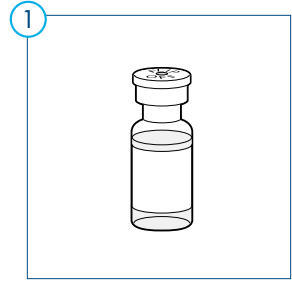
- Omnitrope 5.8 mg is for multiple uses
- The concentration of Omnitrope after mixing is 5 mg/mL
- After mixing, Omnitrope 5.8 mg contains a preservative and should not be used in newborns

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.



MIXING OMNITROPE 5.8 MG

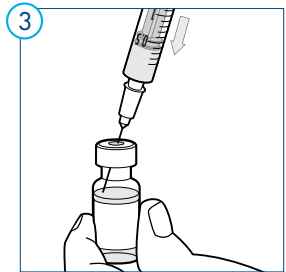
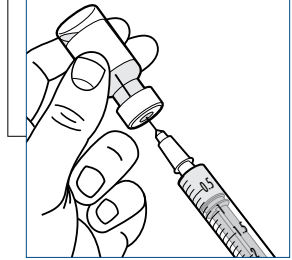
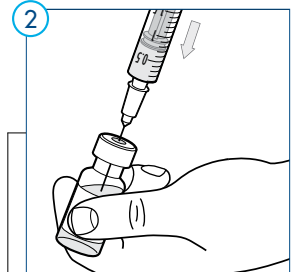
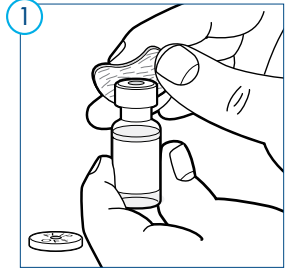
Wash your hands before you start the next steps.

- 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.**

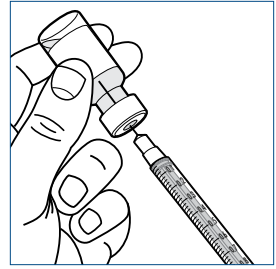
NOTE:

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.



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.

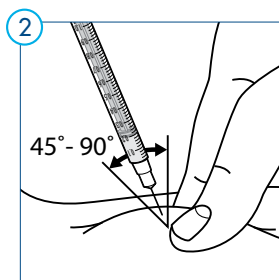
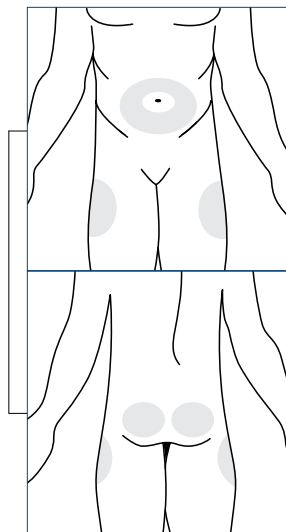
IMPORTANT: To ensure no accidental leakage of medicine, hold the syringe with the needle pointing up until ready to make the injection.

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.



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

FDA=Food and Drug Administration.

Please see Important Safety Information starting on page 28 and [click here](#) for full Prescribing Information.

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**

INDICATIONS

Omnitrope® is a prescription medicine that contains human growth hormone and is used to treat:

- Children with growth failure due to growth hormone deficiency (GHD), Prader-Willi Syndrome, Small for Gestational Age, Turner Syndrome, and Idiopathic Short Stature
- Adults with either adult onset or childhood onset GHD

IMPORTANT SAFETY INFORMATION

Who should not take Omnitrope?

Omnitrope should not be used by children or adults that have:

- a critical illness caused by certain types of heart or stomach surgery, accidental trauma, 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
- closed bone growth plates

What should patients tell their healthcare provider before taking Omnitrope?

Patients should tell their healthcare provider about all of their medical conditions, including if they:

- have had heart or stomach surgery, trauma, or serious breathing problems
- have or have had cancer or any tumor
- have diabetes
- take any prescription and non-prescription medicines, steroids, vitamins, or herbal supplements
- are pregnant or breastfeeding, or plan to become pregnant or breastfeed

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)

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

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

WE'RE HERE TO SUPPORT.

Contact OmniSource®



Call us at [877.456.6794](tel:877.456.6794),
Monday-Friday, 8AM-8PM ET.



For more information about our services
visit us at www.omnitrope.com.



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