

Omnitrope<sup>®</sup> Pen 10

Instructions for Use

For use with Omnitrope<sup>®</sup> (Somatropin [rDNA origin] Injection) 10 mg/1.5 mL cartridges

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**READ FIRST:** Important Safety Information

1. Read the following instructions before using the Omnitrope<sup>®</sup> Pen 10. Ask your healthcare professional if there is something you do not understand.
2. The Omnitrope<sup>®</sup> Pen 10 is a pen injector. It is for use with Omnitrope<sup>®</sup> cartridges 10 mg/1.5 mL (30 IU) and BD<sup>®</sup> pen needles (29G x 12.7 mm or 31G x 8 mm or 31G x 5 mm).
3. People with very poor vision should not use the Omnitrope<sup>®</sup> Pen 10 unless someone with good eyesight is able to help.

## DOS AND DON`TS

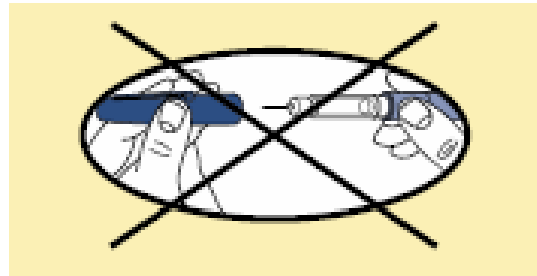
### DOs

1. Always keep Omnitrope<sup>®</sup> cartridges refrigerated.
2. After taking a cartridge out of the refrigerator, allow it to reach room temperature (about 30 minutes) before injecting the medicine.
3. When starting a new cartridge, always ready (prime) the pen.
4. When making an injection, insert the pen needle into the skin in the way that your healthcare professional teaches you. After pen needle insertion, push the injection button in as far as it will go and continue to press firmly for at least five seconds, before you remove the pen needle from the skin. If medicine continues to drip from the pen needle after injection, hold the pen needle in the skin longer the next time you inject.
5. This device **must not be shared with other patients**. However, if you are giving an injection to another person, be careful when removing the pen needle. Accidental pen needle sticks can transmit infections.
6. **For safety and injection comfort, use a new, sterile pen needle with each injection.**

### DON`Ts

1. Do not share the Omnitrope<sup>®</sup> Pen 10. It is made for only one person to use.
2. The pen needle unit is sterile. To avoid contaminating the pen needle after opening, **do not place it on a surface or touch exposed parts.**
3. Never dial your dose or attempt to correct a dialing error with the pen needle in your skin. This may result in a wrong dose.
4. **Never store or carry your Omnitrope<sup>®</sup> Pen 10 with a pen needle attached.**

**Never recap pen with pen needle on.**



Storing or carrying your Omnitrope<sup>®</sup> Pen 10 with a pen needle attached may lead to needle pricks and leaves an open passage for:

- Air to enter the cartridge
- medicine to leak out

Both of these conditions can affect the dose of the injection.

5. Do not use your Omnitrope<sup>®</sup> Pen 10 if the cap or other parts are missing.

**PEN PARTS**

**AUTO-POSITIONING FEATURE**

The Omnitrope® Pen 10 has a black rod with an auto-positioning feature. This auto-positioning feature makes priming easier (fewer steps), especially when a new cartridge is used.

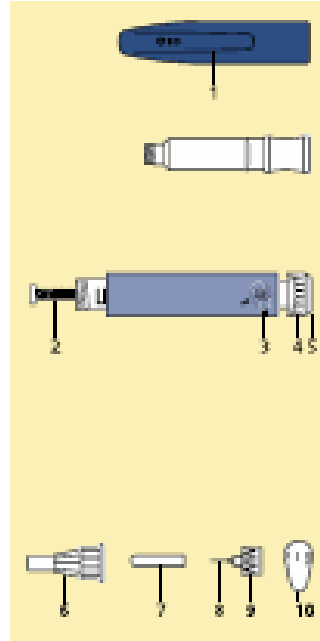
**How it works**

(Pictures are included only to demonstrate the auto-positioning feature. These steps are not necessary to operate pen).



Notice that the black rod moves into the pen easily and returns to the fully extended position automatically. This automatic extension of the black rod positions it correctly against the cartridge plunger.

**PEN PARTS**



**PEN CAP**

- 1. Clip

**CARTRIDGE HOLDER**

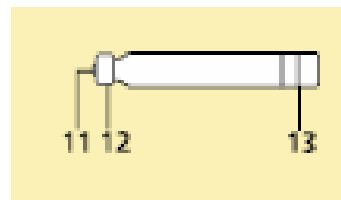
**PEN BODY**

- 2. Black rod
- 3. Dose window with arrow indicator
- 4. White dose knob
- 5. Red injection button

**PEN NEEDLE UNIT**

- 6. Outer pen needle shield
- 7. Inner pen needle shield
- 8. Pen needle
- 9. Hub
- 10. Paper tab

**Note - Pen Needle Unit is supplied assembled and sterile. Do not disassemble at this point.**

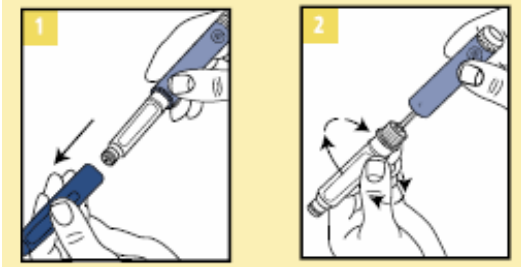


**CARTRIDGE**

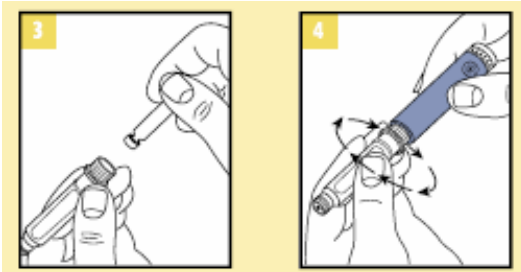
- 11. Rubber septum
- 12. Metal Cap
- 13. Cartridge plunger

## HOW TO USE YOUR OMNITROPE® PEN 10

### LOADING THE CARTRIDGE INTO THE PEN



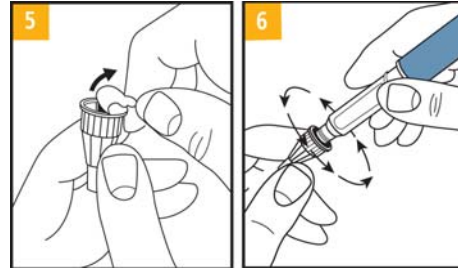
1. Remove the pen cap by pulling it off the pen.
2. Unscrew the cartridge holder from the pen body



3. Insert the cartridge, metal cap first, into the cartridge holder
4. 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 until no gap remains. One of the blue arrows must line-up with the yellow line mark on the pen body.

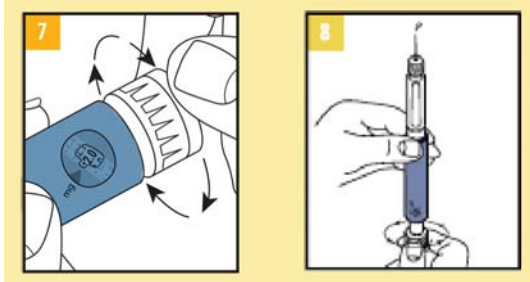
**Note** - Do not overtighten.

### ATTACHING THE PEN NEEDLE



5. Remove the paper tab from the back of a new pen needle.
- 6a. Holding the cartridge holder, push the pen needle unit onto the pen. Then screw the threaded hub of the pen needle onto the cartridge holder as shown.
- 6b. With a gentle pull, remove the outer pen needle shield. Save the outer shield. You will use it to remove the pen needle from the pen after your injection is finished.
- 6c. Do not remove the inner pen needle shield at this time.
- 6d. Check that the cartridge holder is attached to the pen body, with the blue arrow lined-up with the yellow mark on the pen body before each injection.

## PRIMING



Important - Before using a new cartridge, you must prime the Omnitrope<sup>®</sup> Pen 10.

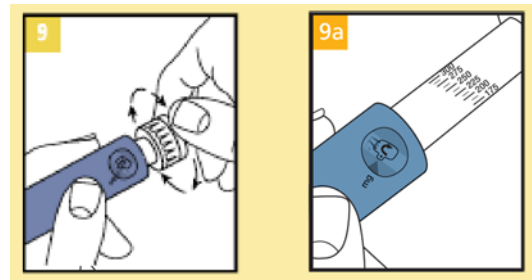
### For a New Cartridge Only

7. 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. Set the dose to 0.1 mg (one click) by turning the dose knob.
8. Remove the inner pen needle shield. With the pen needle pointing up, firmly turn the dose knob back to the "0" position and hold for at least 5 seconds. At least 2 drops of medicine must flow out of the pen needle for the pen to be properly primed.  
If at least 2 drops do not flow out, set the dose to 0.1 mg and repeat the steps until at least 2 drops of medicine appear at the tip of the pen needle.  
When medicine appears, the Omnitrope<sup>®</sup> Pen 10 is properly primed for injection and ready to use.

### For a previously used Cartridge

No priming is needed. Remove the inner pen needle shield and continue with dose dialing.

## DOSE DIALING



9. To set your dose, turn the dose knob until you see the number of mg for your dose in the middle of the dose window lined-up with the arrow. You will hear a click for each dose increment you dial. However, do not rely on counting these clicks to measure the right dose.

### Important - Dose Correction

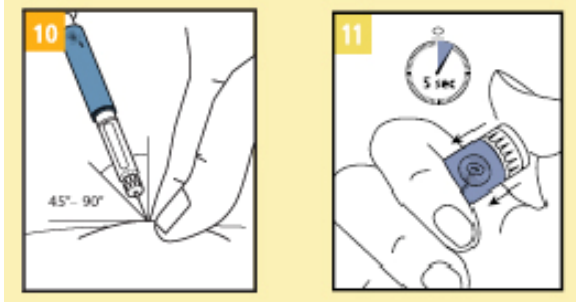
If you turn the dose knob past your dose, **do not dial backwards.**

Hold the pen body and turn the dose knob until it is fully extended as shown in picture 9a. You will see a bent arrow (↷) in the dose dialing window. The injection button can now be fully pressed, resetting the dial to "0" without giving medicine. The right dose can now be redialed as described in step 9.

**Note** - 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.

## MAKING THE INJECTION

10. Insert the pen needle into the skin as instructed by your healthcare professional.



11. After inserting the pen needle, push the injection button in as far in as it will go and press firmly. A clicking sound will be heard while your dose is injecting. Continue to press firmly for at least 5 seconds, before you remove the pen needle from the skin.

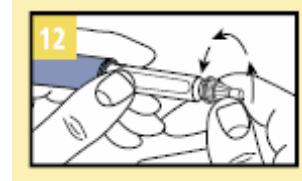
**If medicine continues to drip** from the pen needle after injection, hold the pen needle in your skin for a longer time the next time you inject.

**If you cannot push the Injection button in as far in as it goes** and the dose window does not read "0", the cartridge is empty and the full dose of medicine has not been injected. The dose indicator window will show the amount of medicine still needed. Remove the pen needle from the skin and note the number. Reset the dose knob to "0" by holding the pen and turning the dose knob until it is fully extended as shown in picture 9a. The dose injection button can now be fully pressed

to "0". Remove the pen needle from the pen (see step 12 below) and remove the empty cartridge by unscrewing the cartridge holder. Insert a new cartridge and prime the pen as described in steps 7 and 8. Set the dose, which you noted, and inject. This completes your dose.

**Important** - Before replacing a cartridge, be sure that the pen needle unit is **NOT** attached to the Omnitrope<sup>®</sup> Pen 10.

## REMOVING THE PEN NEEDLE



12. Carefully replace the outer pen needle shield. Hold the pen by the cartridge holder and unscrew the pen needle from the cartridge holder. Recap the pen.
13. Store your Omnitrope<sup>®</sup> Pen 10 with attached Omnitrope cartridge in its pouch or refrigerator storage box. Store in a refrigerator between 36 and 46°F (2 and 8°C).
14. Dispose of used pen needles in a special container called a "sharps" container. Your healthcare professional can give you a sharps container or tell you how to make one. Do not dispose of used pen needles in the trash.

**TROUBLESHOOTING**

<b>PROBLEM</b>	<b>POSSIBLE CAUSE</b>	<b>HOW TO FIX</b>
Dial unit does not turn easily.	Dust or dirt	Turn the dial beyond the highest setting on the scale. Wipe all exposed surfaces with a clean, damp cloth. Please also refer to the chapter "Care and Storage".
You have dialed a higher dose than needed.		Correct dose as described in step 9, "Dose correction".
The injection button cannot be pushed or stops during injection. (Dose knob does not return to "0").	Cartridge is empty and full dose has not been dispensed.	Remove the pen needle as per step 12 and replace the empty cartridge with a new cartridge. Refer to step 11, "If the injection button stops".
	Clogged pen needle.	Remove the pen needle as per step 12 and replace it with a new needle as described in step 5.
No clicking is heard during the injection (Dose knob moves freely).	Pen is in dose correction mode.	Remove pen needle from skin. Press injection button all the way in so the dial returns to zero and repeat from step 9 to make the injection.
Medicine continues to drip from the pen needle after injection.	Pen needle was removed from the skin too early.	Hold the pen needle in your skin longer next time you inject.
	Cartridge holder is not properly attached to the pen body.	Line-up blue arrow on cartridge holder with yellow mark on pen body.



## CARE AND STORAGE

Once your Omnitrope<sup>®</sup> Pen 10 contains a somatotropin cartridge, it has to be stored in the refrigerator between 36 and 46°F (2 and 8°C).

Protect your Omnitrope<sup>®</sup> Pen 10 and cartridge from light by storing in its pouch or refrigerator storage box.

The Omnitrope cartridge must be discarded 28 days after the first injection. The Omnitrope<sup>®</sup> Pen 10 can be reloaded with a new cartridge and be used multiple times.

Your Omnitrope<sup>®</sup> Pen 10 must be properly cared for.

- Only a clean, damp cloth should be used for routine cleaning. Never wash the pen in water or with strong surgical disinfectants.
- Avoid exposure to dust, moisture and temperature extremes. Do not expose to heat or freeze.

If your Omnitrope<sup>®</sup> Pen 10 is damaged or you cannot get it to work contact your local Omnitrope<sup>®</sup> Pen 10 provider (phone 800-525-2492). For questions or additional information please call 1800 525 8747. Do not attempt to repair the pen yourself.

## GUARANTEE

Your Omnitrope<sup>®</sup> Pen 10 is covered by a 2 year guarantee. Contact your local pen provider after you have used the pen for 2 years to have it replaced by a new one.

If your Omnitrope<sup>®</sup> Pen 10 is defective in materials or workmanship within the period of the guarantee, the local pen provider will replace the Omnitrope<sup>®</sup> Pen 10 and/or rectify the fault at its own cost.

In case of complaints, please contact your local pen provider to report a complaint.

This guarantee is invalid if your Omnitrope<sup>®</sup> Pen 10 has not been used in accordance with the manufacturer's instruction leaflet or if the defect has been caused by neglect, misuse or accident.

ACCURACY - Omnitrope<sup>®</sup> Pen 10 complies with the accuracy requirements of the International Standard EN ISO11608-1/2000 Pen Injectors for medical use - Requirements and test methods.

**IMPORTANT PERSONAL NOTES**

Date I first used the Omnitrope® Pen 10:  
\_\_\_\_\_ (dd/mm/yy)

Pen log no:  
\_\_\_\_\_

Additional Comments:  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

**SERVICE MATERIALS\***



**POUCH** to store and protect your pen and other components, such as needles



**REFRIGATOR STORAGE BOX** to protect the drug from odors and accidental spills



**COOLBAG** to help maintain Omnitrope® at refrigerator temperature when traveling

\* Optional; please check availability with your local Sandoz representative

Produced for:  
Sandoz GmbH  
Biochemiestr. 10  
A-6250 Kundl  
Austria

Authorized representative  
Becton Dickinson France S.A.S.  
38801 Le Pont de Claix Cedex  
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USA

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