INSTRUCTIONS FOR USE

For complete dosing and safety information, please refer to the Saizen® [somatropin (rDNA origin) for injection] Package Insert.
INSTRUCTIONS FOR USE

- EMD Serono’s one.click® auto-injector pen is to be used exclusively with Saizen® [somatropin (rDNA origin) for injection] 8.8 mg contained in the click.easy® Reconstitution Device in accordance with your medical practitioner’s prescription.
- The one.click® auto-injector pen inserts the needle automatically and accurately to the desired depth in the fatty subcutaneous tissue under the skin and administers a pre-selected dose of Saizen® 8.8 mg with just one click.
- Single use disposable sterile needles for the one.click® auto-injector pen are supplied separately. Use only 0.33 x 12.7 mm - (29G x ½ ”) needles.
- The one.click® auto-injector pen containing the cartridge of reconstituted Saizen® placed in its storage box should be stored at 2-8°C/ 36-46°F in a refrigerator. The reconstituted Saizen® should be used within 21 days.
I. DESCRIPTION
one.click® AUTO-INJECTOR PEN COMPONENTS
Please refer to drawing below

1. Blue activation cap
2. Depth adjuster
3. Cartridge cover
4. Cartridge holder (transparent plastic)
5. Plunger disk
6. Plunger rod
7. Main body
8. Yellow one.click® button
9. Dose indicator
10. Green dose dial
11. Outer Needle cover
12. Inner needle cover
13. Needle
14. Sterility seal
15. Cartridge
16. Label
17. Cartridge bung

MDT-474 Cyan
MDT-474 Magenta
MDT-474 Yellow
MDT-474 Black
DOSE ACCURACY TABLE

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Dose accuracy in accordance with ISO 11608:1: Pen-injectors for medical use, Part 1: Requirements and test methods

MDT-474  Cyan
MDT-474  Magenta
MDT-474  Yellow
MDT-474  Black
II. INSTALLING / CHANGING THE CARTRIDGE

1. Unlock and remove the blue activation cap (1) by twisting the cap counterclockwise. (Picture 1) The depth adjuster (2) should remain attached to the cartridge cover (3) during the cartridge installation procedure.

2. Unscrew the cartridge cover and then the cartridge holder. (Picture 2). Ensure that the plunger rod comes back to baseline position (fully retracted into main body). If the plunger rod does not come back to baseline position, push the plunger rod against a flat surface and it will move back inside the main body.
3. Remove the empty cartridge from the cartridge holder (Picture 3), if any.
   NOTE: Clean the empty cartridge holder of your one.click® auto-injector pen each time you change cartridges. Simply soak the empty cartridge holder in warm water for 10 minutes and let it dry in a vertical position.

4. Insert a new cartridge containing the reconstituted Saizen® 8.8 mg from the click.easy® Reconstitution Device into the clean cartridge holder inserting the top of the cartridge (silver cap) into the cartridge holder first.

5. Screw the cartridge holder with the cartridge back onto the one.click® auto-injector pen main body.

6. Turn the cartridge holder clockwise until the disc on the plunger rod is against the cartridge (Picture 4).
   When you hear a slight ratcheting sound, stop turning the cartridge holder.
   NOTE: For an accurate injection it is very important that the disc on the plunger rod is properly positioned against the cartridge bung.
   Be sure to continue to turn the cartridge holder until you hear the ratcheting sound.

7. Screw the cartridge cover back onto the one.click® auto-injector pen main body tightly.
III. SETTING THE INJECTION DEPTH

Turn the depth adjuster to the position recommended by your medical practitioner by turning the depth adjuster counterclockwise until the A, B or C is exposed. The depth adjuster can also be left in the starting position. If you continue to turn the depth adjuster past the C setting, the ring will separate from the cartridge cover. The depth adjuster can be reattached to the cartridge cover by placing the depth adjuster onto the cartridge cover and turning clockwise until firmly screwed in place.

The exposed needle length is approximately as follows:

<table>
<thead>
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<th>Setting</th>
<th>Starting Position</th>
<th>A</th>
<th>B</th>
<th>C</th>
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<tr>
<td>Exposed needle length</td>
<td>8 mm</td>
<td>6 mm</td>
<td>4 mm</td>
<td>2 mm</td>
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</tbody>
</table>

The depth adjustment should be checked before each injection and may need slight adjustment to ensure the proper setting.
IV. INJECTION WITH ONE.CLICK® AUTO-INJECTOR PEN:

You are now ready to carry out your injection by following the simple steps below:

1. Take a new needle and remove the protective sterility seal. Use only the needles provided with your one.click® auto-injector pen.
   Additional needles can be obtained through your physician or pharmacy.
   CAUTION: Do not use the needle if the sterility seal is damaged or unstuck.

2. Screw the new needle onto the cartridge holder and remove the outer needle cover. Do not remove the inner needle cover. (Picture 5)
3. Place the color end of the blue activation cap on a flat, non-slip surface.

4. Grip the one.click® auto-injector pen on the cartridge cover and press down until a click is heard. (Picture 6)

5. Remove the blue activation cap. It will automatically remove the inner needle shield. The inner needle shield is now lodged inside the blue activation cap.

   **CAUTION:** Do not press the yellow one.click® button while activating. If the yellow one.click button is pushed during activation, proceed to Step 6 to remove the inner needle shield from the blue activation cap, then proceed directly to Step 12 in order to remove the needle from the cartridge cover. Then repeat the activation process starting from Step 1 above.
6. Remove the inner needle shield from the blue activation cap by placing the clear end on a flat surface. Press the top of the blue activation cap down towards the flat surface and the inner needle shield will pop out. (Picture 7)

7. Turn the green dose dial clockwise slowly until the required dose appears in the dose indicator window. (Picture 8) If the green dose dial is accidentally turned passed the required dose, turn the green dose dial counterclockwise until proper dose appears in the dose indicator window. When setting the dose, each "click" represents 0.02 mL. The minimum dose for injection is 1 "click" which is equivalent to 0.02 mL or 0.12 mg of Saizen®. The maximum dose is 29 "clicks" which is equivalent to 0.580 mL or 3.38 mg of Saizen®.

NOTE: Please refer to DOSE ACCURACY TABLE above (clicks / mL / mg) for other dose settings.

CAUTION: Never use force when adjusting the dose. If you have any problems setting the dose on your one.click® auto-injector pen, see "Additional Information" in Section V of this manual.
8. Prepare the injection site according to the instructions given by your medical practitioner. Remember to wash your hands thoroughly with antibacterial soap before preparing to inject the medication. Clean the injection site with an alcohol swab (wipe) or cotton ball with rubbing alcohol using a circular motion. To avoid stinging, you should let your skin dry before you inject your medication. There is no need to pinch the skin at the injection site.

9. Hold the one.click® auto-injector pen at a right angle against the skin. (Picture 9)

10. Press the yellow button for the injection to start. You do not need to continue to press the yellow button. Keep the one.click® auto-injector pen held against the skin during the 10 seconds (approximately) it takes for the the injection to be completed. (Picture 9 above). Ensure that the green dose dial rewinds to zero by looking for the “0” through the dose indicator window. If the one.click® auto-injector pen is held against the skin for the full 10 seconds and there is no evidence of lost medication (“wet” injection), the full dose has been given. If there is evidence of a wet injection, or if the injection is interrupted for any reason during administration and the remaining medication is lost, contact your physician for instructions to either repeat the day’s dose or wait until the next day’s dose to continue therapy.
11. Withdraw the one.click® auto-injector pen from the skin. After the injection, if a drop of blood appears, simply press for a few seconds with a sterile gauze pad.

12. Cover the needle with the outer needle cover and unscrew it. (Picture 10)
   CAUTION: Remember to discard the used needle safely, in a suitable container as recommended by your medical practitioner, such as a sharps container or other biohazard container.

13. Push and screw the blue activation cap back into the cartridge cover.

14. Place your one.click® auto-injector pen with cartridge containing the remaining reconstituted solution of Saizen® in its storage box and immediately place the box back into the refrigerator (2–8°C/36–46°F) (not into the freezer). The cartridge containing the remaining reconstituted solution of Saizen® must be used within 21 days. After 21 days, discard the cartridge even if there is drug remaining in the cartridge.
V. TROUBLESHOOTING GUIDE

What if I cannot dial my complete dosage?
If you cannot dial your dose, you should inject the indicated dose and then complete the injection with a new cartridge. For example: If you reach a dose value of 14 clicks in the window instead of the desired 20 clicks. You should inject the 14 clicks. Then you should change the cartridge, not forgetting to change the needle, and set your next dose to 6 clicks (20 minus 14) and inject this amount. This will allow you to have the correct dose and not waste any product. CAUTION: Never force the dose dial if you do not obtain the required dosing amount.

What if I cannot set a dose?
Verify if the cartridge is empty. If so, follow instruction of section II "Installing/Changing the cartridge" of this manual. If the cartridge is not empty, try to set the dose again. If the problem persists, activate the one.click® autoinjector pen again by installing a new needle and set the dose again. If the problem still persists, call EMD Serono’s Connections for Growth® at 1-800-582-7989 and you will be given instructions on how to replace your one.click® auto-injector pen.

What if I have gone too far in dialing the dose?
Turn the green dose dial backward to correct the dose.

What if the green dose button turns freely?
If the green dose dial turns freely with no clicking, the one.click® auto injector pen is probably not activated. Repeat the activation step (point 3,4,5 of Section IV) ensuring that the blue activation cap is pushed down far enough into the one.click® auto injector pen or that the cartridge cover is screwed on completely.
What if the needle is stuck in the one.click® auto injector pen and I can not remove it?
When the one.click® auto injector pen is activated, the needle is hidden. To remove a stuck needle, you need to remove the cartridge cover. Once the cartridge cover is removed you can safely remove the needle by putting the outer cover on and unscrewing it.

What if I can not place the blue activation cap to activate the one.click® auto injector pen?
You should check if an old inner needle shield has not been left in the blue activation cap.

What if I forget to insert the needle?
You will not be able to activate the one.click® auto injector pen nor to dial a dose.

What if the disc on the plunger rod is not properly positioned against the cartridge plunger?
Verify that the cartridge holder is properly screwed up into the main body. Turn until a slight ratchet sound is heard.

What if the green dose dial does not come back to zero?
Replace the cartridge in the one.click® auto injector pen with a new cartridge. If the problem persists, please call EMD Serono's Connections for Growth® at 1-800-582-7989 and you will be given instructions on how to replace your one.click® auto-injector pen.

What if the plunger rod does not move back into the main body when unscrewing the cartridge container?
Push the plunger rod against a flat surface and it will move back inside the main body.

How do I remove the inner needle shield from the activation cap?
According to the one.click® auto injector pen instruction for use (Chapter IV, Picture 6 and Picture 7), the removal of the inner needle shield is shown by pressing down the blue activation cap against a table. You should not hold on the side of the activation cap when pressing, but: Press on the top cover to expel the activation cap, (the clear end being on a flat surface).
VI. GENERAL INSTRUCTIONS

CARE of your one.click® auto-injector pen:
1. Clean the cartridge holder of your one.click® auto-injector pen each time you change cartridges. Simply soak the empty cartridge holder in warm water for 10 minutes and let it dry in a vertical position. If you have to change cartridges to administer your full dose, it is recommended that you clean the cartridge holder as indicated above before installing the new cartridge to complete your full dose.
   Caution: Never use soap or any organic solvent on the cartridge holder. Never rinse or immerse under water any part of the one.click® auto-injector pen except the cartridge holder.
2. If your one.click® auto-injector pen contains a cartridge of reconstituted Saizen®, it should not be exposed to light or freezing temperatures.

TRANSPORTING your one.click® auto-injector pen:
Even for short travel distances, your one.click® auto-injector pen containing a cartridge of reconstituted Saizen® placed in its storage box should be transported in a cooling bag in order to maintain a temperature of 2°-8°C/ 36°-46°F. You should consult your medical practitioner before traveling long distances.

STABILITY AND STORAGE
Saizen® 8.8 mg reconstituted solution contained in the one.click® auto-injector pen should be stored in a refrigerator (2°-8°C / 36°-46°F) and should be used within 21 days. Do not freeze.
VII. GUARANTEE

Every effort has been made to ensure that the one.click® auto-injector pen will function correctly for at least two years. After two years of operation your one.click® auto-injector pen should be replaced. A new one.click® auto-injector pen can be obtained through EMD Serono’s Connections for Growth® at 1-800-582-7989.

Date I received my one.click® auto-injector pen:

____________________ / ____________ / ____________
Day  Month  Year

You should also record this date on the label on the bottom of the one.click® auto-injector pen storage box.

Detailed information on EMD Serono’s Saizen® is provided in the respective package insert of the drug product.

If you are experiencing any problems with your one.click® auto-injector pen, please contact EMD Serono’s Connections for Growth® at 1-800-582-7989.

Rx only
Manufactured for: EMD Serono, Inc., Rockland, MA 02370

March 2012
AA0000-2012/03

MDT-474  Cyan
MDT-474  Magenta
MDT-474  Yellow
MDT-474  Black