



Instructions for Use

for pen injectors 6, 12 and 20

Pen injector only to be used for subcutaneous administration of Saizen® (somatropin) solution for injection



REF U1222214,
U1222215, U1222216

Table of Contents

Important information _____	2
Step 1: Gather your supplies _____	5
Step 2: Select your aluetta pen injector and cartridge _	7
Step 3: Inspect your cartridge _____	9
Step 4: Insert your cartridge _____	11
Step 5: Choose and prepare your injection site _____	15
Step 6: Attach your needle _____	17

Step 7: Prime your aluetta pen injector _____	19
Step 8: Dial your dose _____	21
Step 9: Inject your dose _____	25
Step 10: Remove and throw away your used needle and empty cartridge _____	27
Step 11: Store your aluetta pen injector _____	31
Explanation of symbols _____	34



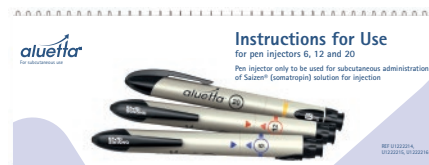
What is in the box?

Note: aluetta™ pen injector 6 is for illustration purposes. The following steps are the same for all presentations.

Storage box and
aluetta pen injector



aluetta pen injector
Instructions for Use



Important information

The aluetta pen injector facilitates the administration of Saizen treatment, including self-administration for patients at home. The aluetta pen injector is a reusable and refillable pen injector to be used with Saizen (somatropin) solution for injection only as indicated in the Package Insert. The aluetta pen injector is for use under the skin only (subcutaneous).

The aluetta pen injector can be used independently by adults and adolescents aged 13 years and older (adolescents should be supervised by an adult). Saizen (somatropin) injection for children below the age of 13 should be administered by an adult.

You must receive training before using the aluetta pen injector. Always follow all directions and training provided by your healthcare professional.

Fold page open for device parts overview

Get familiar with your pen injector, needle and cartridge

Note: Your healthcare professional will tell you what the right dose and needle is for you.

Pen injector cap

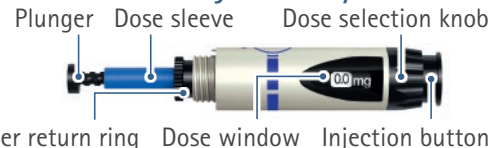


Cartridge holder



Cartridge window

Pen injector body



Pencylcap® and Ultra-Fine™ needles



AutoShield™ DUO Safety needle



Saizen® cartridge



aluetta pen injector presentations



The aluetta pen injector uses single use, disposable needles. Only the following needles must be used: B. Braun Pencylcap 29G x 12 mm and 31G x 8 mm needles, Becton Dickinson (BD) Ultra-Fine 31G x 5 mm needles and Becton Dickinson (BD) AutoShield DUO 30G x 5 mm safety needles.

Only Pencylcap and AutoShield DUO needles are represented in this Instructions for Use. Usage of Ultra-Fine needle is similar. Ask your healthcare professional to determine which needle is best for you.

Read all of these instructions for use carefully before you start using your device. This information will allow preventing incorrect treatment, infection, or needle stick injuries.

Warning:

- Do not reuse needles.
- Do not share your aluetta pen injector and/or needles with anyone.
- Do not use if the aluetta pen injector has been dropped, or the cartridge is cracked or damaged.

Doing so may cause an infection. Contact your healthcare professional for questions.

- Always keep the aluetta pen injector out of the reach of other children.
- You might need to use more than one cartridge to give a prescribed dose.
- There are no known contraindications or undesirable effects using the aluetta pen injector.
- Refer to the Saizen Patient Information Leaflet for contraindications or undesirable effects of Saizen (somatropin) for injection.

Step 1: Gather your supplies

5

- 1.1** a. Gather a needle and the aluetta pen injector carton.
Take a new Saizen cartridge (Figure 1.1a).
- b. When using the aluetta pen injector for the first time, write the date you first use it and the expiration date on the label on the back of the storage box (Figure 1.1b).

Figure 1.1a



Figure 1.1b



Important: Your aluetta pen injector should be replaced 3 years after you use it for the first time and no later than the "Use by" date (🕒) you can find on the storage box label. You can get a new aluetta pen injector by contacting your healthcare professional. Follow your local guidelines to dispose of your aluetta pen injector.



Step 2: Select your aluetta pen injector and cartridge

7

2.1 Wash your hands with soap and water then dry them well.

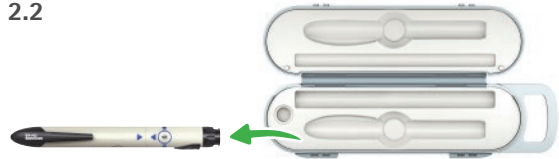
Figure 2.1



2.2 Remove the aluetta pen injector from the storage box.

Figure 2.2

Note: All pen injectors allow dosing in increments of 0.1 mg across a range from 0.0 to 5.5 mg.



2.3 Confirm the label says Saizen.

2.4 The aluetta pen injector and cartridge are available in 3 presentations: 6 mg, 12 mg and 20 mg.

Caution: Always make sure the Saizen amount (in milligrams) on the cartridge label matches the number printed on the aluetta pen injector, and that this is the combination your healthcare professional prescribed to you.

Figure 2.3

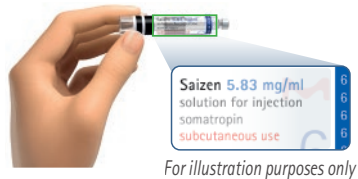
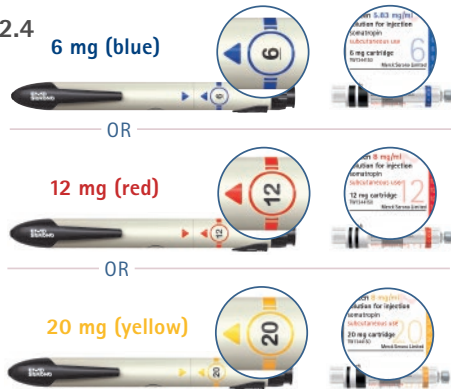


Figure 2.4



Step 3: Inspect your cartridge

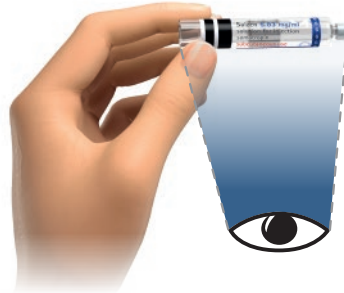
9

3.1 Confirm the cartridge is not damaged or cracked.

3.2 Confirm that medicine:

- is clear
- is colourless
- does not contain particles.

Figure 3.1 & 3.2



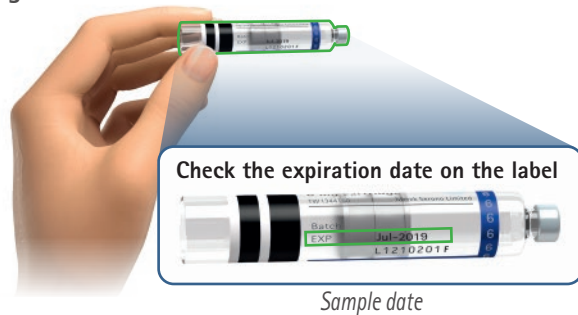
3.3 Confirm the expiration date on the cartridge has not passed.

Warning:

- Do not use the cartridge if it is damaged, or if the medicine is discoloured or cloudy.
- Do not use the cartridge if the expiration date on the cartridge has passed.

Doing so could cause an illness. Call your healthcare professional for questions.

Figure 3.3



Step 4: Insert your cartridge

11

When to insert a new cartridge:

- the first time you use the aluetta pen injector
- the cartridge is empty
- the cartridge has expired

4.1 Pull the cap off the aluetta pen injector.

4.2 Twist and remove cartridge holder from pen injector body.

Figure 4.1



Figure 4.2



Step 4: Insert your cartridge (continued)

13

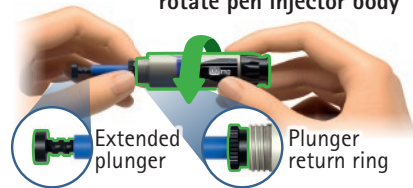
4.4 If the plunger is extended, hold plunger return ring and rotate the pen injector body until you cannot turn anymore. Make sure the plunger touches the dose sleeve.

Caution: Do not force or push plunger.

4.5 Hold cartridge holder and push a new cartridge in with metal cap first.

Figure 4.4

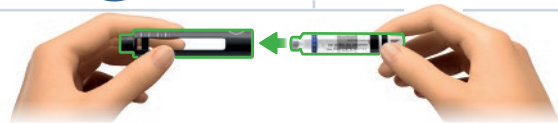
If the plunger is extended, hold plunger return ring and rotate pen injector body



Correct position of plunger touching dose sleeve



Figure 4.5



4.6 Line up pen injector body with cartridge holder and twist cartridge holder back onto pen injector body until you cannot twist anymore.

The number (6, 12 or 20) printed on cartridge holder and pen injector body should line up.

Figure 4.6



Step 5: Choose and prepare your injection site

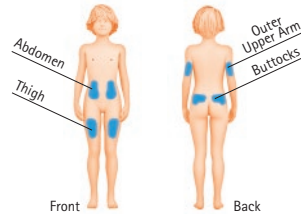
15

Note: Your healthcare professional should show you the injection sites to use.

5.1 Select a different injection site each time you inject to reduce redness, irritation or other skin problems.

5.2 Prepare your injection site by wiping it with an alcohol pad; allow your skin to dry.

Figure 5.1



Examples of common injection sites include:

- Abdomen
- Thigh
- Outer Upper Arm
- Buttocks

Figure 5.2





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Step 6: Attach your needle

17

Note: Applies to Pencylcap, Ultra-Fine and AutoShield DUO needles.

6.1 Check the peel paper on the needle to make sure it is not broken and expiry date has not passed.

Warning:

- Do not use needle if peel paper is broken or expiry date has passed. Doing so may cause an infection. Discard in your sharps container and get a new needle.

6.2 Peel off the peel paper from a new needle and discard in trash.

Figure 6.2



Step 7: Prime your aluetta pen injector

19

Important: Only prime the aluetta pen injector when starting a **new** cartridge to remove air.

7.1 Turn the dose selection knob to 0.2 mg, the dose window will show "0.2".

Figure 7.1



7.2 If you use the Pencylcap or Ultra-Fine needles:

- Pull off outer needle cover and place it in the well of the storage box. You might need this again for removing the needle after the injection.
- Carefully pull off needle shield and dispose it.

Figure 7.2



OR If you use the **AutoShield DUO Safety needle**:
Pull off outer needle cover and discard in the trash.

- 7.3 With the needle pointing up, gently tap the cartridge with your finger so that any air bubbles rise to the top.
- 7.4 Continue holding the aluetta pen injector with needle pointing up. Push the dose injection button until it stops. A tiny drop(s) of liquid will appear at the tip of the needle.

Warning:

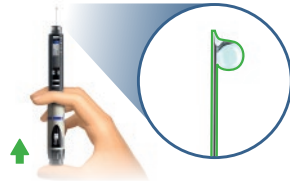
- Do not wipe the droplet from the needle after priming.

Important: If you do not see drop(s) of Saizen come out of the needle tip, repeat the priming steps up to 5 times. If the problem continues after trying 5 times, remove the cartridge, call your healthcare professional.

Figure 7.3



Figure 7.4



Step 8: Dial your dose

21

Note: Always set your dose according to your prescription. Call your healthcare professional if you are unsure of the prescribed dose.


8.1 Turn the dose selection knob until your intended dose is visible in the dose window.

Important: If you cannot turn the dose selection knob to your prescribed dose, the cartridge does not contain enough medicine. You will need to use two cartridges.

See "Using multiple cartridges to complete your prescribed dose" on page 22 for instructions.

Figure 8.1





Step 8: Dial your dose (continued)

Using multiple cartridges to complete your prescribed dose: If the dose selection knob does not turn to your prescribed dose, the cartridge does not have enough Saizen left. A new cartridge is required to deliver your full dose.

- 8.2** Follow the Step 9 "Inject your dose" to inject the first part of your prescribed dose and empty the cartridge. Use the dose amount of your first injection to calculate the remaining dose.
- 8.3** Proceed to Step 11 "Maintain and store your aluetta pen injector" to clean the cartridge holder.
- 8.4** When ready for the second injection, wash your hands again and take a new cartridge.
- 8.5** Follow the instructions starting with Step 3 "Inspect your cartridge" to replace the empty cartridge with a new cartridge and perform the priming as in Step 7 "Prime your aluetta pen injector".

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Step 8: Dial your dose (continued)

23

8.6 Calculate your remaining dose by subtracting the Prescribed dose minus the dose already injected – see sample calculation on the right.

8.7 To dial your dose, turn the dose knob until your intended dose is visible in the dose window.

8.8 Rotate injection site as instructed in Step 5.

8.9 Proceed from Step 9 “Inject your dose” to inject the remaining dose.

Sample calculation of remaining dose:

Prescribed dose	1.5 mg
Minus amount already injected in first injection	(0.7 mg)
<hr/>	
Remaining dose to inject	0.8 mg





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Step 9: Inject your dose

25

Caution: To avoid accidentally bending your needle, insert straight (90° angle) into the injection site.

- 9.1** Hold the aluetta pen injector at a 90° angle to the injection site.
Face the dose window towards you and then push the needle into your skin.
- 9.2** Use your thumb to press the injection button all the way in and hold it down while slowly counting to 10.

Figure 9.1



Figure 9.2



9.3 **Important:** Before removing the aluetta pen injector from the skin, make sure the number "0.0" appears in the dose window to ensure you injected the full dose.

9.4 If the number "0.0" does not appear, press the injection button again and continue pressing until the number "0.0" appears.

9.5 Remove the needle from your skin and then release the injection button.

If you use the AutoShield DUO Safety needle:

After injection, the protective sleeve locks automatically and you should see the red locking indicator.

Figure 9.3



Figure 9.5

Pencylcap and
Ultra-Fine needles



AutoShield DUO Safety needle



Step 10: Remove and throw away your used needle and empty cartridge

27

Warning: You must remove the needle from the aluetta pen injector and throw it away after each injection to avoid risk of infection.

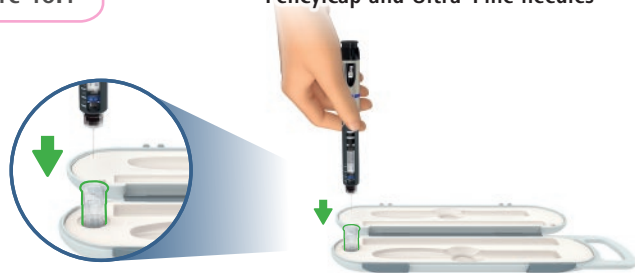
10.1 If you use the Pencylcap or Ultra-Fine needles:

Warning: Do not recap the Pencylcap or Ultra-Fine needles with the needle shield as it can lead to needle stick injuries.

To help you recap the needle, push the aluetta pen injector into the outer needle cover in the well of the storage box until you cannot push it any more.

Figure 10.1

Pencylcap and Ultra-Fine needles



Warning: Do not place your fingers on either end of the needle as it can lead to a needle stick injury.

10.2 For the Pencylcap, Ultra-Fine and AutoShield DUO Safety needles:

Hold the needle at the sides and twist it off to remove it from the aluetta pen injector.

Figure 10.2



OR

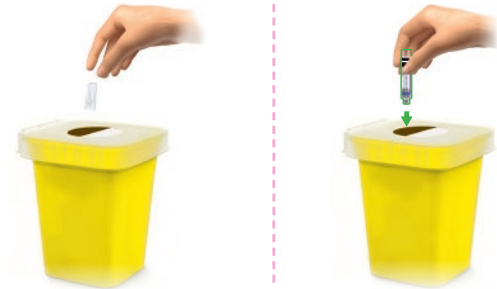


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10.3 Disposing of your used needles and empty cartridges

- Put your used needles and empty cartridges in a sharps disposal container right away after use. Do not throw away (dispose of) cartridges or needles in your household trash unless your community guidelines permit this.
- If you do not have a 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,

Figure 10.3



- upright and stable during use,
- leak-resistant, and
- properly labelled 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 local laws about how you should throw away used needles and syringes.
- Do not recycle your used sharps disposal container.

10.4 After removing the needle, recap the aluetta pen injector.

Figure 10.4



Step 11: Store your aluetta pen injector

31

- 11.1** You can wipe the outside of aluetta pen injector with a clean damp cloth whenever needed.
- 11.2** You can also soak the empty cartridge holder in warm water for few minutes, and then allow it to dry fully before reassembling the pen.

Figure 11.1



Caution:









- Do not immerse aluetta pen injector in water.
- Do not use any cleaning solutions, chemicals or alcohol wipes.



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Explanation of symbols

	Consult instructions for use		Indicates the date after which the medical device is not to be used
	Manufacturer		Date of manufacture
	Catalogue Number		Batch Code
	Medical Device		CE marking of conformity

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Support and Questions

Contact the MOMENTUM Patient Services program at 1-877-724-9361 for questions related to your aluetta pen injector, to Saizen (somatropin) solution for injection or in the event of device malfunction.

Report any serious incident involving your aluetta pen injector to the MOMENTUM Patient Services program at 1-877-724-9361 and your local competent authority.

(2018) **CE 2797**

This manual is also available electronically at
www.arestradingdevices.com



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