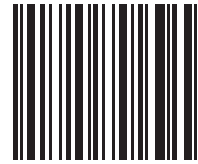


Nutropin AQ NuSpin[®] 10

(somatropin) injection, for subcutaneous use

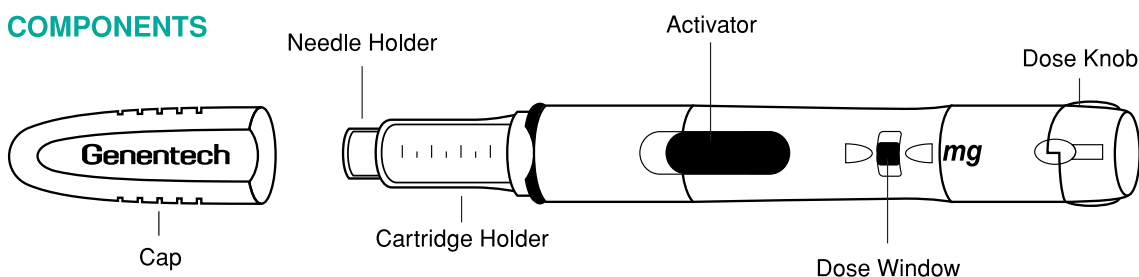
Genentech

Rx only



10181026

COMPONENTS



INSTRUCTIONS FOR USE

Description: The Nutropin AQ NuSpin 10 is a multi-dose, dial-a-dose injection device prefilled with Nutropin AQ (somatropin) injection, for subcutaneous use. It features automatic injection of the drug and is disposable.

The Nutropin AQ NuSpin 10 (Teal Color, 10 mg/2 mL) delivers doses from 0.1 to 3.5 mg in increments of 0.1 mg.

Intended Use: The Nutropin AQ NuSpin 10 is intended to be used by a healthcare professional or patient to deliver Nutropin AQ (somatropin) injection, for subcutaneous use from an injection device. The device can be used in any setting, including the home, and is disposable.

IMPORTANT NOTES

- Always follow the directions of your healthcare professional and the instructions provided on the back. Contact your healthcare professional if you have any questions.
- Check the label on the NuSpin 10 to make sure the medicine matches your prescription and it has not expired.
- Inspect the cartridge before use to ensure that the medicine in it is clear. If it is cloudy or hazy, do not inject. Return the NuSpin 10 to your healthcare professional.
- Store your NuSpin 10 inside the refrigerator at 2–8°C (36–46°F). Protect from light.
- The product can be used for 28 days after it has been primed and kept under proper storage conditions.
- For the first use of each NuSpin 10, always follow the New NuSpin 10 Set Up Instructions to ensure that air is expelled from the cartridge.
- Do not store with the needle attached. The needle should be removed and safely disposed of immediately after use.
- Keep NuSpin and all medicines out of the reach of young children.

FREQUENTLY ASKED QUESTIONS

1. What type of needles should be used?

Your Healthcare Professional will recommend a needle that is appropriate for you. The following needles will fit and work on the Nutropin AQ NuSpin:

- BD Ultra-Fine™ 29 g x 1/2 inch (12.7 mm)
- BD Ultra-Fine™ III short pen needle 31 g x 5/16 inch (8 mm)
- NovoFine® Pen needle 30 g x 1/3 inch (8 mm)
- BD AutoShield™ Pen Needle 29 g x 1/3 inch (8 mm) -- hides the needle

Pen needles from other countries may not fit on your NuSpin device. If you travel outside the United States, make sure you take enough needles for the duration of your stay.

2. Do I need to change the needle every time I use my Nutropin AQ NuSpin?

Yes. A new needle must be used for every injection. The needle is sterile only for one single injection.

3. Do I need to prime the Nutropin AQ NuSpin each time?

No. The NuSpin 10 only needs to be primed once, at first use. After the first use of each NuSpin 10, follow the instructions and skip Step 2.

4. When and how do I dispose of my Nutropin AQ NuSpin?

Your NuSpin 10 is prefilled and the cartridge cannot be replaced. When your NuSpin 10 is empty, dispose of the entire NuSpin 10 as instructed by your healthcare professional. If the empty NuSpin 10 is disposed of with

the needle attached, discard the entire device using the same procedure as for needle disposal.

5. Where should I store my Nutropin AQ NuSpin?

When not in use, your NuSpin 10 should be stored inside a refrigerator at 2–8°C (36–46°F) to maintain the potency of Nutropin AQ (somatropin) injection, for subcutaneous use. During use, we recommend that you have your NuSpin 10 outside of the refrigerator for **no longer than one hour per day**. When traveling, place your NuSpin 10 in a water-resistant container before placing in a cooler.

DO NOT FREEZE. KEEP DRY.

6. What should I do if my Nutropin AQ NuSpin is dropped or damaged?

If you drop the NuSpin 10, check to see if it is damaged. You should also check to see that the black dose knob and the Activator are moving properly. If you notice the NuSpin 10 is damaged, contact your healthcare professional or call 1-866-NUTROPIN for advice.

7. What should I do if my Nutropin AQ NuSpin needs cleaning?

Use a damp cloth to wipe away dirt. Do not place underwater. Do not use alcohol.

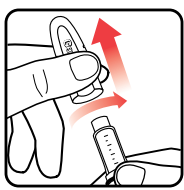
Genentech, Inc., A Member of the Roche Group
1 DNA Way, South San Francisco, CA 94080-4990
Initial US Approval January 2008
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Please see other side for additional instructions.

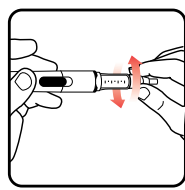
INSTRUCTIONS FOR USE

NEW NuSpin 10 SET UP: STEP-BY-STEP INSTRUCTIONS FOR THE FIRST USE OF EACH NEW NUTROPIN AQ NuSpin 10

STEP 1: Attach the needle

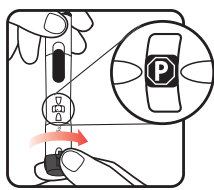


Before you begin, wash your hands. Twist gently and pull to remove the NuSpin 10 cap. Inspect the cartridge before use to ensure that the medicine in it is clear. If it is cloudy or hazy, do not inject. Open a new needle by peeling off the paper tab from the needle package.

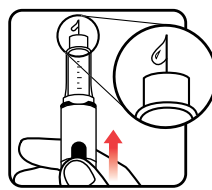


Attach the needle by carefully screwing the needle onto the needle holder. Do not overtighten. Remove both protective covers from the needle and save the outer cover.

STEP 2: Prime the Nutropin AQ NuSpin



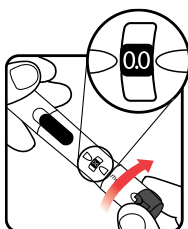
Turn the dose knob to the P position in the dose window. It may take multiple clicks to get to P. Hold the NuSpin 10 with the needle pointing upwards. Gently tap the cartridge holder to move any air bubbles to the NuSpin 10 tip.



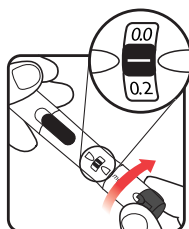
Slide the Activator toward the needle. If you do not see fluid at the needle tip, redial to P and slide the Activator forward again. Repeat until you see fluid.

ROUTINE USE: DOSING AND ADMINISTRATION

STEP 3: Set the dose

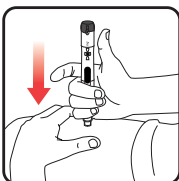


Make sure the dose window reads ►0.0◄. Turn the dose knob until the dose prescribed by your healthcare professional appears in the dose window.

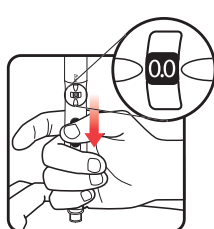


If your dose is “between” two numbers in the dose window, the ►—◄ between those two numbers indicates your dose. Turn the dose knob to ►—◄. The P position indicates a 0.7 mg dose on your NuSpin 10. If you turn the dose knob too far, simply turn it back to the correct dose. (Example above shows a dose of 0.1 mg, represented by ►—◄).

STEP 4: Give the injection

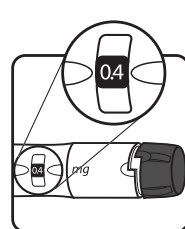


Select and prepare your injection site as instructed by your healthcare professional. Position your hand so you can easily slide the Activator. Push the needle into the skin.



Slide the Activator toward the needle. Hold the Activator down until the dose knob returns to ►0.0◄ and continue to **hold in place for 5 seconds**. Withdraw the Nutropin AQ NuSpin 10 until the needle is removed from the skin. If the dose knob returns to ►0.0◄, you have received your full dose.

Check dose given



If the dose knob stops before it returns to ►0.0◄, your Nutropin AQ NuSpin 10 is empty and you have not received your full dose. The number shown in the dose window is the amount needed to obtain a full dose. Your healthcare professional will advise you on the procedure for using the last dose in the NuSpin 10.

REMOVAL AND DISPOSAL OF THE NEEDLE

Carefully place the outer cover of the needle package over the needle, unscrew, and dispose of it as instructed by your healthcare professional.

STORAGE AND NEXT USE

Replace the cap and store your NuSpin 10 inside the refrigerator at 2–8°C (36–46°F). Protect from light. For the next use, it is already primed. Follow the instructions and skip Step 2.