

Package leaflet: Information for the user

NutropinAq 10 mg/2 ml (30 IU) solution for injection somatropin

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What NutropinAq is and what it is used for
2. What you need to know before you use NutropinAq
3. How to use NutropinAq
4. Possible side effects
5. How to store NutropinAq
6. Contents of the pack and other information

1. What NutropinAq is and what it is used for

NutropinAq contains somatropin which is a recombinant growth hormone similar to the human's natural growth hormone made by your body. It is recombinant, meaning it is made outside of the body by a special process. Growth Hormone (GH) is a chemical messenger made by a small gland in your brain called the pituitary. In children it tells the body to grow, help the bones to develop normally and, in later adult life, GH helps to maintain a normal body shape and metabolism.

In children, NutropinAq is used:

- When your body does not make enough growth hormone and for this reason you are not growing properly.
- When you have Turner syndrome. Turner syndrome is a genetic abnormality in girls (absence of female sexual chromosome(s)) that prevents growth.
- When your kidneys are damaged, and they lose their ability to function normally with an impact on growth.

In adults NutropinAq is used:

- If your body does not make enough growth hormone as an adult. This can start during adult life or continue from when you were a child.

Benefits if using this medicine

In children, it helps the body to grow and the bones to develop normally.

In adults, it helps to maintain normal body shape and metabolism for example lipid profile and glucose levels.

2. What you need to know before you use NutropinAq

Do not use NutropinAq:

- if you are allergic to somatropin or any of the other ingredients of this medicine (listed in section 6).
- in children if the bones have already stopped growing.
- if you have an active tumour (cancer). Tell your doctor if you have or have had an active

tumour. Tumours must be inactive, and you must have finished your anti-tumour treatment before you start treatment with NutropinAq.

- if you have complications after a major surgery (open-heart or abdominal surgery), a multiple trauma, acute respiratory failure, or similar conditions.

Warning and precautions

Talk to your doctor or pharmacist before using NutropinAq.

- If you experience visual changes, bad or frequent headache, associated with feeling sick (nausea) or vomiting, especially at the start of treatment, tell your doctor immediately. These could be signs of a temporary increase in pressure within the brain (intracranial hypertension).
- If during growing, a limp or hip or knee pain develops, ask the doctor for advice.
- If you notice a curve of your spine (scoliosis) you will need to be checked often by your doctor as scoliosis may progress in any child during rapid growth.
- Your doctor should monitor you for high blood sugar levels (hyperglycaemia) during treatment with NutropinAq. If you are treated with insulin, your doctor may need to adjust your insulin dose. If you have diabetes and associated severe/worsening eye disease you should not be treated with NutropinAq.
- Your doctor should check your thyroid function periodically and if necessary, prescribe adequate treatment. If you have an underactive thyroid gland leading to low levels of thyroid hormone (hypothyroidism) it should be treated before you start NutropinAq treatment. If your hypothyroidism is not treated, it could stop NutropinAq from working.
- If you have a replacement therapy with glucocorticoids you should consult your doctor regularly as you may need adjustment of your glucocorticoid dose.
- If you have had a tumour (cancer) in the past, especially a tumour affecting the brain, your doctor should pay special attention and examine you regularly for a possible return of the tumour.
- A small number of growth hormone-deficient patients treated with growth hormone have had leukaemia (blood cancer). However, no cause and effect relationship with growth hormone treatment has been proven.
- If you undergo a kidney transplant NutropinAq treatment should be stopped.
- If you have complications after major surgery (open-heart or abdominal surgery), multiple trauma, acute respiratory failure, or similar conditions, your doctor should decide whether it is safe to continue NutropinAq treatment.
- There may be an increased risk of developing an inflammation of the pancreas (pancreatitis), which causes severe pain in the abdomen and back. Contact your doctor if you or your child develops stomach ache after taking NutropinAq.
- If you have Prader-Willi syndrome, you should not be treated with NutropinAq unless you have growth hormone deficiency.

Other medicines and NutropinAq

Tell your doctor or pharmacist if you are using, have recently used or might take any other medicines.

- if you have a replacement therapy with glucocorticoids it may reduce the effect of NutropinAq on growth. You should consult your doctor regularly as you may need adjustment of your glucocorticoid dose.
- if you are treated with insulin, your doctor may need to adjust your insulin dose.
- if you are treated with sex steroids, anticonvulsants or cyclosporin ask the doctor for advice.
- if you are diagnosed with adrenal insufficiency during NutropinAq treatment, you require steroid treatment. If you are already treated for adrenal insufficiency you may require an

adjustment of your steroid dose.

- in particular, inform your doctor if you are taking or have recently taken any of the following medicines. Your doctor may need to adjust the dose of NutropinAq or of the other medicines:
 - Oestrogen taken orally or other sex hormones

Pregnancy and breast-feeding

You should stop taking NutropinAq if you are pregnant.

Caution should be exercised while breast-feeding during treatment with NutropinAq.

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines

No effect on ability to drive or use machines has been noticed while using NutropinAq.

NutropinAq is essentially “sodium free”

This medicinal product contains less than 1 mmol sodium (23 mg) per vial, i.e., essentially “sodium-free”.

3. How to use NutropinAq

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. NutropinAq therapy should be carried out under regular guidance of a doctor who is experienced in growth hormone deficiency.

The dose of NutropinAq to be injected will be decided by your doctor. Do not change the dosage without consulting your doctor. The recommended dose is:

In children with growth hormone deficiency:

0.025 - 0.035 mg/kg bodyweight injected each day under the skin (subcutaneous injection).

In girls with Turner syndrome:

Up to 0.05 mg/kg bodyweight injected each day under the skin (subcutaneous injection).

In children with chronic renal insufficiency:

Up to 0.05 mg/kg bodyweight injected each day under the skin (subcutaneous injection). You can continue treatment with NutropinAq until you have a kidney transplant.

In adults with growth hormone deficiency:

Low initial doses of 0.15 - 0.3 mg injected each day under the skin (subcutaneous injection). Then the doctor can increase the dose depending on your response. The final dose is rarely above 1.0 mg/day. In general, the lowest dose leading to a response should be given to you.

Treatment with NutropinAq is a long-term therapy. For further information ask your doctor.

How to inject NutropinAq

The dose of NutropinAq to be injected will be decided by your doctor. You have to inject NutropinAq every day under the skin (subcutaneous injection). It is important to change the place where you have your injection every day to avoid damaging your skin.

NutropinAq is supplied as a multi-dose solution. After removal from the refrigerator, if the solution is cloudy, the content must not be injected. Gently swirl. Do not shake vigorously as it could denature the protein.

To inject NutropinAq you should use the NutropinAq Pen. For each injection you should use a new sterile injection needle. Read all the instructions for use carefully (on the reverse) before you start using NutropinAq Pen. At the start of therapy, it is recommended that a doctor or a nurse give you the injection and train you with the NutropinAq Pen. After this training, you will be able to inject yourself or be injected by a trained care-giver.

If you use more NutropinAq than you should

If you have injected more NutropinAq than you should have, contact your doctor for advice. If you inject too much NutropinAq, your blood sugar level may decrease and become too low and then rise too high (hyperglycaemia).

If you inject too much NutropinAq over a long period of time (years), you may experience some overgrowth of parts of your body such as ears, nose, lips, tongue and cheekbone (gigantism and/or acromegaly).

If you forget to take NutropinAq

Do not take a double dose to make up for a missed dose. Continue with your usual dosage the next day and tell your doctor at your next appointment.

If you stop using NutropinAq

Ask advice from your doctor before you stop using NutropinAq. If you stop using NutropinAq too early or for too long, the results will not be as expected.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Tell your doctor immediately if you notice any change or increase in growth of birthmarks and/or moles (melanocytic naevus). In case of a tumour or re-growth of previous tumours (confirmed by your doctor), treatment with NutropinAq must be stopped immediately. This side effect is uncommon, it may affect up to 1 in 100 patients.

Tell your doctor immediately if you experience visual changes, bad or frequent headaches, associated with feeling sick (nausea) or vomiting. These could be symptoms of a temporary increase in pressure within the brain (intracranial hypertension). If you have intracranial hypertension, your doctor may decide to temporarily reduce or discontinue NutropinAq therapy. Then therapy may be started again after the episode is over. This side effect is rare, it may affect up to 1 in 1,000 patients.

Other side effects include:

Very common (may affect more than 1 in 10 patients)

Swelling of the hands and feet due to an accumulation of fluid (peripheral oedema) sometimes associated with localised muscle pain (myalgia) and pain in joints (arthralgia). These side effects appear usually in adults early in treatment and are short-lived. Oedema was reported as common in children.

Common (may affect up to 1 in 10 people)

Underactivity of the thyroid gland leading to low levels of thyroid hormone (hypothyroidism). If your hypothyroidism is not treated, it could stop NutropinAq from working. Your doctor should check your thyroid function periodically and if necessary, prescribe adequate treatment.

Reduced ability to absorb sugar (glucose) from your blood leading to high blood sugar levels

(hyperglycaemia). Your doctor should monitor you for signs of this during treatment with NutropinAq. If you are treated with insulin, your doctor may need to adjust your insulin dose.

Feeling of weakness (asthenia) and increased muscle tension (hypertonia)

Pain, bleeding, bruising, rash and itching at the site of injection. These can be avoided by using the correct injection technique and changing the sites of injection.

Some patients may develop antibodies (a type of protein produced by the body) to somatropin. When these antibodies were found in patients, it did not prevent them from growing.

Uncommon (may affect up to 1 in 100 people)

Decrease in the number of red blood cells in the blood (anaemia), decrease in blood sugar level (hypoglycaemia) and increase in phosphate levels (hyperphosphatemia).

Personality changes or abnormal behaviour.

Persistent stinging, burning sensation, pain and/or numbness in the palm of the hand due to a trapped nerve at the wrist (carpal tunnel syndrome).

Rapid involuntary movements of the eyes (nystagmus), swelling of the optic nerve in the eye (papilloedema), double vision (diplopia), headache, somnolence and vertigo.

Increased heart rate (tachycardia) and high blood pressure (hypertension). Vomiting, stomach pain, wind (flatulence) and feeling of sickness (nausea).

Sensitive and dry skin (exfoliative dermatitis), changes in thickness of the skin, excessive growth of hair on the face and body (hirsutism), hives (urticaria).

Curvature of the spine (scoliosis). If you have scoliosis, you will need to be frequently checked for an increase in the curve.

Bone disorder where the upper leg (femur) moves apart from the hip (slipped capital femoral epiphysis). This happens generally in patients who grow rapidly. Patients with endocrinological disorders are more prone to develop a slipped capital femoral epiphysis.

Decrease in muscle size (muscle atrophy), joint pain (arthralgia) and bone pain.

Difficulty to hold-in urine (urinary incontinence), high frequency (pollakiuria) and volume (polyuria) of urination.

Bleeding from the womb (uterine haemorrhage), genital discharge and breast enlargement (gynaecomastia).

Localised loss/gain of fat from the skin (lipodystrophy, injection site atrophy/hypertrophy)
Enlarged adenoids with similar symptoms as enlarged tonsils (see rare).

Rare (may affect up to 1 in 1,000 people)

Increase in blood sugar levels (hyperglycaemia, diabetes mellitus). Diabetes mellitus can lead to increased urination, thirst and hunger. If you experience any of these symptoms, you should inform your doctor.

Enlarged tonsils leading to snoring, difficulty breathing or swallowing, brief interruption of breathing during sleep (sleep apnoea), or fluid in the ear, as well as infections of the ear. If this appears to be particularly troublesome, you should discuss it with your doctor.

Abnormal sensations of tingling, pricking or numbness (paraesthesia), abnormal bone development, disease affecting progress of bone growth (osteochondrosis) and muscle weakness.

Other rare side effects seen with NutropinAq treatment include itching over the whole body, rash, blurred vision, increased weight, dizziness, diarrhoea, swelling of the face, fatigue, pain, fever, depression and difficulty to sleep (insomnia).

Indication specific side effects seen during clinical trials

In children with growth hormone deficiency brain (central nervous system) tumours were commonly reported. From the 236 patients enrolled into the clinical studies 3 patients had a central nervous system tumour. Of the 3 patients with a central nervous system tumour, 2 patients experienced a recurrent medulloblastoma and 1 patient experienced a histiocytoma. See also section “warning and precautions”.

Girls with Turner syndrome commonly reported abnormally heavy bleeding at menstruation.

Children with chronic renal insufficiency commonly reported inflammation of the lining of the abdomen (peritonitis), bone necrosis and an increase of creatinine blood levels. They are more likely to develop increased pressure in the brain (intracranial hypertension), with the greatest risk at the beginning of treatment, although children with organic growth hormone deficiency and Turner syndrome also have an increased incidence.

Adults with growth hormone deficiency commonly reported abnormal sensations of tingling, pricking or numbness (paraesthesia), abnormally high levels of blood glucose, excess of lipids (fat) in the blood, sleeplessness, joint disorders, arthrosis (degenerative joint disease), muscle weakness, back pain, breast pain and breast enlargement (gynaecomastia).

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system (see details below). By reporting side effects, you can help provide more information on the safety of this medicine.

United Kingdom (Great Britain)

Yellow Card Scheme

Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

5. How to store NutropinAq

Keep out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the label of the cartridge and the carton after EXP. The expiry date refers to the last day of that month.

Store in a refrigerator (2°C - 8°C). Do not freeze.

Keep the blister in the outer carton.

After first use, the cartridge may be stored for up to 28 days at 2°C - 8°C. Do not remove the cartridge that is being used from the NutropinAq Pen between injections.

Do not use NutropinAq if you notice that the solution is cloudy.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to

throw away medicines you no longer use. These measures will help to protect the environment.

6. Content of the pack and other information

What NutropinAq contains

The active substance of NutropinAq is somatropin*.

*Somatropin is a human growth hormone produced in *Escherichia coli* cells by recombinant DNA technology.

The other ingredients are sodium chloride, liquefied phenol, polysorbate 20, sodium citrate dihydrate, citric acid anhydrous and water for injections.

What NutropinAq looks like and contents of the pack

NutropinAq is a solution for injection (in a cartridge (10 mg/2 ml) - pack size of 1, 3 and 6). The solution for multidose use is clear and colourless.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder: Ipsen Pharma, 65 quai Georges Gorse, 92100 Boulogne-Billancourt, France

Manufacturer: IPSEN PHARMA BIOTECH S.A.S., Parc d'Activités du Plateau de Signes, CD no 402, 83870 Signes, France

For any information about this medicinal product, please contact the local representative of the Marketing Authorisation Holder.

United Kingdom (Great Britain)

Ipsen Limited

Tel: Tel: + 44 (0) 1753 627777

This leaflet was last revised in March 2022.

Is this leaflet hard to see or read? Please phone +44 (0) 1753 627777 and ask for help.

NutropinAq Pen: Instructions for use with NutropinAq

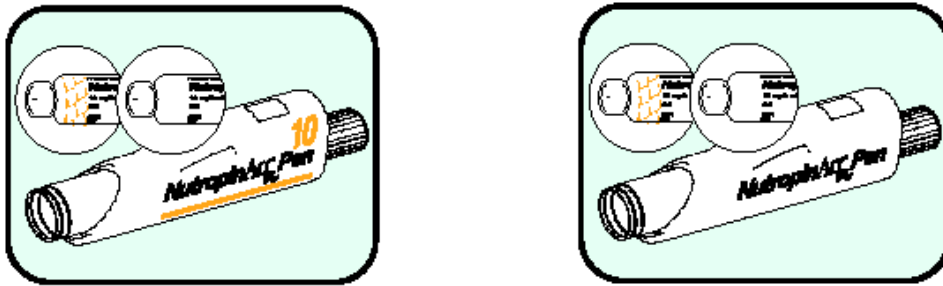
DO NOT INJECT THE MEDICINE UNTIL YOUR DOCTOR OR NURSE HAS THOROUGHLY TRAINED YOU IN THE PROPER TECHNIQUES.

Caution:

Before using your NutropinAq Pen, please read the following instructions carefully. We also suggest you consult your doctor or nurse for a demonstration.

The NutropinAq Pen is designed for use only with cartridges of NutropinAq (for subcutaneous use only).

As shown by the illustrations below, NutropinAq pen and cartridges are available in two designs (with or without additional yellow colour). The working of the pen and the content of the cartridges are the same for both designs. Either of the NutropinAq cartridge designs can be used with either of the NutropinAq Pen designs.



Only use the pen needles recommended by your doctor or nurse.

The dosage scale located beside the window of the cartridge holder should not be used as a dose measurement. It should only be used to estimate the dosage remaining in the cartridge. Always refer to the LCD (Liquid Crystal Display), not audible clicks, for setting an injection of NutropinAq. The clicks are only audible confirmation that the black dose knob has been moved.

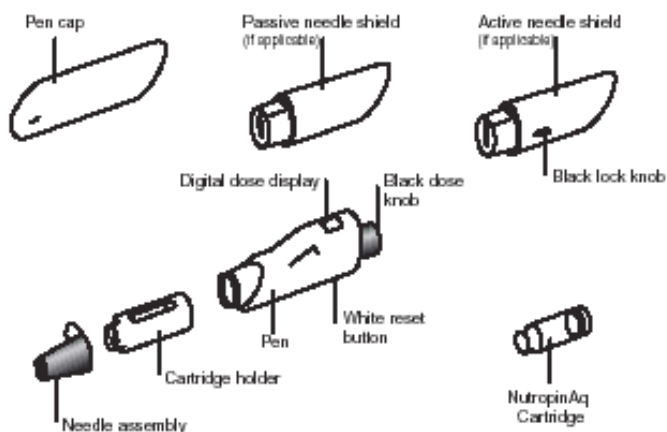
Always store the pen and cartridges in a clean, safe place in the refrigerator at a temperature between 2-8°C and out of children's reach and sight. Protect from intense light. Use a cooler to store your NutropinAq Pen when travelling. The NutropinAq is designed to withstand a nominal (one hour maximum) period of time outside of the refrigerator on a daily basis. Avoid areas of extreme temperature. Check the expiry date of the cartridge before use.

To guard against the spread of infection, follow these safety measures:

- Wash your hands thoroughly with soap and water before using your pen.
- Clean the cartridge rubber seal with an alcohol swab or cotton ball saturated with alcohol.
- Avoid touching the cartridge rubber seal at all times.
- If you accidentally touch the cartridge rubber seal, clean it with an alcohol swab.
- Do not use the same needle for more than one person.
- Use needles only once.

NutropinAq Pen Components:

Shown below are the items necessary for giving an injection. Gather all of these components prior to use.



Your NutropinAq cartridge and Pen will be supplied separately.

Part I: Preparing and Injecting

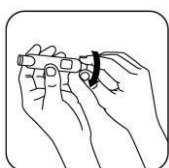
Follow the instructions in this section if you are using the pen for the first time or are replacing an empty cartridge.

Inspect all new cartridges prior to use. Occasionally, after refrigeration, you may notice that small colourless particles are present in the NutropinAq solution. This is not unusual for solutions containing proteins like NutropinAq and does not affect the strength of the product. Allow the cartridge to come to room temperature and gently swirl. Do not shake. If the solution is cloudy or hazy or contains any solid matter, the cartridge should not be used. Return the cartridge to your pharmacist or prescribing doctor.

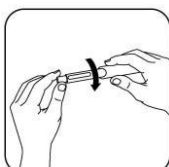


1. Remove the green pen cap and unscrew the cartridge holder from the pen. If necessary, remove the empty cartridge and discard it properly.

2. Press the white reset button.



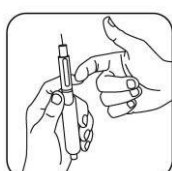
3. Turn the black dose knob counter-clockwise back to its starting position until it no longer turns. (*See illustration.*) Then turn the dose knob clockwise until the first click position is reached (approximately $\frac{1}{4}$ turn). This ensures that the plunger push rod is reset to the starting position. If this is not done when the dosage knob is first pushed in, NutropinAq will be wasted or the cartridge may crack.



4. Insert cartridge into the cartridge holder, then screw the cartridge holder back onto the pen. (*Be careful not to touch the rubber seal.*)

5. Remove the paper seal from a new needle assembly and screw it onto the cartridge holder.

6. Carefully remove both protective caps from the needle by pulling gently. Do not throw the larger cap away as it will be used later for proper needle removal and disposal.



7. Holding the pen with the needle pointing upward, gently tap the cartridge holder

to move any air bubbles to the top. While still holding the pen in the upright position, push in the black dose knob until it clicks into position. You should see a drop of solution appear.

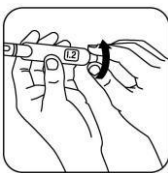
Be patient. If the medicine does not appear within a few seconds, you may need to push the reset button again.



8. If no drop of medicine appears, push the white reset button again. Now turn the black dose knob clockwise (*See illustration*) by one click (0.1mg). If you accidentally turn it too far, go back one click (0.1 mg).

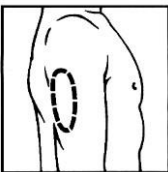
9. While still holding the pen in the upright position, push in the black dose knob again and watch the needle tip for a drop of medicine to appear. Repeat steps 8 and 9 until it appears.

10. Press the white reset button.

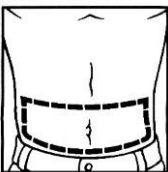


11. Set the required dose by turning the black dose knob. If you cannot dial the full dose, either start a new cartridge (as described in Part I), or inject the partial dose. Then, start a new cartridge (as described in Part I) to administer the remaining portion of your medication. Your doctor or nurse will advise you on the procedure for administering the last dose in the cartridge.

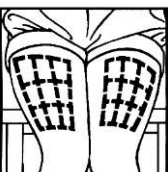
Prepare the injection site by wiping with an antiseptic impregnated swab. Injection sites include the upper arms, abdomen, and upper thighs. Change the injection sites to avoid discomfort. Even if you develop a preference for one site, you still should rotate the injection site.



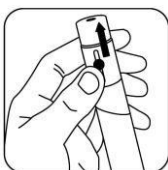
Upper Arm



Abdomen



Thigh



12. If you are using the passive shield (or no shield) proceed to step 13. If you are using the active shield, slide the shield onto the pen and push the 2 black lock knobs on the needle shield toward the tip.

13. Set the tip of the pen on the prepared injection site and press the needle into the skin by pushing the pen downward until the shield is totally depressed. Your doctor or nurse will show you how to do

this. Now you are ready to administer the dose. Press down on the black dose knob. Keeping pushed the dose button for 5 seconds after expelling the dose, then withdraw the pen from the skin. A drop of blood may appear. Put a plaster on the injection site if you wish.

14. Pull the needle shield off the pen (if you have used one) and place the larger needle cap on a flat surface. Slide the needle in to pick it up and push the cap completely down over the needle. Twist off the needle and discard it properly. Your doctor or nurse will tell you how to dispose of the items you have used for the injection. Always store your disposal container out of the reach of children.

15. Attach the pen cap and return it to its case with the black dose knob pressed in. You should always store the pen in a refrigerator. Do not remove cartridge between injections. **DO NOT FREEZE.**

For subsequent injections with the NutropinAq Pen, attach a new needle, push the white reset button and dial your dose.

Part II: Storage and Maintenance

Follow these tips to ensure proper care of your NutropinAq Pen:

- Always keep your NutropinAq Pen and cartridge refrigerated and protected from light when not in use.
- You may remove the pen and cartridge from the refrigerator up to 45 minutes prior to use.
- Do not let your NutropinAq Pen and/or cartridge freeze. Contact your doctor or nurse for a replacement if either the pen or cartridge does not work.
- Avoid excessive temperatures. The solution in the cartridge is stable for up to 28 days after first use when stored at 2 - 8°C.
- If your pen requires cleaning, do not place under water. Use a damp cloth to wipe away dirt. Do not use alcohol.
- When priming a new cartridge, you may need to repeat Part I, steps 8 and 9 up to a total of 6 times (0.6 mg) to remove air bubbles. Small bubbles may remain and will not affect the dose.
- The pen should contain the NutropinAq that is being used. Do not remove cartridge between injections.
- The NutropinAq cartridge may be used for up to 28 days.
- Do not store the NutropinAq Pen with needle attached.
- Avoid the use of the pen adjacent to or stacked with other equipment because it could result in increased electromagnetic emissions or decreased electromagnetic immunity and results in improper performance of the pen.

In addition, Portable Radio Frequency communications equipment should be used no closer than 30 cm (12 inches) to any part of the pen. Otherwise, it could lead to a degradation of the performance of the pen.

Part III: Needles for the NutropinAq Pen

Your doctor or nurse will recommend a needle that is appropriate for you. Always use the needles recommended.

Needles from other countries may not fit on your NutropinAq Pen. If you travel outside the European Union, make sure you take enough needles for the duration of your stay.

Part IV: Commonly Asked Questions

Q: Do I need to change the needle every time I use my NutropinAq Pen?

A: Yes. A new needle should be used for every injection. The needle is only sterile on the first use.

Q: Where should I store my NutropinAq Pen?

A: Your NutropinAq Pen should be stored in the case, inside a refrigerator when a cartridge is inserted. When travelling, place your pen case in a cooler. **DO NOT FREEZE.**

Q: Why do I keep my medication in the refrigerator?

A: To maintain its strength.

Q: Can I store my NutropinAq Pen in the freezer?

A: No. Freezing will damage the pen and medicine.

Q: How long can I keep my NutropinAq Pen and cartridge outside the refrigerator?

A: We recommend no longer than one hour. Your doctor or nurse will advise you regarding pen storage.

Q: What is the maximum dose the NutropinAq Pen can deliver in one injection?

A: The NutropinAq Pen can give a minimum dose of 0.1 mg up to a maximum dose of 4.0 mg (40 clicks). If you attempt to dose more than 4 mg at a time, the medicine will either be forced out of the needle and wasted or excess pressure will be placed upon the cartridge and it may crack.

Q: Is it possible to turn the black dose knob back if I click too many times?

A: Yes. You can turn the black dose knob backwards until the correct number appears in the LCD.

Q: What should I do if there is not enough solution left in the cartridge for my next dose?

A: Your doctor or nurse will advise you what to do for the last dose in the cartridge.

Q: Why do I have to rewind the black dose knob on my NutropinAq Pen every time I replace the cartridge?

A: This ensures that the plunger push rod completely resets itself back to the starting position. If this is not done, liquid will come out of the needle when a new cartridge is placed into the pen.

Q: Can I use my NutropinAq Pen without the shields?

A: Yes. Your NutropinAq Pen works without shields. The shields are optional to help you administer your injection.

Q: What should I do if I drop my NutropinAq Pen?

A: If you drop the NutropinAq Pen, check to see if the cartridge is damaged. You should also check the pen to see that the black dose knob is moving up and down properly and that the LCD counter is working. If your cartridge or pen is damaged, ask your doctor or nurse for a replacement.

Q: How long can I use my NutropinAq Pen?

A: The NutropinAq Pen is designed to last 24 months from the time you first use your pen.

Q: What does a blinking “bt” mean in the LCD?

A: The battery in your NutropinAq Pen is losing its charge. Please contact your doctor or nurse for a replacement pen. Batteries typically last 24 months and have a 4-week life from the time the „bt“ first starts blinking.

Q: What does a blinking “[≡]” mean in the LCD?

A: First warning of End of life: upon start up the flashing “end of life” warning signal indicates the coming termination of the pen’s lifetime. The “end of life” warning signal is displayed instead of the last dose. The pen will work for approximately one more month before the display will be permanently shut off.

Q: How do I replace my NutropinAq Pen?

A: Contact your doctor or nurse if you need a replacement part or if you need to replace your entire

pen.

For more information, please contact the local representative. Your local representative and the manufacturer for the NutropinAq Pen device are the same as for the medicinal product detailed overleaf. Please see section 6 overleaf for contact details.

Manufacturer: IPSEN PHARMA BIOTECH S.A.S., Parc d'Activités du Plateau de Signes, CD no 402, 83870 Signes, France

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