**B. PACKAGE LEAFLET**

**Package leaflet: Information for the user**

**Eladynos 80 micrograms/dose solution for injection in pre-filled pen**
abaloparatide

▼This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

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


## 1. What Eladynos is and what it is used for

Eladynos contains the active substance abaloparatide. It is used to treat osteoporosis in women after menopause.

Osteoporosis is especially common in women after menopause. The disease causes bones to become thin and fragile. If you have osteoporosis, you are more likely to break bones, especially in your spine, hips and wrists.

This medicine is used to make bone stronger and less likely to break.

## 2. What you need to know before you use Eladynos

**Do not use Eladynos if you**
- are allergic to abaloparatide or any of the other ingredients of this medicine (listed in section 6)
- are pregnant or breast-feeding
- are still able to get pregnant
- have high blood calcium levels
- have severely reduced kidney function
- have unexplained high blood levels of the enzyme alkaline phosphatase
- have had radiation therapy involving your bones

- have ever been diagnosed with bone cancer or other cancers that have spread to your bones

**Warnings and precautions**
Talk to your doctor or pharmacist before or while using Eladynos if you:
- get dizzy when standing up, which may be because of a fall in blood pressure. Some patients may get dizzy or have a fast heartbeat within 4 hours after Eladynos has been injected. The first injection/injections should be performed under the guidance of a health care professional who may observe you during the first hour after injection. Always inject Eladynos in a location where you can sit or lie down right away if you get dizzy.
- have heart disease or high blood pressure. Your doctor may want to monitor you more closely.
- have continuing nausea, vomiting, constipation, low energy or muscle weakness. These may be signs of too much calcium in your blood.
- have high level of calcium in the urine, have or have had kidney stones. Eladynos may worsen your condition.

Before you begin treatment with Eladynos your blood pressure and condition of your heart will be examined.

The recommended treatment time of 18 months should not be exceeded.

**Children and adolescents**
Eladynos should not be used in children and adolescents under 18 years.

**Other medicines and Eladynos**
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Especially tell your doctor or pharmacist if you take:
- digoxin or digitalis: medicines used to treat heart weakness, as the levels of calcium in your blood may increase with use of abaloparatide
- medicines to control high blood pressure, as they may worsen symptoms of low blood pressure, including dizziness

**Pregnancy and breast-feeding**
Do not use Eladynos if you are pregnant, may become pregnant or are breast-feeding.

**Driving and using machines**
Some patients may feel dizzy after injecting this medicine. If you feel dizzy do not drive or use machines until you feel better.

**Eladynos contains sodium**
This medicine contains less than 1 mmol sodium (23 milligrams) per dose, that is to say essentially "sodium-free".

## 3. How to use Eladynos

Always use this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is **one injection (**80 micrograms) **once daily** under the skin in the lower abdomen (belly). See grey shaded area of the first figure in Step 5 in the "Instructions for use" at the end of the package leaflet.

Preferably, inject Elyadynos at the same time each day to help you remember to use your medicine.

Do not inject Eladynos in the same place on your belly on consecutive days. Change where you inject this medicine each day to reduce the risk of injection site reactions. Only inject into clear skin. Do not inject into areas where the skin is tender, bruised, red, scaly or hard. Avoid areas with scars or stretch marks.

Please carefully follow the **"Instructions for use"** at the end of the package leaflet**.**

Your doctor may advise you to take supplementary calcium and vitamin D. Your doctor will tell you how much you should take each day.

**Duration of use**
Inject Eladynos each day for as long as prescribed by your doctor. The maximum total duration of treatment with Eladynos should not exceed 18 months.

**If you use more Eladynos than you should**
If you accidentally use more Eladynos than you should, contact your doctor or pharmacist. The effects of overdose that might be expected include nausea, vomiting, dizziness (especially when getting up quickly), faster heartbeat and headache.

**If you forget to use Eladynos**
If you miss a dose, use it as soon as possible within 12 hours of the normally scheduled time. Then inject your next dose the usual time next day.

If it is more than 12 hours since you should have used Eladynos, skip the missed dose. Then inject your next dose as usual on your next scheduled day.

Do not use a double dose to make up for a forgotten dose. Do not use more than one injection in the same day.

**If you stop using Eladynos**
Discuss this with your doctor before stopping treatment. Your doctor will advise you and decide how long you should be treated with Eladynos.

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.

**Stop taking Eladynos and immediately contact your doctor or go to the emergency centre if you experience the following symptoms (severe allergic reaction):**
swelling of the face or tongue; wheezing and trouble breathing; hives, itching and flushed skin; severe vomiting or diarrhea; lightheadedness or loss of consciousness (frequency not known). These symptoms may be serious and potentially life-threatening.

Other side effects can occur with the following frequencies:
**Very common** (may affect more than 1 in 10 people)
- increase in calcium level seen in urine tests
- dizziness – see section 2 "Warnings and Precautions"

**Common** (may affect up to 1 in 10 people)
- increase in calcium level seen in blood tests
- increase in uric acid level seen in blood tests
- headache
- palpitations, increased heartbeat
- increase in blood pressure
- abdominal pain
- constipation, diarrhoea
- feeling sick (nausea), vomiting
- weakness, tiredness, feeling unwell
- injection site reactions such as bruising, rash and pain
- pain in bones, joints, hands, feet or back
- muscle spasms (back and legs)
- difficulty sleeping
- kidney stones
- itching, rash

**Uncommon**: may affect up to 1 in 100 people
- allergic reactions
- feeling bloated
- pain
- feeling dizzy or lightheaded on standing or sitting up because of a drop in blood pressure

**Reporting of side effects**
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow card Scheme, website: http://www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

## 5. How to store Eladynos

Keep this medicine out of the sight and reach of children.

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

Before first use, store in a refrigerator (2 °C–8 °C). Do not freeze. Avoid placing the pens close to the ice compartment of the refrigerator to prevent freezing. Do not use Eladynos if it is, or has been, frozen.

After first use, store below 25 °C and discard after 30 days.

Eladynos may only be stored at room temperature (below 25 °C) for 30 days.

Note the date of Day 1 in the space provided on the carton. Day 1 is the date of first use or the date the pen was removed from the refrigerator. This is to ensure you do not use the pen for more than 30 consecutive days or store the pen for longer than 30 days. After 30 days, throw away your pen in accordance with local requirements, even if it still contains unused medicine.

- Dispose of your old pen prior to opening a new Eladynos pen, to avoid potential confusion.
- Do not store the pen with the needle attached.
- Do not use this medicine if the solution is cloudy, coloured or contains particles.

Do not throw away any medicines or needles via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

## 6. Contents of the pack and other information

**What Eladynos contains**

- The active substance is abaloparatide.
  Each dose of 40 microliters contains 80 micrograms of abaloparatide.
  Each pre-filled pen contains 3 mg of abaloparatide in 1.5 mL of solution (corresponding to 2 milligrams per mL).
- The other ingredients are:
  - phenol
  - water for injections
  - sodium acetate trihydrate (See section 2 “Eladynos contains Sodium”) and acetic acid (both for pH adjustment)

**What Eladynos looks like and contents of the pack**

Eladynos is a colourless and clear solution for injection (injection). It is supplied in a carton containing one or three pre-filled multi-dose pens with 30 doses.

Not all pack sizes may be available.

**Marketing Authorisation Holder**

Theramex Ireland Limited
3rd Floor, Kilmore House,
Park Lane, Spencer Dock,
Dublin 1
D01 YE64
Ireland

**Manufacturer**

Theramex Poland Sp. z o. o.
Amsterdam Building,
ul. Poleczki 35,
02-822 Warszawa
Poland

**This leaflet was last revised in March 2024.**

Detailed information on this medicine is available on the European Medicines Agency web site: http://www.ema.europa.eu

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**Instructions for Use**

Do not inject Eladynos until you or your caregiver receive training from a doctor, nurse or pharmacist on how to use the Eladynos pen.

DO NOT start the administration procedure until you have read the package leaflet and this instructions for use contained in your Eladynos carton thoroughly. Follow the instructions carefully whenever using the Eladynos pen.

Contact your doctor, nurse or pharmacist if you have any questions about how to use the Eladynos pen.

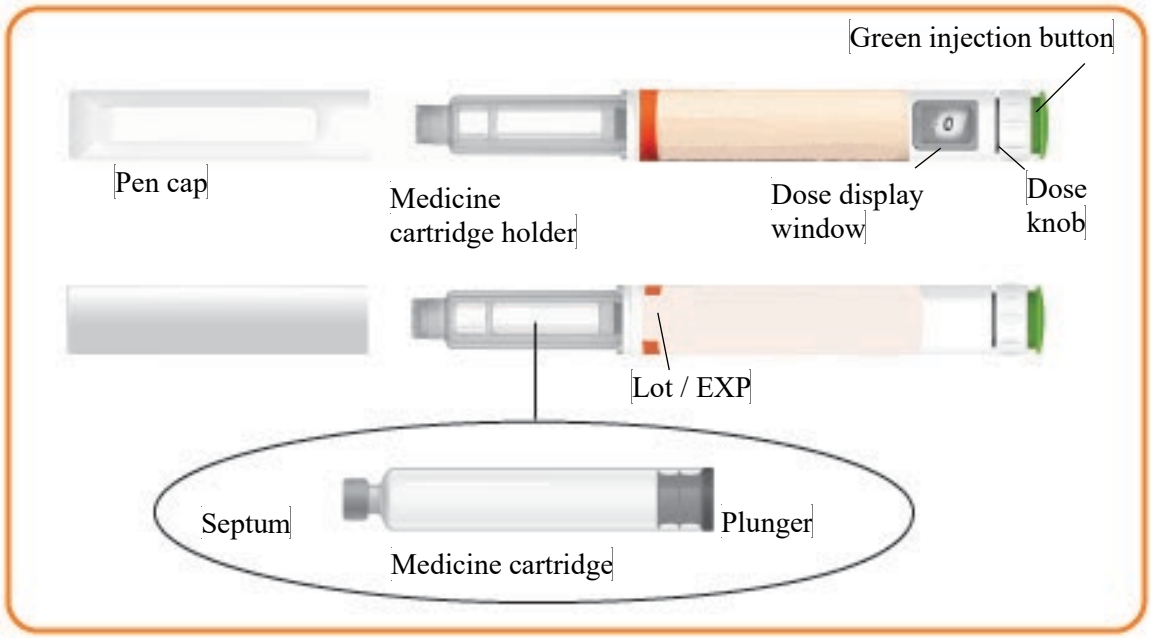
**Important information before using your Eladynos pen**

- Do not share needles with other people. You may transmit a serious infection. Never share your Eladynos pen, even if the needle has been changed.
- Use a new needle for each injection.

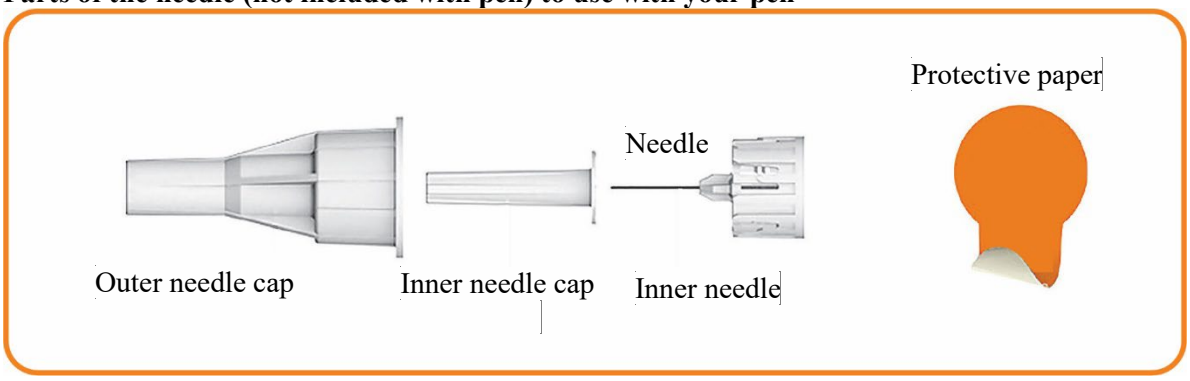
**Supplies you will need for each injection using your Eladynos pen**

- 1 needle
  Needles are not included with your Eladynos pen. The correct needles to use with your Eladynos pen are 8 mm, 31-gauge needles.
- 1 alcohol swab
- 1 cotton ball or gauze pad
- 1 sharps disposal container for needles and Eladynos pens. See Section 5 of the Package leaflet for disposal information.

**Parts of the Eladynos Pen**




**Parts of the needle (not included with pen) to use with your pen**



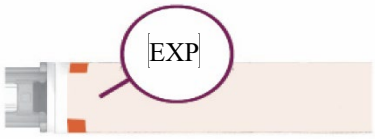

**Injecting Eladynos**

**Step 1 Check the Eladynos pen**

Wash your hands.

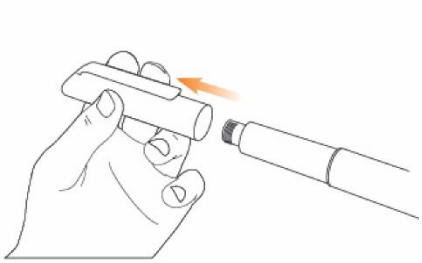
**Check the pen label** to make sure it is the correct medicine.

**Check the expiry date (EXP)** on the pen to make sure it has not passed.




Note the date of Day 1 to ensure you do not use the pen for more than 30 consecutive days.

Pull off the pen cap from your pen.



**Check that the pen, including the medicine cartridge is not damaged.**

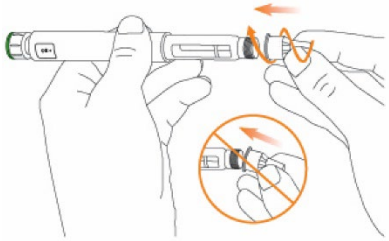
The liquid should be clear, colourless and free of particles; if not, do not use.

You may see small air bubbles in the liquid. This is normal.

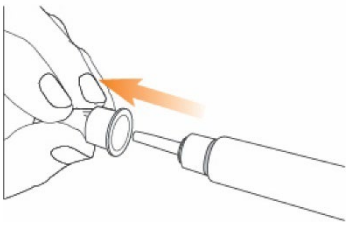
**Step 2 Attach needle to your Eladynos pen**

Remove the protective paper from a new needle.

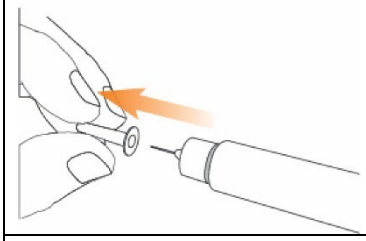
**Push the capped needle straight** onto the pen and **twist until it is secure**. Make sure the needle is straight so that it doesn't bend when inserting. The pen will not work if the needle is not properly attached. Do not over-tighten as this may make the needle difficult to remove.
If the needle becomes bent, see below under "Troubleshooting".



Pull off the **outer needle cap** from the needle and keep it to use after your injection.



Carefully pull off the **inner needle cap** and dispose of it.



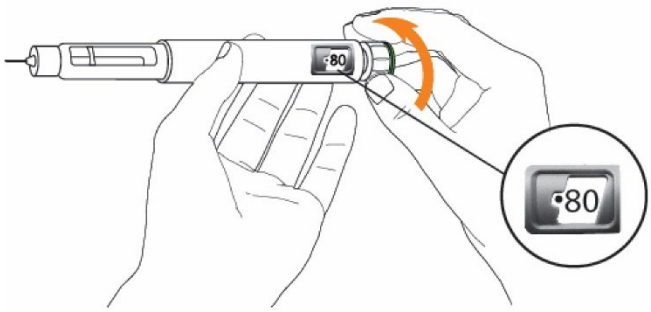
**Step 3 Day 1 Only – Testing an Eladynos pen prior to first injection**

Your pen has medicine for 30 days, plus a small amount to test each pen once to confirm it is working properly.
Attention: If you test the pen before every injection your pen will run out of medicine early. Therefore, **perform Step 3 only on Day 1**, prior to the first injection with each pen.

For Day 2 through Day 30 do not test the pen again; go directly to Step 4 to set the dose for your injection.

Holding the pen as illustrated, turn the dose knob on your pen away from you until it stops.

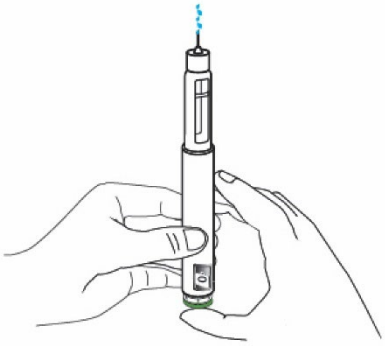
**You will see "•80" lined up** in the dose display window.




Hold the pen with the needle pointing up.

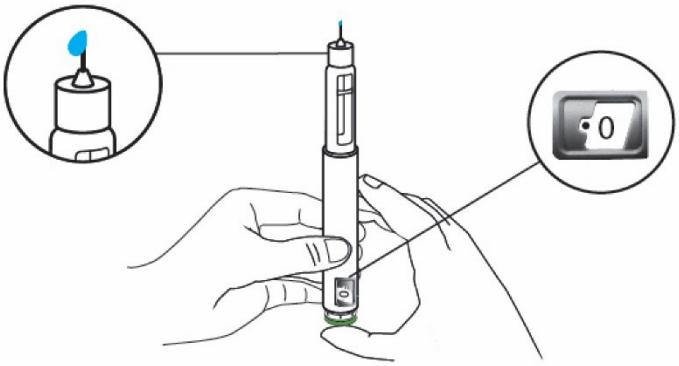
Press the green injection button until it will not go any further.

You should see liquid, as a drop or stream, come from the needle tip.



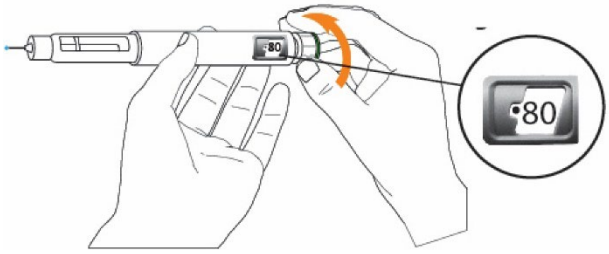
You should see **"●0" lined up** in the dose display window.

Note: If liquid does not come from the needle tip, see under "Troubleshooting"




**Step 4 Set the dose on your Eladynos pen**

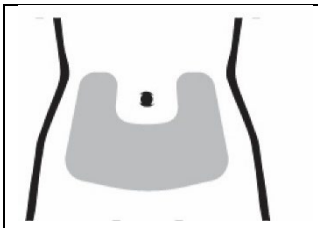
Turn the white knob on your pen away from you until the knob stops and **"●80" is lined up in the display window**. Your pen is now ready for injection.




Note: If you cannot set the pen to "●80", see below under "Troubleshooting".

**Step 5 Choose and clean your injection site**

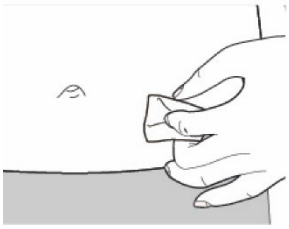
Injections should be given in the lower abdomen as shown by the grey shaded area. Avoid the 5 cm area around your belly button.



Select a different injection site on your abdomen each day. Only inject into clear skin. Do not inject into areas where the skin is tender, bruised, red, scaly or hard. Avoid areas with scars or stretch marks.

Wipe the injection site with an alcohol swab and allow it to dry.

Do not touch, fan or blow on the injection site after you have cleaned it.

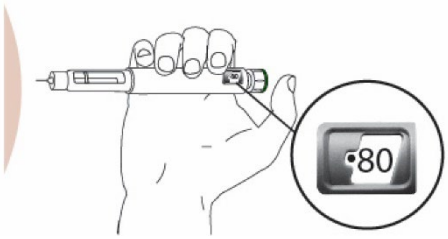


Note: Your doctor, nurse or pharmacist may recommend that you pinch up the skin at the injection site.

Once the needle enters the skin, the pinch can be released.

**Step 6 Giving your Eladynos pen injection**

Insert the needle straight into your skin.

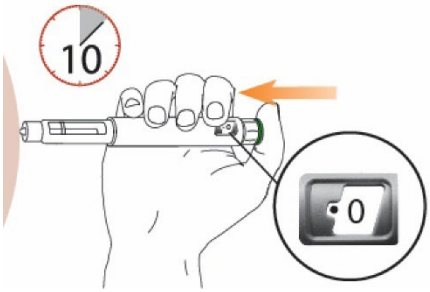



**Press and HOLD the green button until ALL** events below are complete

- "●0" is displayed
- hold for 10 seconds to give full dose
- withdraw pen from skin

and THEN release the button.

Do not press the green button without a needle attached.



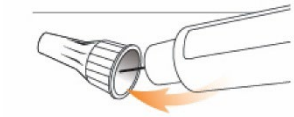

Note: Do not move the pen after inserting. If the green injection button cannot be pressed down or stops before the "●0", see below under "Troubleshooting".

Slowly remove the pen from the injection site by pulling the pen needle straight out.

You may have slight bleeding, this is normal. Do not rub the injection site. If slight bleeding occurs, press a cotton ball or gauze pad to the injection site as required. You may also cover the area with a small adhesive bandage.

**Step 7 Remove the pen needle**

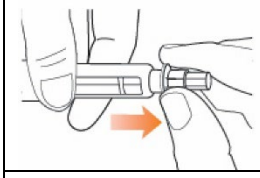
Caution: To prevent needle stick injury, follow this step carefully.
Carefully place the **outer needle cap back on the needle**. Then carefully press on the outer needle cap until it snaps into place and is secure.



**Unscrew the capped needle**. To unscrew the capped needle, squeeze the cap at the base against the needle, then turn it 8 or more times before gently pulling until the capped needle comes off.

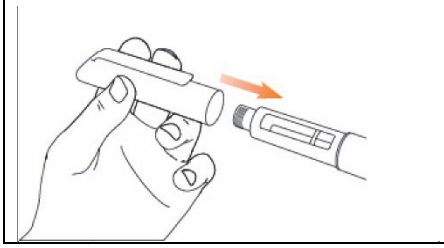
Note: Do not push down on the outer needle cap while unscrewing the needle.

Note: You should see a gap widening between the outer needle cap and the pen as you unscrew the needle.



**Step 8 After your injection**

Firmly **replace the pen cap** onto the Eladynos pen.
Keep the cap on your pen between injections.



**Troubleshooting**

**What should I do if the needle is bent?**

- Carefully remove the bent needle and follow Step 2 to attach a new needle to the pen. The pen needle has a visible portion which goes into your skin and there is a hidden inner needle portion that goes into the pen's septum.
- Review the parts of the pen needle, paying close attention to the inner needle portion. The visible portion of the needle may look straight, but the inner needle can become bent when attaching the needle to the pen.
- Be sure to keep the entire pen needle straight when attaching it to the pen to avoid bending the inner needle.

**What should I do if liquid does not come out of the needle tip when testing the pen on Day 1?**

- If you do not see liquid come out of the needle, the pen setup is not complete. The needle may be blocked, bent or improperly attached.
- Follow Step 2 to attach a new needle to the pen and repeat Step 3 "Testing an Eladynos pen prior to first injection".
- If you still do not see a drop of liquid contact your pharmacist, nurse or doctor.

**What should I do if I cannot turn the white dose knob to set the Eladynos pen to "●80"?**

- There is not enough medicine in the pen to give you a full dose. You will need to get a new pen.

**What should I do if the green injection button is difficult to press?**

- If the green injection button cannot be pressed down or stops before the "●0" in the dose display window, the new pen test is not complete. The needle may be blocked or improperly attached.
- Follow Step 2 to attach a new needle to the pen.
- If the green injection button still cannot be pressed down or stops before the "●0" is in the display window, contact your pharmacist, nurse or doctor.