

Eladynos®

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

- ▼ This medicine is new or being used differently. Please report side effects. See the [full CMI](#) for further details.

1. Why am I using Eladynos?

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

For more information, see Section [1. Why am I using Eladynos?](#) in the full CMI.

2. What should I know before I use Eladynos?

Do not use if you have ever had an allergic reaction to Eladynos or any of the ingredients listed at the end of the CMI or if you have or have had any of the conditions listed in Section [2. What should I know before I use Eladynos?](#).

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use Eladynos?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Eladynos and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use Eladynos?

- One injection is given once daily under the skin in the lower abdomen (belly).
- The injection site should be changed each day to reduce the risk of reactions.

More instructions can be found in Section [4. How do I use Eladynos?](#) in the full CMI.

5. What should I know while using Eladynos?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist, or pharmacist
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	<p>you visit that you are using Eladynos.</p> <ul style="list-style-type: none"> • Always use a new needle for each injection
Things you should not do	<ul style="list-style-type: none"> • Do not share needles with other people. Never share your Eladynos pen, even if the needle has been changed. • Do not use a single Eladynos pen for more than 30 days. • Do not take Eladynos for more than 18 months. • Do not use Eladynos if the solution is cloudy, coloured or contains particles.
Driving or using machines	<ul style="list-style-type: none"> • Eladynos may cause dizziness in some people. If you feel dizzy do not drive or use machines until you feel better
Looking after your medicine	<ul style="list-style-type: none"> • Before first use, store Eladynos in a refrigerator (2°C - 8°C). Do not freeze. If Eladynos is or has been frozen do not use it.

- After first use, store below 25°C. Store away from moisture, heat, or sunlight.
- Discard 30 days after first use, even if it still contains unused medicine.

For more information, see Section [5. What should I know while using Eladynos?](#) in the full CMI.

6. Are there any side effects?

Stop taking Eladynos and immediately contact your doctor or go to your local Emergency Department if you experience the following symptoms kidney stones, heart palpitations or increased heart beat or signs of a severe allergic reaction: swelling of the face or tongue, wheezing and trouble breathing, hives, itching and flushed skin, severe vomiting, or diarrhea; light-headedness or loss of consciousness. Other side effects can occur with an increase in calcium level seen in urine tests and dizziness being very common.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

- ▼ 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. You can report side effects to your doctor, or directly at www.tga.gov.au/reporting-problems.

Eladynos®

Active ingredient(s): *abaloparatide*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Eladynos. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Eladynos.**

Where to find information in this leaflet:

- [1. Why am I using Eladynos?](#)
- [2. What should I know before I use Eladynos?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use Eladynos?](#)
- [5. What should I know while using Eladynos?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using Eladynos?

Eladynos contains the active ingredient abaloparatide. Eladynos belongs to a class of drugs known as parathyroid hormones and analogues.

Eladynos 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.

2. What should I know before I use Eladynos?

Warnings

Do not use Eladynos if:

- you are allergic to abaloparatide, or any of the ingredients listed at the end of this leaflet.
- you are pregnant or suspect you may be.
- you are breast-feeding.
- you have high blood calcium levels.
- you have severely reduced kidney function.
- you have unexplained high blood levels of the enzyme alkaline phosphatase.
- you have had radiation therapy involving your bones.

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

Check with your doctor if you:

- get dizzy when standing up.
- have any other medical conditions such as heart disease or high blood pressure.
- have or have ever had kidney stones or have high levels of calcium in your urine.
- take any medicines for any other condition.

Before you start treatment with Eladynos your blood pressure and the condition of your heart will be examined by your doctor.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Eladynos is for postmenopausal women only.

If you become pregnant or think you may be pregnant, stop taking Eladynos immediately and contact your doctor.

Do not use Eladynos during pregnancy or breastfeeding.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins, or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with Eladynos and affect how it works.

Specifically tell your doctor 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 Eladynos.
- Medicines to control high blood pressure, as they may worsen symptoms of low blood pressure, including dizziness.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Eladynos.

Your doctor may advise you to take supplementary calcium and vitamin D while taking Eladynos. Your doctor will tell you how much you should take.

4. How do I use Eladynos?

How much to take

- One injection once daily under the skin in the lower abdomen (belly).

- Follow the instructions provided and use Eladynos until your doctor tells you to stop. You should not be treated with Eladynos for more than 18 months.

When to take Eladynos

- Eladynos should be injected at the same time each day to help you remember.

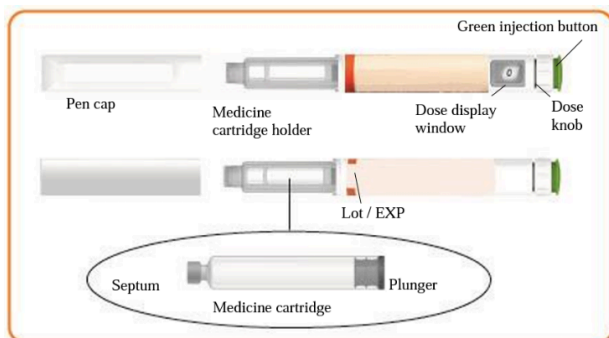
How to inject Eladynos

- Do not inject Eladynos until you or your caregiver receive training from a doctor, nurse, or pharmacist on how to use the Eladynos pen.
- Needles are not included with your Eladynos pen. The correct needles to use with your Eladynos pen are 8 mm, 31-gauge needles.

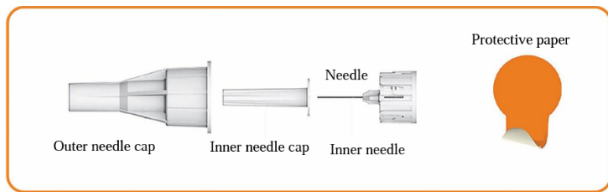
Supplies needed for each injection:

- 1 needle
- 1 alcohol swab
- 1 cotton ball or gauze pad
- 1 sharps disposal container for needles and Eladynos pen.

Parts of the Eladynos Pen



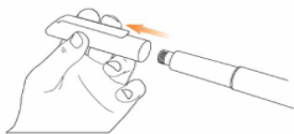
Parts of the needle (not included with the pen) to use with your Eladynos pen



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 and 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

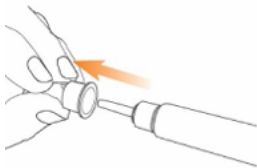
Remove the protective paper from a new needle.



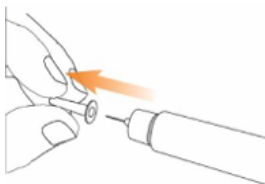
Push the capped needle straight onto the pen and twist until it is secure. Make sure the needle is straight so that it doesn't bend when inserting. The pen will not work if the needle is not properly attached. Do not over-tighten as this may make the needle difficult to remove. If the needle becomes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

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. From

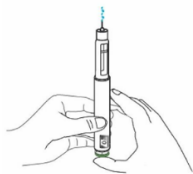
Day 2 through to Day 30 do not test the pen again; go directly to Step 4 to set the dose for your injection.

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.

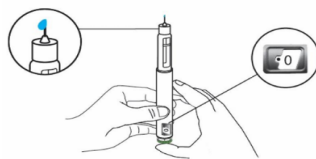


Hold the pen with the needle pointing up. Press the green injection button until it will not go any further. You should see liquid as a drop or stream, come from the needle tip.



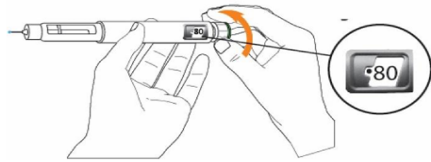
You should see "**•0**" lined up in the dose display window.

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 dose 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 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.

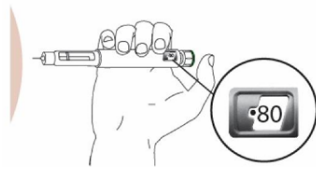
Wipe the injection site with an alcohol swab and allow it to dry. Do not touch, fan, or blow on the injection site after you have cleaned it.



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.

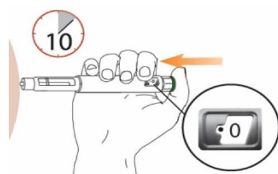


Press and HOLD the green button until ALL the below events are complete:

- "•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".

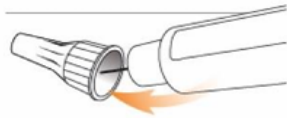
Slowly remove the pen from the injection site by pulling the pen needle straight out.

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.



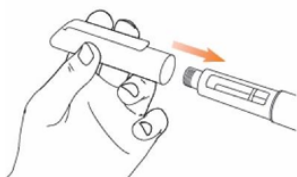
Note: You should see a gap widening between the outer needle cap and the pen as you unscrew the needle.



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 and 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.

If you forget to use Eladynos

Eladynos should be used regularly at the same time each day. If you miss injecting your dose at the usual time, inject it as soon as possible within 12 hours of the normally scheduled time. Then inject your next dose the usual time the next day.

If it is more than 12 hours since you should have used Eladynos, skip the missed dose and inject your next dose when you are meant to.

Do not take a double dose to make up for the dose you missed.

If you use too much Eladynos

If you think that you have used too much Eladynos, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre

(by calling 13 11 26), or

- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

If you take too much Eladynos you may experience nausea, vomiting, dizziness (especially when getting up quickly), faster heartbeat and headache.

5. What should I know while using Eladynos?

Things you should do

- Use a new needle for each injection.
- Your doctor may advise you to take supplementary calcium and vitamin D while taking Eladynos. Your doctor will tell you how much you should take.

Call your doctor straight away if you:

- Start getting dizzy when standing up which may be because of a fall in blood pressure. Some people get dizzy or have a fast heartbeat within 4 hours of Eladynos being 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 continuing nausea, vomiting, constipation, low energy levels or muscle weakness. These may be signs of too much calcium in your blood.

Remind any doctor, dentist, or pharmacist you visit that you are using Eladynos.

Things you should not do

- Do not share needle with other people. You may transmit a serious infection. Never share your Eladynos pen, even if the needle has been changed.
- Do not use a single Eladynos pen for more than 30 days. You should discard your pen 30 days after the first use even if it contains unused medicine.
- Do not take Eladynos for more than 18 months.
- Do not use Eladynos if the solution is cloudy, coloured or contains particles.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Eladynos affects you.

Eladynos may cause dizziness in some people. If you feel dizzy do not drive or use machines until you feel better.

Looking after your medicine

Follow the instructions in the carton on how to take care of your medicine properly.

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

After first use, store below 25°C and discard after 30 days. Store away from moisture, heat, or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

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.

When to discard your medicine

After 30 days, throw away your pen in accordance with local requirements, even if it still contains unused medicine.

- Dispose of the pen prior to opening a new Eladynos pen to avoid any potential for confusion.

Do not use this medicine if the solution is cloudy, coloured or contains particles.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal. Do not dispose of needles via wastewater or household waste.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none">• Dizziness• Increased calcium in urine• Increased calcium in blood• Increased uric acid in blood• Headache• Increase in blood pressure	Speak to your doctor if you have any of these less serious side effects and they worry you.

Less serious side effects	What to do
<ul style="list-style-type: none"> ● Abdominal pain ● Constipation, diarrhea ● Feeling sick (nausea), vomiting ● Weakness, tiredness, feeling unwell ● Injection site reactions such as bruising, rash and pain ● Pain in bones, joints, hand, feet or back ● Muscle spasms (back and legs) ● Difficulty sleeping ● Itching, rash 	

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> ● Kidney stones ● Palpitations, increased heartbeat <p>Symptoms of severe allergic reaction:</p> <ul style="list-style-type: none"> ● Swelling of the face or tongue 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

Serious side effects	What to do
<ul style="list-style-type: none"> ● Wheezing and trouble breathing ● Hives, itching and flushed skin ● Severe vomiting or diarrhea ● Light-headedness or loss of consciousness 	

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What Eladynos contains

Active ingredient (main ingredient)	Abaloparatide
Other ingredients (inactive ingredients)	Phenol Water for injections Sodium acetate trihydrate Acetic acid
Potential allergens	None

Do not take this medicine if you are allergic to any of these ingredients.

What Eladynos looks like

Eladynos is a colourless and clear solution for injection. It is supplied as a pre-filled multi-dose pen. Each pen contains 30 doses. Eladynos can be supplied in a single (1) pack or a triple (3) pack (Aust R 430937).

Not all pack sizes may be marketed.

Who distributes Eladynos

Theramex Australia Pty Ltd

Level 22, 60 Margaret Street
Sydney NSW 2000

1800 THERAMEX or 1800 843 726

Email: medinfo.au@theramex.com

This leaflet was prepared in November 2024.