

PALYNZIQ[®]

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.

WARNING: Important safety information is provided in a boxed warning in the [full CMI](#). Read before using this medicine.

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

1. Why am I using PALYNZIQ?

PALYNZIQ contains the active ingredient pegvaliase. PALYNZIQ is used to reduce the levels of phenylalanine in the blood of patients who have phenylketonuria (PKU) whose blood phenylalanine levels cannot be adequately controlled by other means such as by diet. For more information, see Section [1. Why am I using PALYNZIQ?](#) in the full CMI.

2. What should I know before I use PALYNZIQ?

Do not use if you have ever had an allergic reaction to PALYNZIQ, any of the ingredients listed at the end of the CMI or another medicine that contains polyethylene glycol (PEG). **Talk to your doctor if you have any other medical conditions, take any other medicines, are pregnant or plan to become pregnant or are breastfeeding, or cannot use or do not want to use an adrenaline injection device to treat a severe allergic reaction to PALYNZIQ.** For more information, see Section [2. What should I know before I use PALYNZIQ?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with PALYNZIQ 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 PALYNZIQ?

- PALYNZIQ is given as an injection under the skin.
- Always use this medicine exactly as your doctor has told you. You will start PALYNZIQ at the lowest dose. Your doctor will then slowly increase your dose and/or how often you inject PALYNZIQ.

For at least the first 6 months of PALYNZIQ treatment, you must have someone with you when you self-inject PALYNZIQ, and for at least 1 hour after your injection. More instructions can be found in Section [4. How do I use PALYNZIQ?](#) in the full CMI and Section [8. Instructions for use.](#)

5. What should I know while using PALYNZIQ?

PALYNZIQ can cause severe allergic reactions that may be life-threatening and these can happen any time after a PALYNZIQ injection.

Things you should do	<ul style="list-style-type: none">• If you have a severe allergic reaction, use an adrenaline injection device and seek urgent medical assistance from your doctor or Emergency Department at your nearest hospital. Do not continue using PALYNZIQ.• Remind any doctor or dentist you visit that you are using PALYNZIQ.
Things you should not do	<ul style="list-style-type: none">• Do not stop using this medicine unless you have a severe allergic reaction or are advised to by your doctor.
Driving or using machines	<ul style="list-style-type: none">• Be careful before you drive or use any machines or tools until you know how PALYNZIQ affects you.
Looking after your medicine	<ul style="list-style-type: none">• Follow the instructions in the carton on how to take care of your medicine properly. Store in a refrigerator (2°C – 8°C). Do not freeze.

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

6. ARE THERE ANY SIDE EFFECTS?

There are several side effects associated with this medicine. It is important to be aware of them so that you can identify any symptoms if they occur. The most common and serious side effects are sudden severe allergic reactions. 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.

- Severe allergic reactions have been reported during treatment with PALYNZIQ and can happen any time during treatment.
- You will receive your first injection of PALYNZIQ in a healthcare facility where you will be monitored for at least 1 hour after your injection for an allergic reaction.
- Your healthcare provider may recommend that you have a trained adult observer with you when you self-inject PALYNZIQ to watch for signs and symptoms of a severe allergic reaction and, if needed, give you an injection of adrenaline and call for emergency medical help.
- Your healthcare provider will prescribe an adrenaline auto-injector for you to carry and use in case of a severe allergic reaction.

PALYNZIQ[®]

Active ingredient: *pegvaliase*

Consumer Medicine Information (CMI)

This leaflet provides important information about using PALYNZIQ. **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 PALYNZIQ.**

Where to find information in this leaflet:

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

1. Why am I using PALYNZIQ?

PALYNZIQ contains the active ingredient pegvaliase.

It is an enzyme that can break down a substance called phenylalanine in the body.

PALYNZIQ is a treatment for patients aged 16 years and older with phenylketonuria (PKU), a rare inherited disorder that causes phenylalanine from proteins in food to build up in the body. People who have PKU have high levels of phenylalanine and this can lead to serious health problems. PALYNZIQ reduces the levels of phenylalanine in the blood of patients who have PKU whose blood phenylalanine levels cannot be adequately controlled by other means such as by diet.

2. What should I know before I use PALYNZIQ?

Warnings

Do not use PALYNZIQ if:

- you have a severe allergy to pegvaliase, or any of the ingredients listed at the end of this leaflet.
Always check the ingredients to make sure you can use this medicine.
- you have a severe allergy to another medicine that contains polyethylene glycol (PEG).

Check with your doctor if you:

- have any other medical conditions
- take any medicines for any other condition
- cannot use or do not want to use an adrenaline injection device to treat a severe allergic reaction to PALYNZIQ.

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?](#)

Allergic reactions

You may have allergic reactions when being treated with PALYNZIQ. Your doctor will tell you how to manage your allergic reactions based on the severity of the reaction, and will prescribe you additional medicines to manage the reaction.

Before using PALYNZIQ, tell your doctor if you cannot use or do not want to use an adrenaline injection device to treat a severe allergic reaction to PALYNZIQ.

PALYNZIQ can cause severe allergic reactions that may be life-threatening and these can happen any time after a PALYNZIQ injection.

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or breastfeeding or intend to become pregnant. PALYNZIQ is not recommended during pregnancy unless your condition requires treatment with PALYNZIQ and other ways of controlling your blood phenylalanine levels do not work. If your phenylalanine levels are too high or too low during pregnancy, this may harm you or your baby. You and your doctor will decide the best way for you to manage your blood phenylalanine levels. It is very important to keep your phenylalanine levels under control before and during pregnancy.

It is not known if PALYNZIQ passes into breast milk or if it will affect your baby. Talk to your healthcare provider about the best way to feed your baby if you use PALYNZIQ.

It is not known if PALYNZIQ has an effect on fertility. Animal studies suggest that women may have difficulty becoming pregnant if their phenylalanine levels are abnormally low.

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 PALYNZIQ and affect how it works.

Injection of other medicines that contain PEG while using PALYNZIQ

PALYNZIQ includes an ingredient called polyethylene glycol (PEG). If you inject PALYNZIQ with another injectable medicine that contains PEG, such as PEGylated medroxyprogesterone acetate (used for contraception) and some of the COVID-19 vaccines, you may have an allergic reaction.

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

4. How do I use PALYNZIQ?

How much to use

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

PALYNZIQ is given as an injection under the skin (subcutaneous injection).

Dose

- You will start PALYNZIQ at the lowest dose. You will use the 2.5 mg syringe once a week for at least the first 4 weeks. The 2.5 mg syringe has a white plunger.

- Your doctor will then slowly increase your dose and/or how often you inject PALYNZIQ. Your doctor will tell you how long to stay at each dose. Slowly increasing your dose over time allows your body to adjust to this medicine.
- The goal is to reach a daily dose that lowers your blood phenylalanine levels to within the target range of 120 to 600 micromol/l and does not cause too many side effects. Patients usually need a daily dose of 20 mg, 40 mg, or 60 mg to reach their target blood phenylalanine level.

Example of steps to reach your blood phenylalanine goal

PALYNZIQ dose and how often to take it	Syringe colour
2.5 mg once a week	White plunger
2.5 mg two times a week	
10 mg once a week	Green plunger
10 mg twice a week	
10 mg four times a week	
10 mg daily	
20 mg daily	Blue plunger
40 mg daily (2 injections of 20 mg pre-filled syringe) ¹	
60 mg daily (3 injections of 20 mg pre-filled syringe) ¹	

¹ If you need more than one injection to receive your daily dose, all injections should be done at the same time of day and injection sites should be at least 5 centimetres away from each other. Do not divide your daily dose throughout the day.

- Your doctor will continue to check your blood phenylalanine levels during treatment and may adjust your dose of PALYNZIQ or ask you to change your diet.
- At the beginning of your treatment when the doses are adjusted often, your doctor will need to check your blood phenylalanine every week, and thereafter at least once a month to see if this medicine is working for you.

Starting PALYNZIQ

- Your healthcare provider will give you the PALYNZIQ injection until you (or a caregiver) can do it yourself.
- Your doctor will prescribe medicines for you to take before your PALYNZIQ injection, such as paracetamol, fexofenadine, and/or ranitidine. These medicines help to reduce the symptoms of an allergic reaction.
- A healthcare provider will monitor you for at least 1 hour after you get PALYNZIQ for signs and symptoms of an allergic reaction.

- Your doctor will also prescribe adrenaline injection device to use for any severe allergic reactions. Your healthcare provider will also tell you which signs and symptoms to look out for and what to do if you have a severe allergic reaction.
- Your doctor will show you how and when to use the adrenaline injection device. Keep it with you at all times.

Continuing PALYNZIQ

- This medicine comes in pre-filled syringes with 3 different strengths (2.5 mg-white plunger, 10 mg-green plunger, or 20 mg-blue plunger). You may need more than one pre-filled syringe for your prescribed dose. Your healthcare provider will tell you which syringe, or a combination of syringes, to use and will show you (or a caregiver) how to inject PALYNZIQ.
- The “Instructions for Use” (section 8 of this leaflet) shows you:
 - how to prepare and inject PALYNZIQ and
 - how to discard PALYNZIQ syringes properly after you use them
- Your doctor will prescribe medicines for you to take before your PALYNZIQ injection, such as paracetamol, a H1 receptor antagonist such as fexofenadine, and a H2 receptor antagonist such as famotidine. These medicines help to reduce the symptoms of an allergic reaction.
- For at least the first 6 months of PALYNZIQ treatment, you must have someone with you when you self-inject PALYNZIQ, and for at least 1 hour after your injection to watch for signs and symptoms of a severe allergic reaction and, if needed, give you an injection of adrenaline and call for emergency medical help.
 - Your doctor will train them on the signs and symptoms of a severe allergic reaction and how to give an injection of adrenaline.
 - Your doctor will tell you if you need an observer for longer than 6 months.
- Do not change your protein intake unless your doctor tells you to.

When to use PALYNZIQ

Your doctor will tell you when to use PALYNZIQ.

How to use PALYNZIQ

Please refer to Section 8 of this leaflet “Instructions for use”.

If you forget to use PALYNZIQ

If you miss a dose, take your next dose at the regular time. Do not take two doses of PALYNZIQ to make up for a missed dose.

If you use too much PALYNZIQ

If you think that you have used too much PALYNZIQ, 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.

5. What should I know while using PALYNZIQ?

Things you should do if you:

- Have a severe allergic reaction

Use adrenaline injection device as instructed by your doctor and seek urgent medical assistance from your doctor or the Emergency Department at your nearest hospital. Your doctor will prescribe an adrenaline injection device to use for a severe allergic reaction. Your doctor will train and instruct you and someone helping you on when and how to use adrenaline. Keep the adrenaline injection device with you at all times.

If you have a severe allergic reaction, do not continue to use PALYNZIQ until you have talked with the doctor who prescribes you PALYNZIQ. Tell your doctor that you had a severe allergic reaction. Your doctor will tell you if you can continue PALYNZIQ treatment.

PALYNZIQ can cause severe allergic reactions that may be life-threatening and these can happen any time after a PALYNZIQ injection.

Stop injecting PALYNZIQ if any of the following symptoms occur.

- Swelling of the face, eyes, lips, mouth, throat, tongue, hands and/or feet
- Trouble breathing or wheezing
- Throat tightness or choking feeling
- Trouble swallowing or speaking
- Feeling dizzy or fainting
- Losing control of urine or stools
- Rapid heartbeat
- Hives (like an itchy, bumpy skin rash) that spreads quickly
- Flushing
- Severe stomach cramps or pain, vomiting, or diarrhoea

For at least the first 6 months of treatment, someone must be with you when you are self-injecting PALYNZIQ. This person must stay with you for at least 1 hour after your injection to watch you for signs and symptoms of a

severe allergic reaction and, if needed, give you an injection of adrenaline and call for emergency medical help.

Time needed to lower your blood phenylalanine levels

Your doctor will start you on PALYNZIQ at a low dose and will increase your dose slowly. It will take time to find the dose that works best to lower your blood phenylalanine levels. Most people respond within 18 months, but it can sometimes take up to 30 months.

Injection of other medicines that contain PEG while using PALYNZIQ

PALYNZIQ includes an ingredient called polyethylene glycol (PEG). If you inject PALYNZIQ with another injectable medicine that contains PEG, such as PEGylated medroxyprogesterone acetate (used for contraception) and some of the COVID-19 vaccines, you may have an allergic reaction. Tell your doctor or pharmacist if you are injecting, have recently injected or might inject any other medicines.

Blood phenylalanine levels that are too low

You may have blood phenylalanine levels that are too low when using PALYNZIQ. Your doctor will check your blood phenylalanine levels at least once a month. If your blood phenylalanine levels are too low, your doctor may ask you to change your diet and/or will lower your dose of PALYNZIQ. Your doctor will check your blood phenylalanine levels every week until your blood phenylalanine levels return to normal.

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

Things you should not do

Do not stop using this medicine unless you have a severe allergic reaction or are advised to by your doctor. If you stop taking PALYNZIQ treatment, your blood phenylalanine levels are likely to increase.

Do not use this medicine if the pre-filled syringe is damaged or you notice the solution is discoloured, cloudy, or if you can see particles.

Children and adolescents

It is not known if PALYNZIQ is safe and effective in children and adolescents less than 16 years of age with PKU and therefore should not be used in people aged less than 16 years.

Driving or using machines

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

PALYNZIQ can affect your ability to drive and use machines if you have a severe allergic reaction.

Looking after your medicine

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

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

If needed, you may store PALYNZIQ in its sealed tray outside the refrigerator (below 25°C) for up to a single period of 30 days away from sources of heat. Record the date removed from refrigeration on the unopened product tray. Once stored outside of refrigeration, the product must not be returned to the refrigerator.

Keep it where young children cannot reach it.

When to discard your medicine

Discard your medicine if it is past its expiry date (after “EXP” on packaging), if it has not been stored properly or if the pre-filled syringe is damaged or you notice the solution is discoloured, cloudy, or if you can see particles. The expiry date refers to the last day of that month.

Getting rid of any unwanted medicine

Use safe disposal procedures for syringes. Do not throw away any medicines via wastewater or household waste. If you no longer need to use this medicine or it is out of date or has been stored incorrectly, take it to any pharmacy for safe disposal.

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.

Allergic reactions occur very commonly (*may affect more than 1 in 10 people*) and range in severity. Symptoms of allergic reaction can include skin rash, itching, swelling of head or face, itchy or runny eyes, cough, trouble breathing, wheezing, and feeling dizzy. Your doctor will tell you how to manage any allergic reactions based on their severity and will prescribe you additional medicines to manage the reaction. Some of these allergic reactions can be more serious, as described below, and will require immediate attention.

Serious side effects

Serious side effects	What to do
Sudden severe allergic reactions. <i>Common (may affect up to 1 in 10 people)</i> Stop injecting PALYNZIQ if you notice any serious sudden signs of allergy or combination of signs listed below. <ul style="list-style-type: none">Swelling of the face, eyes, lips, mouth, throat, tongue, hands and/or feet	Use adrenaline injection device as instructed by your doctor and seek urgent medical assistance from your doctor or

<ul style="list-style-type: none"> • Trouble breathing or wheezing • Throat tightness or a choking feeling • Trouble swallowing or speaking • Feeling dizzy or fainting • Losing control of urine or stools • Rapid heartbeat • Hives (like an itchy, bumpy skin rash) that spreads quickly • Flushing • Severe stomach cramps or pain, vomiting, or diarrhoea 	<p>the Emergency Department at your nearest hospital.</p>
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<ul style="list-style-type: none"> • increase in c-reactive protein (CRP) (CRP is a protein that indicates that you have inflammation) <p><i>Common (may affect up to 1 in 10 people)</i></p> <p>Muscle and bone-related</p> <ul style="list-style-type: none"> • joint stiffness • joint swelling • muscle stiffness <p>Skin-related</p> <ul style="list-style-type: none"> • blistering or peeling of the outer layer of the skin 	
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Contact your doctor **immediately** if you have the following:

- A type of allergic reaction called serum sickness which includes a combination of fever (high temperature), rash, muscle and joint aches (*Common – may affect up to 1 in 10 people*)

Less serious side effects

Less serious side effects	What to do
<p><i>Very common (may affect more than 1 in 10 people)</i></p> <p>Lymphatic system-related</p> <ul style="list-style-type: none"> • swollen glands in the neck, armpit or groin <p>Immune system-related</p> <ul style="list-style-type: none"> • allergic reaction, which may include symptoms such as skin rash, fever, joint pain <p>Nervous system-related</p> <ul style="list-style-type: none"> • headache • feeling dizzy <p>Respiratory-related</p> <ul style="list-style-type: none"> • cough <p>Gastrointestinal-related</p> <ul style="list-style-type: none"> • stomach pain • feeling sick, also called nausea • vomiting <p>Skin-related</p> <ul style="list-style-type: none"> • thinning or loss of hair • skin rash • hives (raised itchy rash on the skin) • itchiness • skin redness <p>Muscle and bone-related</p> <ul style="list-style-type: none"> • joint pain • muscle pain <p>Injection site-related</p> <ul style="list-style-type: none"> • skin redness, swelling, bruising, tenderness, or pain where you injected PALYNZIQ <p>Blood test-related</p> <ul style="list-style-type: none"> • decrease in complement factors C3 and C4 proteins (which are parts of your immune system) • too low levels of phenylalanine 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

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 PALYNZIQ contains

Active ingredient (main ingredient)	pegvaliase
Other ingredients (inactive ingredients)	trometamol trometamol hydrochloride sodium chloride cinnamic acid water for injections

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

What PALYNZIQ looks like

PALYNZIQ solution for injection is a clear to slightly opalescent, colourless to pale yellow solution in a pre-filled syringe. The pre-filled syringe includes an automatic needle guard.

Pre-filled syringe 2.5 mg (white plunger) AUST R 341753

Each carton contains 1 pre-filled syringe with 2.5 mg pegvaliase in 0.5 mL solution.

Pre-filled syringe 10 mg (green plunger) AUST R 341754

Each 10 mg carton contains 1 pre-filled syringe with 10 mg pegvaliase in 0.5 mL solution.

Pre-filled syringe 20 mg (blue plunger) AUST R 341752

Each 20 mg carton contains 1 or 10 pre-filled syringes, with 20 mg pegvaliase in 1 mL solution in each syringe.

Not all pack sizes may be marketed.

Who distributes PALYNZIQ

BioMarin Pharmaceutical Australia Pty Ltd

119 Willoughby Road

Crows Nest NSW 2065

Telephone (02) 8520 3255

For enquiries about Palynziq, contact

medinfoasia@bmrn.com or call BioMarin on 1800 387 876.

To report adverse events, contact drugsafety@bmrn.com

or call BioMarin on 1800 387 876.

This leaflet was prepared in August 2022.

8. INSTRUCTIONS FOR USE

BEFORE YOU START

Read this Instructions for use before you start using the PALYNZIQ pre-filled syringe and each time you get a new prescription. There may be new information. Also, talk to your healthcare provider about your medical condition or your treatment.

Follow these instructions carefully while you are using PALYNZIQ. If your healthcare provider decides that you or your caregiver can give your injections of PALYNZIQ at home, your healthcare provider will show you or your caregiver how to inject PALYNZIQ before you inject it for the first time. **Do not** inject PALYNZIQ until your healthcare provider has shown you or your caregiver how to inject PALYNZIQ.

Talk to your healthcare provider if you have any questions about how to inject PALYNZIQ the right way.

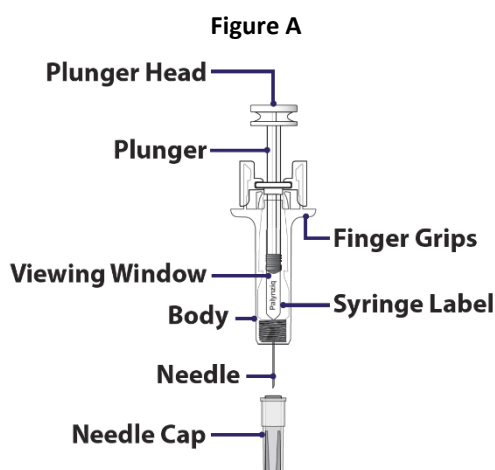
Do not share your pre-filled syringes with anyone else.

For storage instructions, refer to section 5 “*Looking after your medicine*” of this leaflet.

Important things to know about using your PALYNZIQ pre-filled syringe:

- Use each PALYNZIQ pre-filled syringe once only. **Do not** use a PALYNZIQ syringe more than once.
- **Never** pull back on the plunger.
- **Do not** remove the needle cap until you are ready to inject.

Figure A below shows what the pre-filled syringe looks like before use.



Select the correct PALYNZIQ pre-filled syringe(s) for your dose:

When you receive your PALYNZIQ pre-filled syringe(s), check that the name “PALYNZIQ” appears on the carton(s).

- PALYNZIQ pre-filled syringes come in 3 different strengths: 2.5 mg, 10 mg, and 20 mg.
- You may need more than one pre-filled syringe for your prescribed dose. Your healthcare provider will tell you which syringe, or combination of syringes, to use. Ask your healthcare provider if you have any questions.
- Before you inject PALYNZIQ, check each carton and syringe to make sure you have the right pre-filled syringe for your prescribed dose.

Figure B

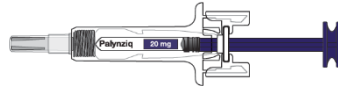
2.5 mg strength



10 mg strength



20 mg strength



PREPARING FOR INJECTION

Step 1: Collect supplies:

Gather your supplies for the injection and place them on a clean flat surface. Take out the required number of cartons needed for your dose from the refrigerator.

Supplies you will need for your PALYNZIQ Injection:

- PALYNZIQ pre-filled syringe(s) in sealed tray(s). Each tray contains 1 syringe.
- gauze pad or cotton ball
- 1 bandage
- 1 sharps disposal or puncture resistant container

Step 2: Remove PALYNZIQ tray(s) from carton and check expiry date:

- Take out the cartons needed for your dose from the refrigerator. Check the expiry date on the carton. If the expiry date has passed, do not use the pre-filled syringe in that carton.
- Open each carton and take out the sealed tray you need for your dose.
- Place each sealed tray on a clean, flat surface out of reach of children and pets.
- Put the carton with any remaining trays back in the refrigerator. If a refrigerator is not available, see section 5 “How to store PALYNZIQ” in this leaflet.

Step 3: Allow PALYNZIQ tray(s) to sit at room temperature for 30 minutes before opening:

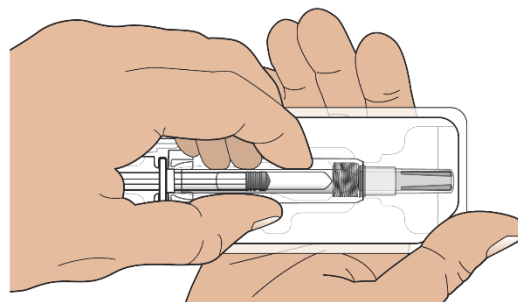
- Let the sealed tray(s) sit at room temperature for **at least 30 minutes**. Injecting cold PALYNZIQ can be uncomfortable.
- **Do not** warm up the pre-filled syringe in any other way. **Do not** use a microwave and do not place in hot water.

Step 4: Remove syringe from tray:

Peel the cover from the tray. Hold the middle of the pre-filled syringe body and take out the pre-filled syringe from the tray (see Figure C).

- **Do not** use the pre-filled syringe if it looks damaged or used. Use a new pre-filled syringe for your injection.
- **Do not** remove the needle cap from your pre-filled syringe.
- **Do not** shake or roll the syringe in your hands.

Figure C

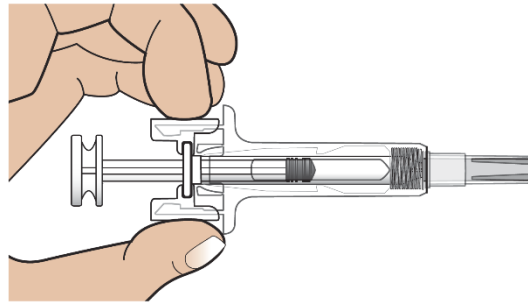


Step 5: Check syringe strength and check for particles:

Check the syringe label to make sure you have the correct strength for your prescribed dose. Look at the liquid through the viewing window (see Figure D). The liquid should look clear and colourless to pale yellow. It is normal to see an air bubble.

- **Do not** flick or try to push the bubble out.
- **Do not** use the pre-filled syringe if the liquid is cloudy, discoloured, or has lumps or particles in it. Use a new pre-filled syringe for your injection.

Figure D



INJECTING PALYNZIQ

Step 6: Choose your injection site.

The recommended injection sites are:

- Front middle of the thighs.
- Lower part of the abdomen except for the 5 centimetre area around the belly button (navel).

If a caregiver is giving the injection, the top of the buttocks and the back of the upper arms may also be used (see Figure E).

Note:

- **Do not** inject into moles, scars, birthmarks, bruises, rashes, or areas where the skin is hard, tender, red, damaged, burned, inflamed, or tattooed.
- If you need more than 1 injection for your daily dose, the injection sites should be at least 5 centimetres away from each other (see Figures E and F).
- Each day, change (rotate) your injection sites. Choose an injection site that is at least 5 centimetres away from the injection site(s) you used the day before. It can be on the same part of the body or a different part of the body (see Figures E and F).

Figure E

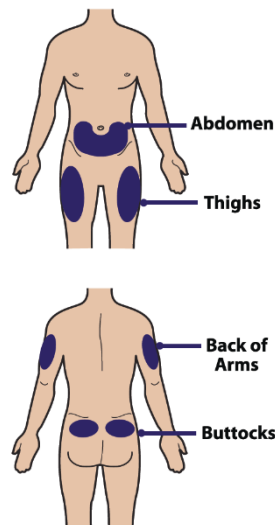
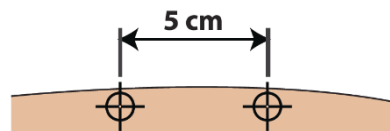


Figure F

Inject at least 5 cm apart



Step 7: Wash your hands well with soap and water (see Figure G).

Figure G



Step 8:

- **Do not** remove the needle cap until you are ready to inject PALYNZIQ.
- Before injecting, check to make sure the needle is not damaged or bent.

INJECT PALYNZIQ

Step 9: Hold the body of the pre-filled syringe with one hand with the needle facing away from you (see Figure I).

- **Do not** use the pre-filled syringe if it has been dropped. Use a new pre-filled syringe for your injection.

Figure I

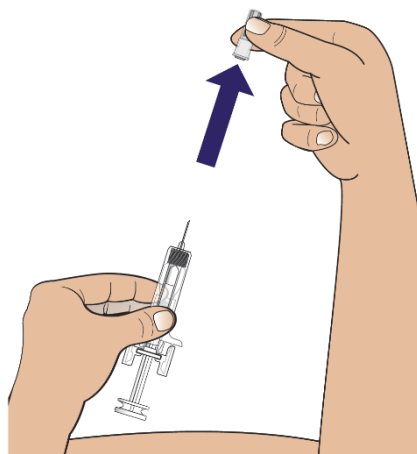


Step 10: Pull the needle cap straight off the needle (see Figure J).

- **Do not** twist the needle cap during removal.
- **Do not** hold the pre-filled syringe by the plunger or plunger head while taking the needle cap off.

You may see a drop of liquid on the tip of the needle. This is normal. **Do not** wipe it away. Throw the needle cap away in a sharps disposal or puncture-resistant container.

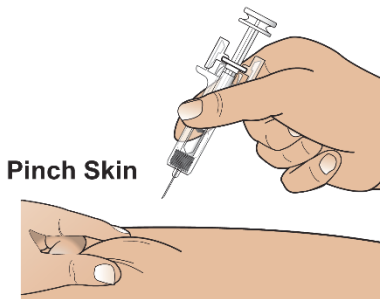
Figure J



Step 11: Hold the body of the pre-filled syringe in 1 hand between your thumb and index finger. Use your other hand to pinch up the skin around the injection site. Hold the skin firmly (see Figure K).

- **Do not** touch the plunger head while inserting the needle into the skin.

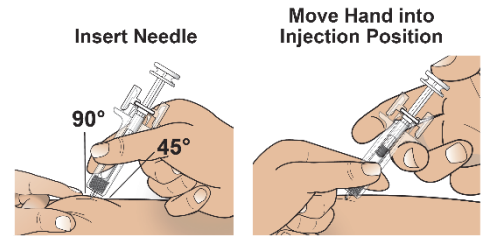
Figure K



Step 12: Use a quick motion to fully insert the needle into the pinched skin at a 45 to 90 degree angle (see Figure L).

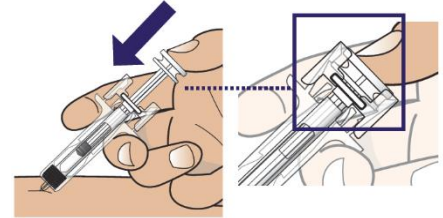
Release the pinch of skin. Use that hand to hold the bottom of the syringe steady. Place the thumb of your other hand on the plunger head (see Figure L).

Figure L



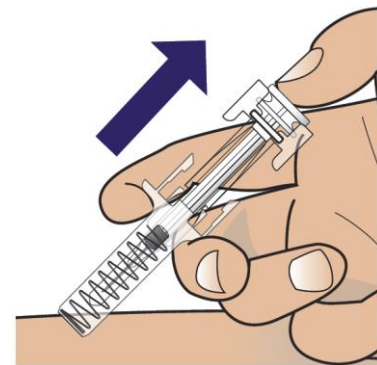
Step 13: Use your thumb to push in the plunger slowly and steadily as far as it will go to inject all the medicine (see Figure M). More pressure may be needed to inject all the medicine for the 10 mg and 20 mg strengths.

Figure M



Step 14: Slowly move your thumb up to release the plunger allowing the needle to automatically be covered by the syringe body (see Figure N).

Figure N



Treat injection site

Step 15: Treat injection site (if needed).

If you see drops of blood at the injection site, press a sterile cotton ball or gauze over the injection site and hold for about 10 seconds. You may cover the injection site with an adhesive bandage if needed.

If more than one syringe is needed:

Step 16: If your health care provider tells you to use more than one syringe for your dose, repeat Steps 4 to 15 listed above for each syringe that you use.

- **Note: Do not** inject multiple injections in the same spot. The injection sites should be at least 5 centimetres away from each other. See Step 6 for choosing an injection site.
- If multiple syringes are needed for a single dose, you should inject at the same time of day. Doses should not be divided over the course of the day.

If your dose requires more than one syringe, repeat Steps 4 to 15 immediately for each syringe you use.

AFTER THE INJECTION

Dispose of the used syringes

Put your used needles and syringes in a sharps disposal or puncture-resistant container right away after use. Check with your doctor, pharmacist or nurse about the right way to throw away the container. Use safe disposal procedures for syringes.

