

Prolutex 25 mg Solution for Injection

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.

1. Why am I using Prolutex?

Prolutex contains the active ingredient progesterone, a naturally-occurring female sex hormone. Prolutex is for women who need extra progesterone while undergoing treatment in an Assisted Reproductive Technology (ART) program who are unable to use or tolerate vaginal preparations or where there is a need or preference to use an injectable form of progesterone.

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

2. What should I know before using Prolutex?

Do not use if you have ever had an allergic reaction to progesterone or any of the ingredients listed at the end of the CMI.

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 am given Prolutex?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines, including medicines obtained without a prescription and herbal medicines, may interfere with Prolutex 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 Prolutex?

Prolutex can be given either under your skin (subcutaneous injection) or into a muscle (intramuscular injection). Intramuscular injections must only be given by a doctor. You will be able to administer 25 mg of Prolutex subcutaneously after suitable advice and training by your doctor or healthcare professional.

The usual dose is a once daily injection of 25 mg for up to 12 weeks of confirmed pregnancy (i.e. 10 weeks of treatment).

More instructions can be found in Section [4. How is Prolutex given?](#) in the full CMI.

5. What should I know while using Prolutex?

Things you should do	<ul style="list-style-type: none">Remind any doctor, dentist or pharmacist you visit that you are using Prolutex.If you forget to use Prolutex, take the dose as soon as you remember and then carry on as before. Do not take a double dose to make up for a forgotten dose. Tell your doctor what you have done.
Things you should not do	<ul style="list-style-type: none">Do not stop using Prolutex without speaking to your doctor or pharmacist first.Do not use Prolutex after the expiry date which is stated on the labelDo not use Prolutex if you notice particles in the solution or if the solution is not clear
Driving or using machines	Progesterone may cause drowsiness and/or dizziness; therefore, caution is advised in drivers and users of machines. Do not drive or use machines until you know how Prolutex affects you.
Drinking alcohol	You should not drink alcohol while you are on Prolutex, as it may make any dizziness or drowsiness worse.

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

6. Are there any side effects?

More common side effects of Prolutex include pain, redness, itching, irritation or swelling at the injection site, headache, bloated stomach, stomach pain, constipation, being sick and feeling sick, breast tenderness and/or pain, hardening of area around injection site, bruising around injection site, fatigue (excessive tiredness, exhaustion, lethargy).

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.

Prolutex 25 mg Solution for Injection

Active ingredient(s): *progesterone*

Consumer Medicine Information (CMI)

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

Where to find information in this leaflet:

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

1. Why am I being given Prolutex?

Prolutex contains the active ingredient progesterone. Progesterone is a naturally occurring female sex hormone.

Prolutex is for women who need extra progesterone while undergoing treatment in an Assisted Reproductive Technology (ART) program who are unable to use or tolerate vaginal preparations.

The medicine works on the lining of the womb and helps you to become pregnant and to stay pregnant.

Your doctor may have prescribed Prolutex for another reason. Ask your doctor if you have any questions about why Prolutex has been prescribed for you.

Prolutex is not addictive.

2. What should I know before I am given Prolutex?

Warnings

Do not use Prolutex if:

- you are allergic to progesterone, or any of the ingredients listed at the end of this leaflet.
- If you are suffering from vaginal bleeding (other than normal periods) that has not been evaluated by your doctor
- If you have had a miscarriage and your doctor suspects some tissue is still in the womb
- If you have had a pregnancy outside of the womb (ectopic pregnancy)
- If you currently have or have had severe liver problems
- If you have known or suspected breast cancer or cancer of the reproductive tract

- If you have or have had blood clots in the legs, lungs, eyes or elsewhere in the body
- If you have porphyria disorders (a group of inherited or acquired disorders of certain enzymes)
- If during pregnancy you have suffered from jaundice (yellowing of eyes and skin due to liver problems) severe itching and/or blisters on the skin
- If you are under 18 years of age.

Tell your doctor immediately, or go to Accident and Emergency at your nearest hospital if you notice any of the following:

- Heart attack (pains in the chest, or back pain and/or deep aching and throbbing in one or both arms, a sudden shortness of breath, sweating, dizziness, light-headedness, nausea, palpitations)
- Stroke (severe headache or vomiting, dizziness, faintness, or changes in vision or speech, weakness or numbness of an arm or leg.)
- Blood clots in the eyes or anywhere in the body (pain in your eyes or pain and swelling in your ankles, feet and hands)
- Worsening of depression
- Severe headaches, changes in vision.

These are very serious side effects; you may need urgent medical attention or hospitalisation.

Check with your doctor if you:

Tell your doctor or pharmacist if you have allergies to:

- any other medicines
- any other substances, such as foods, preservatives or dyes

Tell your doctor if you have had or have any of the following before using Prolutex:

- Liver problems (mild or moderate)
- Epilepsy
- Migraine
- Asthma
- Heart or kidney problems
- Diabetes
- Depression

If any of the above applies to you, your doctor will monitor you carefully during treatment.

Pregnancy and breastfeeding

Ask your doctor or pharmacist for advice before taking any medicine.

- Prolutex can be used during the first three months of pregnancy.

- This medicine should not be used during breast-feeding.

Children and adolescents

The product is not to be used by children or adolescents.

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 and Prolutex may interfere with each other. These include:

- Carbamazepine (used to treat seizures/fits)
- Rifampicin (an antibiotic)
- Griseofulvin (an antifungal medicine)
- Phenytoin and phenobarbital (used to treat epilepsy)
- St. John's Wort-containing herbal products
- Ciclosporin (a medicine for some types of inflammation and after organ transplants)
- Diabetic medicines
- Ketoconazole (an antifungal medicines)

Do not administer Prolutex at the same time as any other injectable medicine.

Your doctor and pharmacist may have more information on medicines to be careful with or avoid while having Prolutex.

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

3. How do I use Prolutex?

How much is given

The usual dose is an injection of 25 mg once-daily. As per template, Follow instructions provided...

How Prolutex is given

Always use Prolutex exactly as your doctor has told you. Remember Prolutex should only be used under the supervision of a doctor experienced in treating fertility problems.

A doctor must perform all intramuscular (IM) injections of Prolutex.

However, you will be able to administer 25 mg of Prolutex subcutaneously yourself after suitable advice and training by your doctor or healthcare professional.

How long Prolutex is given for

Prolutex should normally be administered once-daily until 12 weeks of confirmed pregnancy (i.e. 10 weeks of treatment).

Subcutaneous Injection

Before you inject Prolutex you will receive the following training and advice:

- Practice giving subcutaneous injections
- Where to inject your medicine
- How to prepare your solution for injection
- How to administer your medicine.

Please read all instructions below on preparation and administration of Prolutex.

The steps for self-administration are:

1. Preparing your injection
2. Checking pack
3. Preparing the vial and syringe
4. Filling the syringe
5. Changing the injecting needle
6. Removing air bubbles
7. Injection by subcutaneous administration
8. Disposal of used items.

These steps are explained in full below.

IMPORTANT: each vial should only be used once. The solutions should be used immediately after opening the vial. It should not be stored in the syringe.

Any remaining solution must be discarded.

1. Preparing your injection

It is important to keep everything as clean as possible, so start by washing your hands thoroughly and drying on a clean towel. Choose a clean area to prepare your medicine:

- One vial containing Prolutex solution for injection

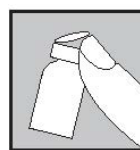
The following are not supplied with your medicine. Your doctor or pharmacist will supply these items.

- One syringe
- One large needle (typically 21G green needle; for intramuscular administration)
- One small fine needle (typically 27G grey needle; for subcutaneous injection)
- Two alcohol wipes
- A sharps container (for safe disposal of needles, vials etc.)

2. Checking pack

- The Prolutex vial syringe and needles all have protective covers.
- Check that all the covers are on firmly and if they are not on properly or are damaged, do not use them
- Make sure that the expiry date is still valid on the vial of Prolutex . Do not use the products if outside the expiry date

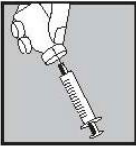
3. Preparing the vial and syringe



- Remove the plastic cap from the top of a Prolutex vial by gently pushing it upwards.
- Wipe the rubber top with an alcohol wipe and allow to dry
- Unpack the syringe, hold the syringe
- Take the packaging off the large 21G green needle, but keep the needle cover on

	<ul style="list-style-type: none"> • Hold the syringe in your hand, attach the large 21G green needle to the syringe, then remove the needle cover
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4. Filling the syringe


	<ul style="list-style-type: none"> • Push the large 21G green needle through the rubber middle of the Prolutex vial top • With the needle still inserted, turn the vial upside down. The needle should support the vial unaided • Make sure the large needle tip is underneath the level of the liquid • Gently pull the plunger to draw all the mixture into the syringe • Pull the large needle out of the vial.
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5. Changing the injecting needle

This step is only required if you are doing a subcutaneous administration; if your doctor is performing an intramuscular injection, they will move on to set the dose and administer the injection.

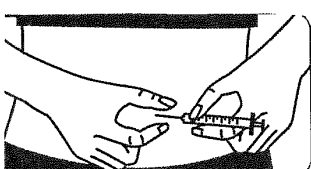
- Put the needle cover on the large 21G green needle and then gently take the large needle off the syringe
- Remove the smaller 27G grey injecting needle, from its package, keeping the needle cover on
- Attach the small 27G grey needle onto the syringe then remove the needle cover.

6. Removing air bubbles

	<ul style="list-style-type: none"> • Holding the syringe straight up with the small 27G grey needle pointing to the ceiling, draw back slightly on the plunger and tap the syringe so that any air bubbles rise to the top. • Slowly press the plunger until all the air is out of the syringe and at least one drop of solution comes out of the tip of the small 27G grey needle
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7. Injection by subcutaneous administration

- Your doctor or healthcare professional will have already shown you where to inject Prolutex (e.g. tummy or front of thigh)
- Open the alcohol wipe and carefully clean the area of skin to be injected, and allow it to dry
- Hold the syringe in one hand. Use the other hand to gently pinch the skin in the injection site area between your thumb and index finger

	<ul style="list-style-type: none"> • Using a dart-like motion insert the fine grade small 27G grey needle into the skin so the skin and needle form a right angle.
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- Insert the small 27G grey needle all the way into the skin. Do not inject directly into a vein
- Inject the solution by pushing gently on the plunger in a slow and steady motion until all the solution is injected beneath the skin. Inject all of the prescribed solution
- Release the skin and pull the needle straight out
- Wipe the skin at the injection site with an alcohol swab using a circular motion.

8. Disposal of used items

- Once you have finished your injection, put all needles, empty vials and syringes into a sharps container.
- Any unused solution must also be thrown away.

Injection by intramuscular administration should only be given by a doctor or healthcare professional

For all intramuscular injections, your doctor or another healthcare professional will perform the injection.

The Prolutex injection will be given into the side of the thigh or bottom. Your doctor or healthcare professional will clean the area of skin to be injected using an alcohol wipe, and allow it to dry. Using a dart-like motion they will insert the large needle into the muscle. They will inject the solution by pushing gently on the plunger in a slow and steady motion until all the solution is injected into the muscle. They will pull the needle straight out and wipe the skin at the injection site with an alcohol wipe.

If you are given too much Prolutex

Tell your doctor or pharmacist. The symptoms of an overdose include drowsiness.

If you use too much Prolutex by SC injection

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

4. What should I know while being given Prolutex?

Things you should do

If you forget to use Prolutex, take the dose as soon as you remember and then carry on as before. Do not take a double dose to make up for a forgotten dose. Tell your doctor what you have done.

Things you should not do

Do not stop using Prolutex without speaking to your doctor or pharmacists first. Abrupt discontinuation of Prolutex

may cause increased anxiety, moodiness, and increase your risk of having seizures (fits).

Do not use Prolutex after the expiry date which is stated on the label after Exp: The expiry date refers to the last day of that month.

Do not use Prolutex if you notice particles in the solution or if the solution is not clear.

Driving or using machines

Be careful driving or operating machinery until you know how Prolutex affects you. As with many other medicines, Prolutex may cause dizziness or drowsiness in some people.

Drinking alcohol

You should not drink alcohol while you are on Prolutex, as it may make any dizziness or drowsiness worse.

Looking after your medicine

Keep out of the sight and reach of children.

Store below 25°C. Do not refrigerate or freeze.

Store in the original package to protect from light.

Getting rid of any unwanted medicine

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

5. Are there any side effects?

Like all medicines, Prolutex can cause side effects, although not everybody gets them. Tell your doctor, nurse or pharmacist as soon as possible if you do not feel well while you are taking Prolutex.

Ask your doctor or pharmacist to answer any questions you may have.

Less serious side effects

Less serious side effects	What to do
<p>Very common: may affect more than 1 in 10 people</p> <ul style="list-style-type: none"> • Pain, redness, itching, irritation or swelling at the injection site <p>Common: may affect more than 1 in 10 people</p> <ul style="list-style-type: none"> • Headache • Bloating stomach • Stomach pain • Constipation • Being sick and feeling sick • Breast tenderness and/or pain • Hardening of area around injection site • Bruising around injection site 	<p>Speak to your doctor, nurse or pharmacist if you have any of these less serious side effects and they worry you.</p>

<ul style="list-style-type: none"> • Fatigue (excessive tiredness, exhaustion, lethargy). <p>Uncommon: may affect up to 1 in 100 people</p> <ul style="list-style-type: none"> • Changes in mood • Dizziness • Insomnia • Stomach and intestinal disturbance (including stomach discomfort and/or tenderness, wind, painful spasms and retching) • Skin rashes (including red warm skin, or raised, itchy bumps or wheals or dry, cracked or blistered or swollen skin) • Breast swelling and/or enlargement • Feeling hot • General feeling of discomfort or “feeling out of sorts” • Pain 	
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Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> • Overstimulation of the ovaries (symptoms include lower stomach pain, feeling thirsty and sick, and sometimes being sick, passing reduced quantities of concentrated urine and weight gain), • Depression • Yellowing of your skin and the whites of your eyes (jaundice) • Severe allergic reaction which may cause difficulty breathing, swelling of the face and throat or a severe rash (anaphylactoid reactions). 	<p>Stop taking this medicine and seek immediate medical help if you have any of these symptoms</p>

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.

6. Product details

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

What Prolutex contains

Active ingredient (main ingredient)	Progesterone (25 mg/1.112 mL)
Other ingredients (inactive ingredients)	<ul style="list-style-type: none">• Hydroxypropylbetadex• Water for Injections

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

What Prolutex looks like

Prolutex is a clear, colourless solution in a clear glass vial. Each vial is used only once and any leftover material is discarded.

It is approved in packs of 7 vials.

Australian Registration Numbers:

25 mg: Aust R 393324

Who distributes Prolutex

Boucher & Muir Pty Ltd

Advanz Pharma Pty Ltd
Level 9, 76 Berry Street,
North Sydney 2060
NSW
Australia

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