

Consumer Medicine Information

WARNINGS

Limitations of use

Proladone suppositories should only be given when your doctor decides that other treatment options are not able to effectively manage your pain or you cannot tolerate them.

Hazardous and harmful use

Proladone suppositories poses risks of abuse, misuse and addiction which can lead to overdose and death. Your doctor will monitor you regularly during treatment.

Life threatening respiratory depression

Proladone suppositories can cause life-threatening or fatal breathing problems (slow, shallow, unusual or no breathing), even when used as recommended. These problems can occur at any time during use, but the risk is higher when first starting Proladone suppositories and after a dose increase, if you are older, or have an existing problem with your lungs. Your doctor will monitor you and change the dose as appropriate.

Use of other medicines while being given Proladone suppositories

Using Proladone suppositories with other medicines that can make you feel drowsy such as sleeping tablets (e.g. benzodiazepines), other pain relievers, antihistamines, antidepressants, antipsychotics, gabapentinoids (e.g. gabapentin and pregabalin), cannabis and alcohol may result in severe drowsiness, decreased awareness, breathing problems, coma and death. Your doctor will minimise the dose and duration of use; and monitor you for signs and symptoms of breathing difficulties and sedation. You must not drink alcohol while using Proladone suppositories.

What is in this leaflet

This leaflet answers some common questions about Proladone.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you using Proladone against the benefits they expect it will have for you.

If you have any concerns about using this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What Proladone is used for

Proladone is a suppository containing oxycodone. It belongs to a group of medicines called opioid analgesics and acts to relieve pain.

Proladone is used to relieve pain after surgery or for treating cancer pain.

Your doctor may have prescribed Proladone for another reason.

Ask your doctor if you have any questions about why Proladone has been prescribed for you.

Proladone is only available with a doctor's prescription.

Addiction

You can become addicted to Proladone even if you take it exactly as prescribed. Proladone may become habit forming causing mental and physical dependence. If abused it may become less able to reduce pain.

Dependence

As with all other opioid containing products, your body may become used to you taking Proladone. Taking it may result in physical dependence. Physical dependence means that you may experience withdrawal symptoms if you stop taking Proladone suddenly, so it is important to take it exactly as directed by your doctor.

Tolerance

Tolerance to Proladone may develop, which means that the effect of the medicine may decrease. If this happens, more may be needed to maintain the same effect.

Withdrawal

Continue taking your medicine for as long as your doctor tells you. If you stop taking this medicine suddenly, your pain may worsen and you may experience some or all of the following withdrawal symptoms:

- nervousness, restlessness, agitation, trouble sleeping or anxiety
- body aches, weakness or stomach cramps
- loss of appetite, nausea, vomiting or diarrhoea
- increased heart rate, breathing rate or pupil size
- watery eyes, runny nose, chills or yawning
- increased sweating.

Proladone given to the mother during labour can cause breathing problems and signs of withdrawal in the newborn.

Before you use Proladone

When you must not use it

Do not use Proladone if you have an allergy to Proladone or any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction are:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin
- discolouration of the skin.

Do not use Proladone if you currently have, or have had, any of the following:

- head injury, or increased pressure in the head
- brain tumour

- epilepsy (also known as fits or convulsions)
- are taking, or have taken in the last 14 days, medicine for depression especially Monoamine Oxidase Inhibitors (MAOIs)
- heart problems such as irregular and/or rapid heartbeat
- asthma
- any difficulty in breathing
- alcoholism.

Do not use this medicine for children as there have been no studies of its effects in children.

Do not use this medicine after the expiry date printed on the packet.

Do not use this medicine if the packaging is torn or shows signs of tampering.

If you are not sure whether you should be using Proladone contact your doctor.

Before you start to use Proladone

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you are pregnant or intend to become pregnant.

Your doctor or pharmacist will discuss the possible risks and benefits of using Proladone during pregnancy.

Tell your doctor if you are breast-feeding or plan to breast-feed.

Like most opioid medicines, Proladone is not recommended while you are breast-feeding.

Tell your doctor if you have, or have had, any medical conditions, especially the following:

- myasthenia gravis, a disease of the muscles
- an underactive thyroid gland
- kidney disease
- liver disease
- if male, prostate problems or difficulty passing water
- bowel disorders
- asthma or breathing problems.

If you have not told your doctor about any of the above, tell them before you start using Proladone.

Taking other medicines

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

Some medicines and Proladone may interfere with each other. These include:

- medicines used to treat hyperactivity
- medicines used to produce calmness or to help you sleep
- medicines called anaesthetics which are used to put you to sleep during an operation or procedure
- barbiturates, medicines used to treat epilepsy, to produce calmness or to help you sleep
- other opioid medicines used to treat pain
- medicines used to treat depression, psychiatric or mental disorder
- medicines used to treat certain mental and emotional conditions e.g. depression
- medicines used to treat high blood pressure or other heart conditions
- medicines used to prevent blood clots
- medicines used to prevent or relieve the symptoms of allergy (such as hay fever)
- medicines used to treat nausea or vomiting.

These medicines may be affected by Proladone or they may affect how well it works.

Tell your doctor if you regularly drink alcohol. Alcohol may interfere with this medicine. Your doctor may advise you to stop drinking alcohol while using this medicine.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while using Proladone.

How to use Proladone

How much to use

Your doctor will tell you how many suppositories you need to use each day.

How to use it

If possible, go to the toilet and empty your bowels before using your suppository.

Suppositories work best if your bowels are empty.

Follow these steps to use a suppository:

1. Wash your hands thoroughly with soap and water.
2. Feel the suppository while it is still in the foil.
3. If it feels soft, keep it in the foil and chill it in the fridge or by holding it under cold water for a few minutes. Do not remove the foil wrapper while you are chilling it.
4. Put on a disposable glove, if desired. They are available from pharmacies.
5. Remove all of the foil wrapper from the suppository.
6. Moisten the suppository by dipping it briefly in cool water.
7. Lie on your side and raise your knee to your chest.
8. Push the suppository gently, pointed end first, into your rectum (back passage).
9. Remain lying down for a few minutes while the suppository dissolves.
10. Throw away the disposable glove and any used material and wash your hands thoroughly to reduce the risk of infection.

Try not to go to the toilet and open your bowels for at least an hour after using the suppository.

The suppository takes about one hour to be completely absorbed and do its work.

If you are not sure how to use a suppository, ask your doctor or pharmacist.

If you forget to use Proladone

If it is almost time for your next suppository (within 2 or 3 hours), skip the suppository you missed and use your next suppository when you are meant to.

Otherwise, use it as soon as you remember, and then go back to using the suppositories as you would normally.

Do not use two suppositories to make up for the one that you missed.

This may increase the chance of you getting an unwanted side effect.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to use your medicine, ask your pharmacist for some hints.

How long to use it

The length of treatment will depend on your condition. Your doctor will advise you when to stop using Proladone.

Do not suddenly stop using Proladone. Your doctor may want you to gradually reduce the amount of Proladone you are using before stopping completely. Stopping gradually will lessen the risk of unwanted side effects.

If you use too much (overdose)

If you or someone else receive too much (overdose), and experience one or more of the symptoms below, immediately call triple zero (000) for an ambulance. Keep the person awake by talking to them or gently shaking them every now and then. You should follow the above steps even if someone other than you have accidentally used Proladone that was prescribed for you. If someone takes an overdose they may experience one or more of the following symptoms:

- Slow, unusual or difficult breathing
- Drowsiness, dizziness or unconsciousness
- Slow or weak heartbeat
- Nausea or vomiting
- Convulsions or fits

If you think you or someone else may have used too much Proladone, you should immediately:

- phone the Poisons Information Centre by calling 13 11 26 (Australia), 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. When seeking medical attention, take this leaflet and remaining medicine with you to show the doctor. Also tell them about any other medicines or alcohol which have been taken.

While you are using Proladone

Things you must do

Tell any other doctors, dentists, and pharmacists who are treating you that you are using Proladone.

If you are about to be started on any new medicine, tell your doctor, dentist or pharmacist that you are using Proladone.

If you plan to have surgery that needs a general anaesthetic, tell your doctor or dentist that you are using Proladone.

If you become pregnant while using Proladone, tell your doctor.

Things you must not do

Do not give Proladone to anyone else, even if they have the same condition as you.

Do not use Proladone to treat any other complaints unless your doctor tells you to.

Do not stop using Proladone or lower or increase the dose without checking with your doctor.

Do not run out of this medicine over the weekend or on holidays.

Your doctor may want you to gradually reduce the amount of Proladone you are using before stopping completely. This may help reduce the possibility of withdrawal symptoms such as nausea, diarrhoea, body aches (see Side effects).

Things to be careful of

Be careful when drinking alcohol while you are using Proladone.

Drinking alcohol while using this medicine could make you feel more dizzy, sleepy or light-headed than usual. Your doctor may suggest you avoid alcohol while you are using Proladone.

Be careful driving or operating machinery until you know how Proladone affects you.

Proladone may cause drowsiness, sleepiness or dizziness in some people and affect alertness. Make sure you know how you react to Proladone before you drive or operate machinery or do anything else that could be dangerous if you are sleepy or dizzy.

If this occurs do not drive.

Be careful using the suppositories for people over 65 years.

Families and carers should be aware that these people may become confused while using Proladone. Special care may be needed.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using Proladone.

Proladone helps most people with pain, but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

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

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

Tell your doctor if you notice any of the following and they worry you:

- confusion
- drowsiness
- constipation
- vomiting
- nausea.

These are the more common side effects of Proladone.

Other side effects are:

- difficulty passing water (urine)
- decreased frequency passing water (urine)
- dry mouth
- sweating
- redness of the face
- loss of appetite
- faintness or feeling weak
- slow heart rate
- abnormal or fast heart rate
- irregular heart beat
- dizziness on standing
- restlessness
- constriction of pupils
- changes of mood
- decrease in body temperature
- muscle stiffness
- itchy rash or other forms of itchiness
- severe headache.

If any of the following happen, stop using Proladone and tell your doctor immediately or go to the Emergency Department at your nearest hospital:

- inability to breathe properly
- severe dizziness, drowsiness and confusion
- symptoms of allergy (eg itchy skin, rash, skin blisters or discolouration of skin upon exposure to sunlight).

These may be very serious side effects. You may need urgent medical attention or hospitalisation.

All of these side effects are very rare.

High doses of Proladone can cause:

- heart failure
- low blood pressure
- inability to breathe properly.

The following side effects may occur when you stop using Proladone:

- body aches
- diarrhoea
- gooseflesh or goose bumps
- loss of appetite
- nervousness
- restlessness
- runny nose
- sneezing
- shivering
- stomach cramps
- feeling sick, also called nausea
- trouble sleeping
- an increase in sweating and yawning
- weakness
- fast heart beat
- unexplained fever.

These symptoms are usually mild if Proladone is stopped gradually.

Other side effects not listed above may occur in some patients. Tell your doctor if you notice anything that is making you feel unwell.

After using Proladone

Storage

Keep your suppositories in the foil pack until it is time to use them.

If you take the suppositories out of the pack they will not keep well.

Keep your suppositories in a cool dry place where the temperature stays below 25°C.

Do not store Proladone or any other medicines in the bathroom or near a sink.

Do not leave it in the car on hot days or on window sills.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop using the suppositories, if the medicine is damaged, you no longer need to use this medicine or you find that they have passed their expiry date, ask your pharmacist what to do with any that are left over.

Product description

What it looks like

Proladone is a smooth, off-white, oval/cone-shaped suppository for rectal use which will dissolve in the rectum (back passage). It is covered by a wax coating for easy insertion into the rectum.

Ingredients

Each Proladone suppository contains 30 mg of oxycodone.

Proladone suppositories also contain:

- lactose monohydrate
- maize starch
- pectin
- povidone
- magnesium stearate
- hard fat.

Proladone does not contain sucrose, gluten, tartrazine, alcohol, dyes or preservatives.

Supplier

Proladone is supplied in Australia by:

**Phebra Pty Ltd,
19 Orion Road,
Lane Cove West, NSW 2066,
Australia.**

Proladone 30 mg
12 suppositories per foil strip

AUST R 14965

Phebra Product Code- TAB007

Date of most recent amendment
Apr 2020.

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