

Norprolac® Tablets

quinagolide

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Norprolac.

It does not contain all the available information. 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 taking this medicine against the benefits they expect it will provide.

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

Keep this leaflet with the medicine.

You may need to read it again.

What Norprolac is taken for

Norprolac is used to treat people who have high blood levels of a hormone called prolactin. This condition is sometimes caused by a type of tumour called a prolactinoma.

Norprolac contains the active ingredient, quinagolide.

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

Your doctor may have prescribed it for another reason.

This medicine is only available with a doctor's prescription. It is not addictive.

There is not enough information to recommend its use in children.

Before you take Norprolac

When you must not take it

Do not take Norprolac if you have an allergy to:

- quinagolide (the active ingredient) or any of the other ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include 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.

Do not take this medicine if you have problems with your kidneys or liver.

There is no experience with the use of this medicine in people whose kidney or liver function is impaired.

Do not take it after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

In that case, return it to your pharmacist.

Before you start to take it

Tell your doctor if you have had any type of mental illness (e.g. schizophrenia).

Your doctor may want to take special precautions while you are taking this medicine.

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

Your doctor can discuss with you the benefits and any risks of taking this medicine during pregnancy.

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

This medicine stops the production of breast milk due to its effect on prolactin. You will not be able to breast-feed while you are taking it.

Tell your doctor if you are lactose intolerant or you have an intolerance to some sugars.

This medicine contains lactose.

Tell your doctor if you are allergic to any other medicines, foods, dyes or preservatives.

Your doctor will want to know if you are prone to allergies.

Taking other medicines

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

It is possible that Norprolac and other medicines that affect prolactin may interfere with each other. This includes some medicines used to treat mental illness.

You may need different amounts of your medicines, or you may need to take different medicines. Your doctor and pharmacist have more information.

If you have not told your doctor about any of these things, tell him/her before you start taking this medicine.

How to take Norprolac

Follow all directions given to you by your doctor and pharmacist carefully.

These instructions may differ from the information contained in this leaflet.

If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

How much to take

You will usually begin treatment with the Norprolac starter pack. It contains 3 light pink 25 microgram tablets and 3 pale blue 50 microgram tablets. You will take the pink tablets once each day for 3 days, followed by the pale blue tablets once each day for 3 days.

After that, the dose you take each day may be slowly increased, depending on how well your prolactin levels are controlled. Packs of 75 microgram tablets are available for this purpose.

How to take it

Take the tablet once each day at bedtime with some food.

Taking it with food will help to prevent stomach upset.

How long to take it

Continue taking Norprolac for as long as your doctor recommends.

Your doctor will check your progress to make sure the medicine is working and will discuss with you how long your treatment should continue.

If you forget to take it

If it is almost time for your next dose, skip the dose you missed and take the next dose when you are meant to.

Otherwise, take it as soon as you remember, and then go back to taking it as you would normally.

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

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

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

If you take too much (Overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone number 13 11 26), or go to Accident and Emergency at your nearest hospital if you think that you or anyone else may have taken too much Norprolac. Do this even if there are no signs of discomfort or poisoning. Keep the telephone numbers for these places handy.

Some of the symptoms of an overdose may include nausea, vomiting, sleepiness, dizziness, light-headedness and hallucinations (seeing or hearing things that are not there).

While you are taking Norprolac

Things you must do

If you do not wish to become pregnant, you must use a reliable means of contraception.

As your prolactin levels become lower, your menstrual periods may return to normal and you could become pregnant.

Keep all of your doctor's appointments so that your progress can be checked.

Your doctor may want to do some tests from time to time.

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking Norprolac.

Tell any other doctor, dentist or pharmacist who treats you that you are taking this medicine.

Things you must not do

Do not give this medicine to anyone else even if their condition seems similar to yours.

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

Things to be careful of

While you are taking Norprolac, be careful to get up slowly from a sitting or lying position.

This medicine can make you dizzy, lightheaded or faint, especially when you first take it. This is because your blood pressure has suddenly dropped. Taking the dose at bedtime and being careful when standing up will help your body get used to the change in blood pressure and will reduce the risk of falling.

Be careful driving, operating machinery or doing jobs that require you to be alert until you know how Norprolac affects you.

Norprolac can make you dizzy, lightheaded or faint and it can also cause extreme sleepiness or mental changes in a few people. If you have any of these symptoms, do not drive or do anything else that could be dangerous.

Be careful when drinking alcohol while taking Norprolac.

The combination may cause unwanted side effects. Your tolerance for alcohol may be lower than usual.

Side effects

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

All medicines 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.

Do not be alarmed by these lists of possible side effects. You may not experience any of them. Ask your doctor or pharmacist to answer any questions you may have.

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

- nausea or vomiting
- dizziness or light-headedness, especially on standing up
- drowsiness or sleepiness (if you have extreme sleepiness, tell your doctor immediately)
- headache
- tiredness
- mental changes such as confusion, changes in behaviour, hallucinations (seeing or hearing things that are not there)
- loss of appetite
- pain in the abdomen
- constipation or diarrhoea
- nasal congestion
- muscular weakness.

The following side effects have also been reported in patients taking drugs like Norprolac:

- compulsive behaviour such as gambling, increase in sex drive, increased libido, compulsive spending and buying or compulsive eating.

This possible behaviour may have serious financial and social consequences.

Tell your doctor if you notice anything else that is making you feel unwell.

Some people may have other side effects not yet known or mentioned in this leaflet.

After using Norprolac

Storage

- keep your medicine in the original container until it is time to take it
- store it in a cool dry place
- do not store it or any other medicine in the bathroom or near a sink
- do not leave it in the car or on window sills.

Keep the medicine 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 taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

Starter packs of Norprolac contain six tablets:

- three light pink 25 microgram tablets marked with "NORPROLAC" on one side and "25" on the other side; and

- three pale blue 50 microgram tablets marked with "NORPROLAC" on one side and "50" on the other side.

Maintenance packs of Norprolac contain 30 tablets:

- pale blue 50 micrograms tablets (as above) - Not marketed
- off-white 75 microgram tablets marked with "NORPROLAC" on one side and "75" on the other side
- off-white 150 micrograms tablets marked with "NORPROLAC" on one side and "150" on the other side - Not marketed.

Ingredients

Norprolac tablets contain 25, 50, 75 or 150 micrograms of the active ingredient, quinagolide (as the hydrochloride salt). They also contain:

- magnesium stearate
- silica colloidal anhydrous
- hypromellose
- maize starch
- microcrystalline cellulose
- lactose
- red iron oxide CI77491 (25 microgram tablet only)
- indigo carmine CI 73015 (50 microgram tablet only).

Sponsor

Norprolac is supplied in Australia by:

Ferring Pharmaceuticals Pty Ltd

Suite 2, Level 1, Building 1,

20 Bridge Street

Pymble, NSW 2073

This leaflet was prepared in June 2014.

Australian Registration Number:

Starter pack AUST R 48993

50 micrograms AUST R 48978 - Not marketed

75 microgram AUST R 48991

150 micrograms AUST R 48992 - Not marketed