

Package Leaflet: Information for the user

Norprolac 25 microgram + 50 microgram tablets

Norprolac 75 microgram tablets

Norprolac 150 microgram tablets

Quinagolide

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again
- If you have any further questions, ask your doctor or pharmacist
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Norprolac is and what it is used for
2. What you need to know before you take Norprolac
3. How to take Norprolac
4. Possible side effects
5. How to store Norprolac
6. Contents of the pack and other information

1. What Norprolac is and what it is used for

Norprolac contains quinagolide which belongs to a group of medicines known as prolactin inhibitors. Quinagolide reduces the secretion of the hormone prolactin.

Norprolac is used to treat elevated levels of prolactin caused by prolactin-secreting tumours of the pituitary gland or by unknown causes.

2. What you need to know before you take Norprolac

Do not take Norprolac:

- if you are allergic to quinagolide or any of the other ingredients of this medicine (listed in section 6).
- if you have severely impaired kidney or liver function.

Warnings and precautions

Talk to your doctor or pharmacist before taking Norprolac

- if you have a prolactin-related fertility disorder, as fertility may be restored by treatment with Norprolac. Women of child-bearing age who do not wish to become pregnant should use a reliable method of contraception during treatment with Norprolac. (See also section “Pregnancy, breast-feeding and fertility”.)
- if you have any of the following diseases: psychiatric disorders or impaired liver or kidney function.
- if you are a child or adolescent under the age of 18.

- if you are elderly.

Tell your doctor if you or your family/carer notices that you are developing urges or cravings to behave in ways that are unusual for you and you cannot resist the impulse, drive or temptation to carry out certain activities that could harm yourself or others. These are called impulse control disorders and can include

behaviours such as addictive gambling, excessive eating or spending, an abnormally high sex drive or an increase in sexual thoughts or feelings. Your doctor may need to adjust or stop your dose.

Norprolac may cause temporary fall of blood pressure when suddenly standing up. You might experience symptoms as light-headedness, and it may, in rare cases, result in fainting.

It is recommended that you get your blood pressure checked by your physician during the first days of treatment and after increase in dosage.

The monitoring of your blood pressure is more relevant in case you have a severe heart disease.

Children and adolescents

The experience in children and adolescents is limited.

Other medicines and Norprolac

Tell your doctor if you are taking, have recently taken or might take any other medicines.

Other medicines may affect the activity and tolerability of Norprolac;

- medicines which block the dopamine receptor (e.g. antipsychotic medicines) may decrease the prolactin lowering effect of Norprolac.

- medicines which interfere with serotonin receptors (e.g. antidepressants) or dopamine receptors (e.g. medicines to treat Parkinson's disease, severe migraine etc.).

- medicines known to effectively block the enzymes involved in the breakdown of medicines.

Norprolac with food, drink and alcohol

The tolerability of Norprolac may be reduced by alcohol

Pregnancy, breast-feeding and fertility

Experience with taking this medicine during pregnancy is limited. If you become pregnant or you are planning a pregnancy while you are on Norprolac treatment, please consult your doctor.

Norprolac treatment should be discontinued when pregnancy is confirmed, unless your doctor tells you otherwise.

Breast-feeding is not normally possible because Norprolac reduces production of breast-milk. You should not breast-feed even if it is possible to do so. This is because it is not known whether quinagolide passes into breast-milk.

Fertility may be restored by treatment with Norprolac. If you do not wish to become pregnant use a reliable method of contraception during treatment with Norprolac (See section 2 above).

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

Driving and using machines

In some persons, Norprolac may cause a reduced ability to react during the first days of treatment, which should be taken into consideration when acute alertness is required, e.g. when driving or when performing precision work.

In rare cases some users may suddenly fall asleep without feeling tired beforehand. If you experience this you should not drive or engage in activities where impaired alertness may put yourself or others at risk of serious injury (e.g. operating machinery).

Norprolac contains lactose

If you have been told by your doctor that you have intolerance to some sugars, then contact your doctor before taking this medicinal product.

3. How to take Norprolac

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

Adults

Norprolac should be taken together with food once daily in the evening.

The dosage is individual and the doctor will prescribe the dose most suitable for you.

The treatment is usually started with a dose of 25 microgram once daily for the first three days followed by 50 microgram once daily for the next 3 days. From day 7 the dosage is 75 microgram daily, which may be increased until the optimal dose is reached. The normal dose is 75-150 microgram daily. Some patients may need 300 microgram a day or more

Use in children and adolescents

The experience in children and adolescents is limited.

Elderly

The experience in elderly is limited.

If you take more Norprolac than you should

If you have taken more Norprolac than you should or if a child has taken the medicine by accident please contact your doctor or nearest hospital.

Expected symptoms of overdose are; nausea, vomiting, headache, dizziness, drowsiness, lowered blood pressure and hallucinations.

If you forget to take Norprolac

If you forget to take Norprolac for one day, you keep taking the medicine as usual the next day.

Do not take a double dose the following day, to make up for a forgotten dose, as this might cause unwanted side effects.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Most of the side effects are dose dependent, therefore, do not change the dose prescribed without the doctors knowledge. Most side effects appear during the first days of treatment and tend to disappear when treatment is continued.

Very common: may affect more than 1 in 10 people

- dizziness
- headache
- nausea
- vomiting
- fatigue

Common: may affect up to 1 in 10 people

- temporary fall of blood pressure when suddenly standing up (may in rare cases result in fainting).
- Anorexia (loss of appetite)
- difficulty in sleeping
- nasal congestion

- abdominal pain
- constipation
- diarrhoea
- muscular weakness

Rare: may affect up to 1 in 1,000 people

- acute psychosis which reverses when treatment is stopped.
- somnolence (extreme drowsiness)

Other: frequency cannot be estimated from the available data

- inability to resist the impulse, drive or temptation to perform an action that could be harmful to you or others, which may include:
 - Strong impulse to gamble excessively despite serious personal or family consequences.
 - Altered or increased sexual interest and behaviour of significant concern to you or to others, for example, and increased sexual drive.
 - Uncontrolled excessive shopping or spending
 - Binge eating (eating large amounts of food in a short time period) or compulsive eating (eating more food than normal and more than is needed to satisfy your hunger)

Tell your doctor if you experience any of these behaviours; they will discuss ways of managing or reducing the symptoms.

The risk of hypersensitive reactions could not be excluded.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via <the national reporting system> <[to be completed nationally]>. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Norprolac

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and blister after EXP. The expiry date refers to the last day of that month.

Store in the original package in order to protect from light and moisture. Do not store above 25 °C.

Do not throw away any medicine via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Norprolac contains

Tablets 25 microgram:

Active substance: 25 microgram quinagolide as quinagolide hydrochloride.

Other ingredients: lactose monohydrate, red iron oxide (E172), microcrystalline cellulose, maize starch, hypromellose, magnesium stearate, anhydrous colloidal silica.

Tablets 50 microgram:

Active substance: 50 microgram quinagolide as quinagolide hydrochloride
Other ingredients: lactose monohydrate, indigo carmine (E132), microcrystalline cellulose, maize starch, hypromellose, magnesium stearate, anhydrous colloidal silica.

Tablets 75 microgram:

Active substance: 75 microgram quinagolide as quinagolide hydrochloride
Other ingredients: lactose monohydrate, microcrystalline cellulose, maize starch, hypromellose, magnesium stearate, anhydrous colloidal silica.

Tablets 150 microgram:

Active substance: 150 microgram quinagolide as quinagolide hydrochloride
Other ingredients: lactose monohydrate, microcrystalline cellulose, maize starch, hypromellose, magnesium stearate, anhydrous colloidal silica.

What Norprolac looks like and contents of the pack

Norprolac 25 microgram tablets:

Light pink with isolated pigment spots, circular, flat, bevelled edge, 7 mm in diameter.
Inscriptions: "NORPROLAC" circular on one side and "25" linear on the other side.

Norprolac 50 microgram tablets:

Light blue with isolated pigment spots, circular, flat, bevelled edge, 7 mm in diameter.
Inscriptions: "NORPROLAC" circular on one side and "50" linear on the other side.

Norprolac 75 microgram tablets:

White, circular, flat, bevelled edge, 7 mm in diameter. Inscriptions: "NORPROLAC" circular on one side and "75" linear on the other side.

Norprolac 150 microgram tablets:

White, circular, flat, bevelled edge, 9 mm in diameter. Inscriptions: "NORPROLAC" circular on one side and "150" linear on the other side.

Package sizes

Titration package 25 + 50 microgram: 3+3 tablets.
Packed in a blister of ALU/PVC/PVDC which is sealed in a moisture-proof aluminium bag.
The outer package is carton.

75 microgram: 30 tablets

150 microgram: 30 tablets.

Packed in blisters of ALU/ALU

The outer package is carton.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

<[To be completed nationally]>

Manufacturer
Ferring GmbH
Wittland 11
D-24109 Kiel

Germany

This leaflet was last revised in 22015-10-14