Package leaflet: Information for the user

Norprolac® 75 micrograms tablets

(quinagolide hydrochloride)

Read all of this leaflet carefully before you start taking this medicine.
- Keep this leaflet, you may need to use it again.
- If you have further questions, please ask your doctor or pharmacist.
- This medicine has been prescribed for you personally and you should not pass it on to others. It may harm them, even if their symptoms are the same as yours.

The name of your medicine is Norprolac 75 micrograms tablets but will be referred to as Norprolac throughout this leaflet.

In this leaflet:

1. What Norprolac is and what it is used for

Norprolac is for oral use only. It is available in strengths of 25 micrograms, 50 micrograms and 75 micrograms. Norprolac contains quinagolide hydrochloride which decreases the production of the hormone prolactin.

Norprolac is used to treat conditions resulting from high levels of prolactin in the blood (hyperprolactinaemia) including:
- excess production of breast milk
- changes in menstrual bleeding patterns
- infertility
- reduced sexual drive.

2. Before you take Norprolac

Do not take Norprolac:
- if you have a medical condition affecting your liver or kidneys
- if you are allergic to any of the ingredients listed in section 6

If you are pregnant or planning a pregnancy, please refer to the pregnancy section of this leaflet.

Before taking Norprolac:
- please consult your doctor if you have ever had any mental illness.
- Norprolac may cause your blood pressure to drop when you stand up, particularly for the first few days of treatment or following an increase in your dosage. This may result in reduced alertness or fainting. To avoid this, stand up slowly from a sitting or lying down position. Your doctor will normally check your blood pressure during the first few days of treatment and when increasing your dosage.
- Inform 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.
- Tell your doctor if you experience symptoms such as depression, apathy, anxiety, fatigue, sweating or pain after reducing your dose or stopping Norprolac treatment.

Taking/using other medicines:
Please inform your doctor or pharmacist if you are taking or have recently taken or used any other medicines – even those not prescribed.

Taking Norprolac with drink:
Drinking alcohol may increase the side effects of Norprolac. If this happens, you should avoid drinking alcohol while you are on treatment with Norprolac.

Pregnancy:
- Fertility may be restored while you are on Norprolac, so women of child-bearing age who do not wish to become pregnant should use a reliable method of contraception.
- If you are planning a pregnancy, it is recommended that Norprolac is stopped when pregnancy is confirmed. However, some patients may need to continue treatment with Norprolac during pregnancy. If you become pregnant while you are on Norprolac, tell your doctor as soon as possible.

Breast-feeding:
Norprolac reduces production of breast-milk, so it is not normally possible to breast-feed while you are taking it. You should not breast-feed even if it is possible to do so. This is because it is not known whether the active ingredient in Norprolac passes into breast-milk.

Driving and using machines:
While you are on Norprolac, caution is advised if you drive or operate machinery. This is because Norprolac:
- may cause your blood pressure to drop, particularly during the first few days of treatment or following dosage increase. This may result in reduced alertness or fainting.
- may also cause somnolence (drowsiness or sleepiness).

If you experience any of these effects, please do not drive or engage in any other activity (e.g. operating machinery) where impaired alertness may put you or others at risk of serious injury or death and please consult your doctor, as your dose may need to be adjusted.

Important information about some of the ingredients in Norprolac:
Norprolac contains the ingredient lactose. Therefore, if you have been told by your doctor that you have an intolerance to some sugars (including lactose), contact your doctor before taking this medicinal product.

3. How to take Norprolac

Adults:
It is important to take your medicine as directed by your doctor. The label on your medicine should tell you how much to take and when to take it. If it does not, or you are not sure, ask your doctor or pharmacist.

Elderly:
Take this medicine only if your doctor has decided that this is appropriate for you. Follow the instructions given to you very carefully.

The tablets should only be removed from the blister when it is time to take your medicine.
- Your treatment will normally begin with the ‘starter pack’ and you will take one 25 micrograms tablet daily (one light pink tablet) for the first three days (marked Day 1, Day 2 and Day 3 on the blister strip).
- This is followed by one 50 micrograms tablet daily (one very pale blue tablet) for the next three days (marked Day 4, Day 5 and Day 6 on the blister strip).
- From Day 7, the recommended dose is one 75 micrograms tablet daily (one whitish tablet). Most patients require a daily dose of 75 to 150 micrograms. Some patients require a daily dose of 300 micrograms or higher. Your doctor will tell you if you need a higher dose. You should not change the dose yourself.

Norprolac should be taken once daily at bedtime preferably with a snack. Remove the tablet from the blister by pushing it through the foil and place it in your mouth. Swallow it with a mouthful of water.

If you take more Norprolac than you should:
If you take more Norprolac than you should, tell your doctor immediately or go to your nearest casualty department.

If you forget to take Norprolac:
If you forget to take a dose, take it as soon as you remember. However, if you do not remember until it is nearly time for the next dose, take your next dose as usual and carry on as before. Do not take double doses to make up for a dose that you miss.

4. Possible side effects

Like all medicines, Norprolac can have side effects. These are most common during the first few days of treatment and tend to go away on continuing treatment.

Very common side effects (affect more than 10 of every 100 patients treated):
- Nausea
- Vomiting
- Headache
- Dizziness
- Tiredness

Common side effects (affect between 1 and 10 of every 100 patients treated):
- Loss of appetite
- Abdominal pain
- Constipation or diarrhoea
- Insomnia
- Increased water retention
- Flushing
- Nasal congestion and a drop in blood pressure, which may result in fainting.

Rare side effects (affect between 1 and 10 of every 10,000 patients treated):
- Somnolence (drowsiness or sleepiness).

Very rare side effects (affect less than 1 of every 10,000 patients treated):
- Treatment with Norprolac has been associated with a change in mental status, which is reversible when treatment is stopped.

Other side effects include:
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, an increased sexual drive.
- uncontrollable 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.

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the **Google Play** or **Apple App Store**. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Norprolac

- Keep out of the sight and reach of children.
- Do not take your tablets after the expiry date which is stated on the carton/blister label after 'Exp'. The expiry date refers to the last day of that month.
- Do not store above 25° C.
- Store in the original package in order to protect from light and moisture.
- If the tablet becomes discoloured or shows any signs of deterioration, seek the advice of your pharmacist.
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Further information

The active ingredient is quinagolide (as quinagolide hydrochloride). Each tablet contains 81.9 micrograms quinagolide hydrochloride equivalent to 75 micrograms of the active ingredient, quinagolide.

The other ingredients are:
lactose monohydrate, microcrystalline cellulose, maize starch, hypromellose, magnesium stearate, colloidal anhydrous silica.

Norprolac are white, round tablets marked with "NORPROLAC" on one side and "75"on the other side. Norprolac is available in blister packs containing 30 tablets.

Manufactured by: Ferring GmbH**,** Wittland 11, D-24109 Kiel,Germany.

Procured from within the EU & repackaged by the Product Licence holder: B&S Healthcare, Unit 4, Bradfield Road, Ruislip, Middlesex, HA4 0NU, UK.

Norprolac® 75 micrograms tablets; PL 18799/2361

Leaflet date: 23.06.2020 **POM**

Blind or partially sighted?
Is this leaflet hard to see or read?
Call **0208 515 3763** to obtain the leaflet in a format suitable for you.

Package leaflet: Information for the user

Quinagolide 75 micrograms tablets

(quinagolide hydrochloride)

Read all of this leaflet carefully before you start taking this medicine.
- Keep this leaflet, you may need to use it again
- If you have further questions, please ask your doctor or pharmacist
- This medicine has been prescribed for you personally and you should not pass it on to others. It may harm them, even if their symptoms are the same as yours.

The name of your medicine is Quinagolide 75 micrograms tablets but will be referred to as Quinagolide throughout this leaflet.

In this leaflet:

1. What Quinagolide is and what it is used for

Quinagolide is for oral use only. It is available in strengths of 25 micrograms, 50 micrograms and 75 micrograms. Quinagolide contains quinagolide hydrochloride which decreases the production of the hormone prolactin.

Quinagolide is used to treat conditions resulting from high levels of prolactin in the blood (hyperprolactinaemia) including:
- excess production of breast milk
- changes in menstrual bleeding patterns
- infertility
- reduced sexual drive.

2. Before you take Quinagolide

Do not take Quinagolide:
- if you have a medical condition affecting your liver or kidneys
- if you are allergic to any of the ingredients listed in section 6

If you are pregnant or planning a pregnancy, please refer to the pregnancy section of this leaflet.

Before taking Quinagolide:
- please consult your doctor if you have ever had any mental illness.
- Quinagolide may cause your blood pressure to drop when you stand up, particularly for the first few days of treatment or following an increase in your dosage. This may result in reduced alertness or fainting. To avoid this, stand up slowly from a sitting or lying down position. Your doctor will normally check your blood pressure during the first few days of treatment and when increasing your dosage.
- Inform 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.

Tell your doctor if you experience symptoms such as depression, apathy, anxiety, fatigue, sweating or pain after reducing your dose or stopping Quinagolide treatment.

Taking/using other medicines:
Please inform your doctor or pharmacist if you are taking or have recently taken or used any other medicines – even those not prescribed.

Taking Quinagolide with drink:
Drinking alcohol may increase the side effects of Quinagolide. If this happens, you should avoid drinking alcohol while you are on treatment with Quinagolide.

Pregnancy:
- Fertility may be restored while you are on Quinagolide, so women of child-bearing age who do not wish to become pregnant should use a reliable method of contraception.
- If you are planning a pregnancy, it is recommended that Quinagolide is stopped when pregnancy is confirmed. However, some patients may need to continue treatment with Quinagolide during pregnancy. If you become pregnant while you are on Quinagolide, tell your doctor as soon as possible.

Breast-feeding:
Quinagolide reduces production of breast-milk, so it is not normally possible to breast-feed while you are taking it. You should not breast-feed even if it is possible to do so. This is because it is not known whether the active ingredient in Quinagolide passes into breast-milk.

Driving and using machines:
While you are on Quinagolide, caution is advised if you drive or operate machinery. This is because Quinagolide:
- may cause your blood pressure to drop, particularly during the first few days of treatment or following dosage increase. This may result in reduced alertness or fainting.
- may also cause somnolence (drowsiness or sleepiness).

If you experience any of these effects, please do not drive or engage in any other activity (e.g. operating machinery) where impaired alertness may put you or others at risk of serious injury or death and please consult your doctor, as your dose may need to be adjusted.

Important information about some of the ingredients in Quinagolide:
Quinagolide contains the ingredient lactose. Therefore, if you have been told by your doctor that you have an intolerance to some sugars (including lactose), contact your doctor before taking this medicinal product.

3. How to take Quinagolide

Adults:
It is important to take your medicine as directed by your doctor. The label on your medicine should tell you how much to take and when to take it. If it does not, or you are not sure, ask your doctor or pharmacist.

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Quinagolide should be taken once daily at bedtime preferably with a snack. Remove the tablet from the blister by pushing it through the foil and place it in your mouth. Swallow it with a mouthful of water.

If you take more Quinagolide than you should:
If you take more Quinagolide than you should, tell your doctor immediately or go to your nearest casualty department.

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4. Possible side effects

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