

PACKAGE LEAFLET: INFORMATION FOR THE USER

Noletil XL 200 mg prolonged-release tablets
Noletil XL 300 mg prolonged-release tablets
Noletil XL 400 mg prolonged-release tablets

quetiapine

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 the side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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

1. What Noletil XL is and what it is used for

Noletil XL contains a substance called quetiapine. This belongs to a group of medicines called anti-psychotics. Noletil XL can be used to treat several illnesses, such as:

- Schizophrenia: where you may hear or feel things that are not there, believe things that are not true or feel unusually suspicious, anxious, confused, guilty, tense or depressed.
- Mania: where you may feel very excited, elated, agitated, enthusiastic or hyperactive or have poor judgment including being aggressive or disruptive.
- Bipolar depression and major depressive episodes in major depressive disorder: where you may feel sad all the time or you may find that you feel depressed, feel guilty, lack energy, lose your appetite or can't sleep.

When Noletil XL is being taken to treat major depressive episodes in major depressive disorder, it will be taken in addition to another drug being used to treat this illness.

Your doctor may continue to prescribe Noletil XL even when you are feeling better.

2. What you need to know before you take Noletil XL

Do not take Noletil XL if:

- You are allergic (Hypersensitive) to Quetiapine or any of the other ingredients of Noletil XL. (See section 6: Further Information)
- you are taking any of the following medicines:
 - Some medicines for HIV
 - Azole medicines (for fungal infections)

- Erythromycin or clarithromycin (for infection)
- Nefazodone (for depression).

Warnings and precautions

Do not take Noletil XL if the above applies to you. If you are not sure than talk to your doctor or pharmacist before you take Noletil XL.

Take special care with Noletil XL:

Before you take your medicine, tell your doctor if:

- You, or someone in your family, have or have had any heart problems, for example heart rhythm problems or if you are taking any medicines that may have an impact on the way your heart beats.
- You have low blood pressure.
- You have had a stroke, especially if you are elderly.
- You have problems with your liver.
- You have ever had a fit (seizure).
- You know that you have had low levels of white blood cells in the past (which may or may not have been caused by other medicines).
- You have diabetes or have a risk of getting diabetes. If you do, your doctor may check your blood sugar levels while you are taking Noletil XL.
- You or someone else in your family has a history of blood clots, as medicines like these have been associated with formation of blood clots.
- You are an elderly person with dementia (loss of brain function). If you are, Noletil XL should not be taken because the group of medicines that Noletil XL belongs to may increase the risk of stroke, or in some cases the risk of death, in elderly people with dementia.

Tell your doctor immediately if you experience any of the following after taking Noletil XL:

- A combination of fever, severe muscle stiffness, sweating or a lowered level of consciousness (a disorder called “neuroleptic malignant syndrome”). Immediate medical treatment may be needed.
- Have a fast and irregular heartbeat, even when you are at rest, palpitations, breathing problems, chest pain or unexplained tiredness. Your doctor will need to check your heart and if necessary, refer you to a cardiologist immediately.
- Uncontrollable movements, mainly of your face or tongue.
- Dizziness or a severe sense of feeling sleepy. This could increase the risk of accidental injury (fall) in elderly patients.
- Fits (seizures).
- A long-lasting and painful erection (Priapism).

These conditions can be caused by this type of medicines.

Thoughts of suicide and worsening of your depression

If you are depressed you may sometimes have thoughts of harming or killing yourself. These may be increased when first starting treatment, since these medicines all take time to work, usually about two weeks but sometimes longer. You may be more likely to think like this if you are a young adult. Information from clinical trials has shown an increased risk of suicidal thoughts and/or suicidal behaviour in young adults aged less than 25 years with depression.

If you have thoughts of harming or killing yourself at any time, contact your doctor or go to a hospital straight away. You may find it helpful to tell a relative or close friend that you are depressed, and ask

them to read this leaflet. You might ask them to tell you if they think your depression is getting worse, or if they are worried about changes in your behaviour.

Weight gain has been seen in patients taking Noletil XL. You and your doctor should check your weight regularly.

Other medicine and Noletil XL:

Please tell your doctor if you are taking or have recently taken any other medicines because it may affect the way the medicines work. This includes medicines that you buy without a prescription and herbal medicines.

Do not take Noletil XL if you are taking any of the following medicines:

- Some medicines for HIV which are strong inhibitors of cytochrome P450 (CYP) 3A4.
- Azole medicines (for fungal infections)
- Erythromycin or clarithromycin (for infections).
- Nefazodone (for depression)

Tell your doctor if you are taking any of the following medicines:

- Epilepsy medicines (like phenytoin or carbamazepine).
- High blood pressure medicines.
- Barbiturates (for difficulty sleeping).
- Thioridazine (another anti-psychotic medicine).
- Medicines that have an impact on the way your heart beats, for example, drugs that can cause an imbalance in electrolytes (low levels of potassium or magnesium) such as diuretics (water pills) or certain antibiotics (drugs to treat infections).
- HIV protease inhibitors like boceprevir or indinavir.

Before you stop taking any of your medicines, please talk to your doctor or pharmacist first.

Noletil XL with food and, drink and alcohol

- Noletil XL can be affected by food and you should therefore take your tablets at least one hour before a meal or prior to bedtime.
- Be careful how much alcohol you drink. This is because the combined effect of Noletil XL and alcohol can make you sleepy.
- Do not drink grapefruit juice while you are taking Noletil XL. It can affect the way the medicine works.

Pregnancy, breast-feeding and fertility

If you are pregnant, trying to get pregnant, or breast-feeding, talk to your doctor or pharmacist before taking Noletil XL.

You should not take Noletil XL during pregnancy unless this has been discussed with your doctor. Noletil XL should not be taken if you are breast-feeding.

The following symptoms may occur in newborn babies, of mothers that have used Noletil XL in the last trimester (last three months of their pregnancy): shaking, muscle stiffness and/or weakness, sleepiness, agitation, breathing problems, and difficulty in feeding. If your baby develops any of these symptoms you may need to contact your doctor.

Driving and using machines

Your tablets may make you feel sleepy. Do not drive or use any tools or machines until you know how the tablets affect you.

Important information about some of the ingredients of Noletil XL.

Noletil XL contains lactose which is a type of sugar. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

Noletil XL contains less than 1 mmol sodium (23 mg) per Noletil XL 200mg, 300mg and 400mg prolonged release tablets, that is to say essentially 'sodium-free'.

Effect on Urine Drug Screens

If you are having a urine drug screen, taking Noletil XL may cause positive results for methadone or certain drugs for depression called tricyclic antidepressants (TCAs) when some test methods are used, even though you may not be taking methadone or TCAs. If this happens, a more specific test can be performed.

3. How to take Noletil XL

Always take Noletil XL exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure. Your doctor will decide on your starting dose. The maintenance dose (daily dose) will depend on your illness and needs but will usually be between 150 mg and 800 mg.

- You will take your tablets once a day.
- Swallow your tablets whole with a drink of water.
- Do not split, chew or crush the tablets.
- Take your tablets without food (at least one hour before a meal or at bedtime, your doctor will tell you when).
- Do not stop taking your tablets even if you feel better, unless your doctor tells you.
- Do not drink grapefruit juice while you are taking Noletil XL. It can affect the way the medicine works.

Liver problems

If you have liver problems your doctor may change your dose.

Elderly people

If you are elderly your doctor may change your dose.

Children and adolescents under 18 years

Noletil XL should not be used by children and adolescents aged under 18 years.

If you take more Noletil XL than you should

If you take more Noletil XL than prescribed by your doctor, you may experience sleepiness, dizziness and abnormal heart beats. Go to your doctor or nearest hospital straight away. Take the Noletil XL with you.

If you forget to take a dose of Noletil XL

If you forget to take a dose, take it as soon as you remember. If it is almost time to take the next dose, wait until then. Do not take a double dose to make up for a forgotten tablet.

If you stop taking Noletil XL

If you suddenly stop taking Noletil XL, you may feel nauseous or vomit, or be unable to sleep or have jerky movements, or your original illness might come back. Your doctor may suggest you reduce the dose gradually before stopping treatment.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

Not all dosing regimes are practical/possible with the present strengths of Noletil XL and other authorised products containing quetiapine are available

4. Possible Side Effect

Like all medicines, Noletil XL can cause side effects, although not everybody gets them.

Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS). Widespread rash, high body temperature, liver enzyme elevations, blood abnormalities (eosinophilia), enlarged lymph nodes and other body organs involvement (Drug Reaction with Eosinophilia and Systemic Symptoms which is also known as DRESS or drug hypersensitivity syndrome). Stop using quetiapine if you develop these symptoms and contact your doctor or seek medical attention immediately.

If any of the following side effects get serious, or if you notice side effects not listed in this leaflet, please tell your doctor or pharmacist:

Very common (affects more than 1 in 10 patients):

- Dizziness (may lead to falls), headache, dry mouth
- Feeling sleepy (this may go away with time, as you keep taking Noletil XL) (may leads to falls).
- Discontinuation symptoms (symptoms which occur when you stop taking quetiapine) include not being able to sleep (insomnia), feeling sick (nausea), headache, diarrhoea, being sick (vomiting), dizziness and irritability. Gradual withdrawal over a period of at least 1 to 2 weeks is advisable.
- Putting on weight.
- Abnormal muscle movements. These include difficulty starting muscle movements, shaking, feeling restless or muscle stiffness without pain.

Common (affects less than 1 in 10 patients):

- Rapid heartbeat
- Feeling like your heart is pounding, racing or has skipped beats.
- Stuffy nose
- Constipation, upset stomach (indigestion)
- Feeling weak, fainting (may lead to falls)
- Swelling of arms or legs
- Low blood pressure when standing up. This may make you feel dizzy or faint (may led to falls)
- Increased levels of sugar in the blood.
- Blurred vision
- Abnormal dreams and nightmares
- Feeling more hungry
- Feeling irritated
- Disturbance in speech or language.
- Thoughts of suicide and worsening of your depression
- Shortness of breath.
- Vomiting (mainly in the elderly).
- Fever.

Uncommon (affects less than 1 in 100 patients):

- Fits or seizures
- Allergic reactions that may include raised lumps (weals), swelling of the skin and swelling around the mouth.
- Unpleasant sensations in the legs (also called restless legs syndrome).
- Difficulty swallowing.
- Uncontrolled movements, mainly of your face or tongue.
- Sexual dysfunction.
- Worsening of pre-existing diabetes.
- Change in electrical activity of the heart seen on ECG (QT prolongation).

Rare (affects less than 1 in 1000 patients):

- A combination of high temperature (fever), sweating, stiff muscles, feeling very drowsy or faint (a disorder called “neuroleptic malignant syndrome”).
- Yellowing of the skin and eyes (jaundice).
- Inflammation of liver (Hepatitis).
- A long-lasting and painful erection (priapism).
- Swelling of breasts and unexpected production of breast milk (galactorrhoea).
- Menstrual disorder.
- Blood clots in the veins especially in the legs (symptoms include swelling, pain and redness in the leg), which may travel through blood vessels to the lungs causing chest pain and difficulty in breathing. If you notice any of these symptoms seek medical advice immediately.
- Walking, talking, eating or other activities while you are asleep.
- Body temperature decreased (hypothermia).
- Inflammation of the pancreas.

Very rare (affect less than 1 in 10,000 patients):

- Severe rash, blisters, or red patches on the skin.
- A severe allergic reaction (called anaphylaxis) which may cause difficulty in breathing or shock.
- Rapid swelling of the skin, usually around the eyes, lips and throat (angioedema).
- Inappropriate secretion of a hormone that controls urine volume.
- Breakdown of muscle fibers and pain in muscles (rhabdomyolysis).

Not known (cannot be estimated from the available data):

- Skin rash with irregular red spots (erythema multiforme)
- Serious, sudden allergic reaction with symptoms such as fever and blisters on the skin and peeling of the skin (toxic epidermal necrolysis)
- Neutropenia
- Drug withdrawal syndrome neonatal
- Disorder of the heart muscle (cardiomyopathy)
- Inflammation of the heart muscle (myocarditis)
- Inflammation of blood vessels (Vasculitis), often with skin rash with small red or purple bumps

The class of medicines to which Noletil XL belongs can cause heart rhythm problems, which can be serious and in severe cases may be fatal.

Some side effects are only seen when a blood test is taken. These include changes in the amount of certain fats (triglycerides and total cholesterol) or sugar in the blood, decreases in the number of certain types of blood cells, decrease in the amount of sodium in the blood and increases in the amount of the hormone prolactin in the blood. Increases in the hormone prolactin could in rare cases lead to the following:

- Men and women to have swelling of breasts and unexpectedly produce breast milk.
- Women to have no monthly period or irregular periods.

Therefore, your doctor may ask you to have blood tests from time to time.

Children and adolescent:

The same side effects that may occur in adults can also be present in children and adolescents.

The following side effects are only observed in children and adolescents:**Very common (affect more than 1 in 10 patients):**

Increase in blood pressure.

The following adverse events were observed more frequently in children and adolescents:

Very common (affect more than 1 in 10 patients):

- Increase in the amount of hormone called prolactin in the blood. Increasing amount of hormone called prolactin in rare cases can lead to the following:
 - Boys and girls to have swelling of breasts and unexpectedly produce breast milk.
 - Girls to have no monthly period or irregular periods.
- Increased appetite.

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 HPRA Pharmacovigilance
Earlsfort Terrace

IRL - Dublin 2

Tel: +353 1 6764971

Fax: +353 1 6762517

Website: www.hpra.ie

e-mail: medsafety@hpra.ie.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Noletil XL

- This medicinal product does not require any special storage conditions
- Keep this medicine out of the sight and reach of children.
- Do not use Noletil XL after the expiry date which is stated on the container and blister after EXP. The expiry date refers to the last day of that month.
- Do not throw away any medicines 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. Contents of the pack and other information

What Noletil XL contains

The active substance is Quetiapine (as Hemifumarate). Each Noletil XL contains either 200 mg, 300 mg or 400 mg of quetiapine (as quetiapine hemifumarate).

The other ingredients are Lactose monohydrate, Hypromellose, Sodium chloride, Povidone K-30, Talc, Magnesium stearate (E470b), Hypromellose 6 cP (E464), Titanium dioxide (E171), Macrogol 400. The 200mg and 300mg tablet also contain iron oxide yellow (E172).

What Noletil XL looks like and contents of the pack

Quetiapine Prolonged-release Tablets 200mg are Yellow coloured, round shaped, biconvex film coated tablets, debossed with 'I2' on one side and plain on other

Quetiapine Prolonged-release Tablets 300mg are Light yellow coloured, round shaped, biconvex film coated tablets, debossed with 'Q300' on one side and plain on other.

Quetiapine Prolonged-release Tablets 400mg are White coloured, round shaped, biconvex, film coated tablets debossed with 'I4' on one side and plain on other.

Pack sizes of 10, 30, 50, 60 and 100 tablets per pack are registered for all strengths. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

Bluefish Pharmaceuticals AB

P.O. Box 49013

100 28 Stockholm

Sweden

Manufacturer:

Bluefish Pharmaceuticals AB, Gavlegatan 22 113 30, Stockholm, Sweden

The medicinal product is authorized in the Member States of the EEA under the following names:

Name of member state	: Name of medicinal product
AT	: Quetiapine Bluefish 200 mg/300mg/400mg – Retardtabletten
FR	: QUETIAPINE ARROW LP 300mg/400mg comprimé à libération prolongée
IE	: Noletil XL 200/300/400 mg prolonged-release Tablet
PT	: Quetiapina Bluefish 200mg/300mg/400mg comprimidos de libertação prolongada

This leaflet was last updated in