PACKAGE LEAFLET: INFROMATION FOR THE USER
Notiabolfen XL 50 mg prolonged-release Tablet
Notiabolfen XL 200 mg prolonged-release Tablet
Notiabolfen XL 300 mg prolonged-release Tablet
Notiabolfen XL 400 mg prolonged-release Tablet
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 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 Notiabolfen XL Prolonged-release Tablet is and what it is used for

Notiabolfen XL Prolonged-release Tablet contains a substance called quetiapine. This belongs to a group of medicines called anti-psychotics. Notiabolfen XL Prolonged-release Tablet 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 feel sad. You may find that you feel depressed, feel guilty, lack energy, lose your appetite or can't sleep.

When Notiabolfen XL Prolonged-release Tablet 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 Notiabolfen XL Prolonged-release Tablet even when you are feeling better.

2. What you need to know before you take Notiabolfen XL Prolonged-release Tablets

Do not take Notiabolfen XL Prolonged-release Tablets:
- If you are allergic (hypersensitive) to quetiapine or any of the other ingredients of this medicine (listed in section 6).
- If you are taking any of the following medicines:
  - Some medicines for HIV

– Azole medicines (for fungal infections)
– Erythromycin or clarithromycin (for infections)
– Nefazodone (for depression).

Do not take Notiabolfen XL Prolonged-release Tablets if the above applies to you. Talk to your doctor or pharmacist before taking Notiabolfen XL Prolonged-release Tablet.

Warnings and precautions
Talk to your doctor or pharmacist or nurse before taking Notiabolfen XL Prolonged-release Tablet :

- You, or someone in your family, have or have had any heart problems, for example heart rhythm problems or weakening of the heart muscle or inflammation of the heart 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 have diabetes or have a risk of getting diabetes. If you do, your doctor may check your blood sugar levels while you are taking Notiabolfen XL Prolonged-release Tablet.
- 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 are an elderly person with dementia (loss of brain function). If you are, Notiabolfen XL Prolonged-release Tablet should not be taken because the group of medicines that Notiabolfen XL Prolonged-release Tablet belongs to may increase the risk of stroke, or in some cases the risk of death, in elderly people with dementia.
- You are an elderly person with Parkinson's disease/parkinsonism.
- 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.

- if you have or have had a condition where you stop breathing for short periods during your normal nightly sleep (called "sleep apnoea") and are taking medicines that slow down the normal activity of the brain ("depressants").
- if you have or have had a condition where you can't completely empty your bladder (urinary retention), have an enlarged prostate, a blockage in your intestines, or increased pressure inside your eye. These conditions are sometimes caused by medicines (called "anti-cholinergics") that affect the way nerve cells function in order to treat certain medical conditions.
- if you have a history of alcohol or drug abuse.

Tell your doctor immediately if you experience any of the following after taking Notiabolfen XL Prolonged-release Tablet :

- 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.
- 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).
- 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.

These conditions can be caused by this type of medicine.

Tell your doctor as soon as possible if you have:

- A fever, flu-like symptoms, sore throat, or any other infection, as this could be a result of a very low white blood cell count, which may require Notiabolfen XL Prolonged-release Tablet to be stopped and/or treatment to be given.
- Constipation along with persistent abdominal pain, or constipation which has not responded to treatment, as this may lead to a more serious blockage of the bowel.

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. These thoughts may also be increased if you suddenly stop taking your medication. 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.

Severe cutaneous adverse reactions (SCARs)
Severe cutaneous adverse reactions (SCARs) which can be life threatening or fatal have been reported very rarely with treatment of this medicine. These are commonly manifested by:

• Stevens-Johnson syndrome (SJS), a widespread rash with blisters and peeling skin, particularly around the mouth, nose, eyes and genitals
• Toxic Epidermal Necrolysis (TEN), a more severe form causing extensive peeling of the skin
• Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS) consists of flu-like symptoms with a rash, fever, swollen glands, and abnormal blood test results (including increased white blood cells (eosinophilia) and liver enzymes)

Stop using Notiabolfen XL Prolonged-release Tablet if you develop these symptoms and contact your doctor or seek medical attention immediately.

Weight gain
Weight gain has been seen in patients taking Notiabolfen XL Prolonged-release Tablet. You and your doctor should check your weight regularly.

Children and Adolescents
Notiabolfen XL Prolonged-release Tablet is not for use in children and adolescents below 18 years of age

Other medicines and Notiabolfen XL Prolonged-release Tablet:

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

Do not take Notiabolfen XL Prolonged-release Tablet if you are taking any of the following medicines
- Some medicines for HIV.
- 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 or Lithium (other 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).

- Medicines that can cause constipation.
- Medicines (called "anti-cholinergics") that affect the way nerve cells function in order to treat certain medical conditions.

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

Notiabolfen XL Prolonged-release Tablets with food, drink and alcohol

- Notiabolfen XL Prolonged-release Tablets 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 Notiabolfen XL Prolonged-release Tablets and alcohol can make you sleepy.
- Do not drink grapefruit juice while you are taking Notiabolfen XL Prolonged-release Tablets. It can affect the way the medicine works.

Pregnancy and breast-feeding
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.
You should not take Notiabolfen XL during pregnancy unless this has been discussed with your doctor. Notiabolfen XL should not be taken if you are breast-feeding.

The following symptoms which can represent withdrawal may occur in newborn babies, of mothers that have used Notiabolfen 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.

Notiabolfen XL Prolonged-release Tablets contains Lactose
Notiabolfen XL Prolonged-release Tablets contains lactose which is a type of sugar. If you have been told by your doctor that you have an intolerance to some sugars, talk to your doctor before taking this medicine.

Notiabolfen XL Prolonged-release Tablets contains sodium
Notiabolfen XL Prolonged-release Tablets contain less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

Effect on Urine Drug Screens
If you are having a urine drug screen, taking **Notiabolfen 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 Notiabolfen XL Prolonged-release Tablets

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

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.

Use in children and adolescents
Notiabolfen XL Prolonged-release Tablet should not be used by children and adolescents aged under 18 years.

If you take more Notiabolfen XL Prolonged-release Tablets than you should
If you take more Notiabolfen XL Prolonged-release Tablets than prescribed by your doctor, you may feel sleepy, feel dizzy and experience abnormal heart beats. Contact your doctor or nearest hospital straight away. Keep the Notiabolfen XL Prolonged-release Tablets with you.

If you forget to take Notiabolfen XL Prolonged-release Tablets
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 Notiabolfen XL Prolonged-release Tablets
If you suddenly stop taking Notiabolfen XL Prolonged-release Tablets, you may be unable to sleep (insomnia), or you may feel sick (nausea), or you may experience headache, diarrhoea, being sick (vomiting), dizziness or irritability. Your doctor may suggest you reduce the dose gradually before stopping treatment.

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

4. Possible side effects

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

Very common side effects : (may affect more than 1 in 10 people)

- Dizziness (may lead to falls), headache, dry mouth.
- Feeling sleepy (this may go away with time, as you keep taking Notiabolfen XL Prolonged-release Tablets) (may lead 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.
- Changes in the amount of certain fats (trigylcerids and total cholesterol).

Common side effects: (may affect up to 1 in 10 people) :

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

Uncommon side effects : (may affect up to 1 in 100 people)

- 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.
- Uncontrollable movements, mainly of your face or tongue.
- Sexual dysfunction.
- Diabetes
- Change in electrical activity of the heart seen on ECG (QT prolongation).
- A slower than normal heart rate which may occur when starting treatment and which may be associated with low blood pressure and fainting.
- Difficulty in passing urine.
- Fainting (may lead to falls).
- Stuffy nose.

- Decrease in the amount of red blood cells.
- Decrease in the amount of sodium in the blood.
- Worsening of pre-existing diabetes.
- Confusion.

Rare side effects : (may affect up to 1 in 1,000 people)

- 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 the 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
- A condition (called "metabolic syndrome") where you may have a combination of 3 or more of the following: an increase in fat around your abdomen, a decrease in "good cholesterol" (HDL-C), an increase in a type of fat in your blood called triglycerides, high blood pressure and an increase in your blood sugar.
- Combination of fever, flu-like symptoms, sore throat, or any other infection with very low white blood cell count, a condition called agranulocytosis.
- Bowel obstruction.
- Increased blood creatine phosphokinase (a substance from muscles).

Very rare side effects: (may affect up to 1 in 10,000 people)

- 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).
- A serious blistering condition of the skin, mouth, eyes and genitals (Stevens-Johnson syndrome). See section 2.
- Inappropriate secretion of a hormone that controls urine volume.
- Breakdown of muscle fibers and pain in muscles (rhabdomyolysis).

Not known: frequency 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) See section 2.
- Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS) consists of flu-like symptoms with a rash, fever, swollen glands, and abnormal blood test results (including increased white blood cells (eosinophilia) and liver enzymes) See section 2.
- Symptoms of withdrawal may occur in newborn babies of mothers that have used Notiabolfen XL Prolonged-release Tablet during their pregnancy
- Stroke.
- 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 Notiabolfen XL Prolonged-release Tablet 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, changes in the amount of thyroid hormones in your blood, increased liver enzymes, decreases in the number of certain types of blood cells, decrease in the amount of red blood cells, increased blood creatine phosphokinase (a substance in the muscles), 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.

Your doctor may ask you to have blood tests from time to time.

Additional Side effects in Children and adolescents:
The same side effects that may occur in adults may also occur in children and adolescents.

The following side effects have been seen more often in children and adolescents
or have not been seen in adults.

Very common: (may affect more than 1 in 10 people)
- Increase in the amount of a hormone called prolactin in the blood. Increase in the hormone prolactin could in rare cases 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.
- Vomiting
- Abnormal muscle movements. These include difficulty starting muscle movements, shaking feeling restless or muscle stiffness without pain.
- Increase in blood pressure.

Common: (may affect up to 1 in 10 people)
- Feeling weak, fainting (may lead to falls).
- Stuffy nose.
- Feeling irritated.

<u>Reporting of side effects</u>
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, Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Notiabolfen XL Prolonged-release Tablets

- 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 label, carton 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 throw away medicines you no longer use. These measures will help to protect the environment.
- This medicinal product does not require any special storage conditions.
-

6. Contents of the pack and other information

What Notiabolfen XL Prolonged-release Tablets contains

- The active substance is quetiapine. Each Notiabolfen XL Prolonged-release Tablet contains either 50 mg, 200 mg, 300 mg or 400 mg of quetiapine (as quetiapine fumarate).
- The other ingredients are:
  Tablet core: Lactose monohydrate, Hypromellose, Sodium chloride, Povidone K-30, Talc, and Magnesium stearate . The 50 mg tablet also contains silicified microcrystalline cellulose (Silicium dioxide & Microcrystalline Cellulose).

  Tablet coating: Titanium dioxide (E171), Macrogol 400 (E1521). The 50 mg tablet also contains Poly (Vinyl alcohol) (E1203), Talc (E553b) and Iron oxide red (E172). The 50 mg, 200mg and 300mg tablet also contain iron oxide yellow (E172). The 200 mg, 300 mg and 400 mg also contains Hypromellose 6 cP (E464)

What Notiabolfen XL Prolonged-release Tablets looks like and contents of the pack
Notiabolfen XL Prolonged-release Tablet 50mg is Peach colored, round shaped, biconvex film coated tablets, debossed with 'Q50' on one side and plain on the other.
Notiabolfen XL Prolonged-release Tablet 200mg is Yellow coloured, round shaped, biconvex film coated tablets, debossed with 'I2' on one side and plain on other. 200mg tablet diameter is approximately 9.6 mm.
Notiabolfen XL Prolonged-release Tablet 300mg is Light yellow coloured, round shaped, biconvex film coated tablets, debossed with 'Q300' on one side and plain on other. 300mg tablet diameter is approximately 11.2 mm.
Notiabolfen XL Prolonged-release Tablet 400mg is White coloured, round shaped, biconvex, film coated tablets debossed with 'I4' on one side and plain on other. 400mg tablet diameter is approximately 12.8 mm.
PVC/PVDC-Alu blister pack: Pack sizes of 10, 30, 50, 60 and 100 tablets per pack are registered forNotiabolfen XL 200 mg/300mg/400mg Prolonged-release Tablet.

PVC/PVDC-Alu blister pack or OPA/Alu/PVC – Alu blister pack: Pack size of 6, 10, 20, 28, 30, 50, 60, 90 and 100 tablets per pack are registered for Notiabolfen XL 50mg Prolong-release Tablet.

Not all pack sizes may be marketed.

Marketing Authorisation Holder
Accord Healthcare Ireland Ltd,
Euro House,
Euro Business Park,
Little Island,
Cork T45 K857,
Ireland

Manufacturer
GAP S.A.,
46, Agissilaou str.
Agios Dimitrios, Athens
Post Code:17341
Greece

Or

Accord Healthcare Polska Sp.z o.o.,
ul. Lutomierska 50,95-200 Pabianice, Poland

Or

Accord Healthcare B.V.,
Winthontlaan 200,
3526 KV Utrecht,
The Netherlands

Notiabolfen XL 50mg prolonged-release Tablets:
ARROW GENERIQUES- LYON,
26 avenue Tony Garnier, LYON, 69007,
France

This leaflet was last revised in 05/2022.