

PATIENT INFORMATION LEAFLET

GYREX® 100 mg film coated tablet

Administered orally.

- **Active Substance:** 115,13 quetiapine fumarate, equivalent to 100 mg quetiapine
- **Excipient(s):** Polyvinyl pyrrolidone, calcium hydrogen phosphate dihydrate, microcrystalline cellulose, sodium starch glycolate, bovine lactose monohydrate, magnesium stearate, hydroxypropyl methylcellulose, titanium dioxide, talc, polyethylene glycol

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. Do not pass it on to others.*
- *Please tell your doctor that you are taking this medicine if you seek medical assistance during the use of this medicine.*
- *Follow these instructions carefully. Do not take **higher or lower** doses than recommended.*

In this leaflet:

1. **What is GYREX® and what is it used for?**
2. **What you need to know before you take GYREX®?**
3. **How to use GYREX®?**
4. **Possible side effects**
5. **How to store GYREX®?**

Are explained.

1. What is GYREX® and what is it used for?

GYREX® tablets are yellow, round, and convex film-coated tablets with a “Q100” logo on one side.

GYREX® is available in blister packs containing 30 and 60 tablets.

GYREX® is a medication belonging to the class of antipsychotics (medications used in the treatment of psychiatric disorders) and contains the active ingredient quetiapine.

GYREX® contains lactose monohydrate of bovine origin.

GYREX® is effective in the treatment of the following conditions:

- Major depressive episodes accompanying bipolar disorder: In this case, you feel sad. You may feel pessimism, guilt, loss of energy, decreased appetite and insomnia.
- Moderate to severe mania episodes in bipolar disorder: you become overly enthusiastic, excited, happy, curious or hyperactive (you need less sleep than usual, become more talkative, you may notice thoughts or ideas racing through) or you may become aggressive or destructive, including

There is a weakness in your decision-making ability.

- To prevent recurrence of manic and depressive episodes in patients with bipolar disorder who have previously responded to quetiapine treatment.
- Schizophrenia: you may hear or feel things that do not actually exist; You believe things that are not true, or you feel strange doubts, anxiety, confusion, guilt, tension, boredom.

Your doctor may continue to prescribe GYREX® even if you feel well.

2. What do you need to know before you take GYREX®?

GYREX® should not be used by elderly patients with loss of brain function (dementia) causing memory and thought impairment. This is because medicines from the group that includes GYREX® may increase the risk of stroke and, in some cases, death in older patients with dementia.

In clinical studies with GYREX® and other drugs in this class, an increased risk of death has been reported in elderly patients with dementia and behavioral disorders. GYREX® is not approved for this type of use.

The use of antidepressant medications, particularly in children and young adults up to 24 years of age, may increase the risk of suicidal thoughts or behaviors. Therefore, especially during the initial phase of your treatment, as well as when increasing, decreasing, or discontinuing your medication, your doctor will closely monitor you for any unexpected behavioral changes such as agitation or excessive activity, and for the potential risk of suicide. If you experience any worsening of your condition, or if you have thoughts of suicide or self-harm, contact your doctor immediately.

GYREX® is not recommended for use in patients under 18 years of age.

DO NOT TAKE GYREX® in the following conditions

If;

- You are allergic to the active ingredient quetiapine or any component of GYREX® (see the list of excipients),
- You are using any of the following medications:
 - Certain HIV medications (such as didanosine, lopinavir, ritonavir, which are HIV protease inhibitors),
 - Azole antifungals (such as ketoconazole, fluconazole, itraconazole),
 - Some antibiotics used to treat infections (such as erythromycin, clarithromycin),
 - Certain antidepressants (such as nefazodone),

If you are unsure, consult your doctor or pharmacist before taking GYREX®.

TAKE special care with GYREX® in the following conditions

If you:

- Have or have had a heart condition (such as arrhythmia, heart muscle weakness, or heart inflammation, or if you are taking any medication affecting your heart rhythm),
- Have low blood pressure,
- Have had a stroke, especially if you are elderly,
- Have liver disease,
- Have a history of seizures (epileptic fits),
- Have diabetes or are at risk for diabetes. Your doctor may monitor your blood sugar levels while you are using GYREX®,
- Have had a low white blood cell count in the past due to medications or other reasons,
- Are elderly with dementia. GYREX® should not be used in elderly patients with dementia as it may increase the risk of stroke or, in some cases, death,
- Have Parkinson's disease or parkinsonism,
- Have a history of blood clotting in veins in you or your family, as this class of medications can be associated with blood clot formation,
- Experience or have experienced short periods of breath cessation during sleep (sleep apnea), and if the medications you are taking slow down normal brain activity (sedatives),
- Have a condition where you cannot completely empty your bladder (urinary retention), an enlarged prostate, bowel obstruction, or increased pressure in your eyes, which can sometimes be related to "anticholinergic" drugs used to treat certain medical conditions,
- Have a problem with your veins. GYREX® may rarely cause venous thrombosis, so all risk factors should be assessed and necessary precautions taken before and during treatment,
- Have a history of alcohol or drug abuse.

If you experience any of the following symptoms after using GYREX®, contact your doctor immediately

- The combination of fever, severe muscle stiffness, sweating and loss of consciousness, known as neuroleptic malignant syndrome. This may require urgent medical treatment.
- Uncontrolled movements, mostly of the face or tongue,
- Dizziness or severe sleepiness. This may increase the risk of accidental injury (fall) in elderly patients.
- Seizures,
- Prolonged and painful erection (priapism).
- Fast and irregular heartbeat even at rest, palpitations, breathing problems, chest pain, or unexplained fatigue. Your doctor will need to check your heart and, if necessary, refer you to a cardiologist immediately.

These types of medications may cause such symptoms.

If you experience the following symptoms, tell your doctor as soon as possible:

- Fever, flu-like symptoms, sore throat, or other infection, which may be the result of a low white blood cell count; GYREX® may need to be stopped and/or treatment given.
- Constipation accompanied by persistent abdominal pain or constipation that does not respond to treatment; because this may be followed by more serious obstruction of the intestine.

Suicidal thoughts and worsening depression

If you are experiencing depression, you might sometimes have thoughts of harming or killing yourself. As it generally takes around two weeks, and sometimes longer, for the effects of these medications to become apparent, these thoughts may increase when you first start treatment. These thoughts may also increase if you suddenly stop taking your medication. This is more likely if you

are a young adult. Clinical studies have shown that young adults under 25 with depression have a higher risk of suicidal thoughts and/or behaviors.

If at any time you have thoughts of harming or killing yourself, contact your doctor immediately or go to a hospital. It might be helpful to tell a family member or close friend about your depression and ask them to read this leaflet. You can ask them to let you know if they notice any worsening of your depression or changes in your behavior.

Severe cutaneous adverse reactions (SCARs)

Severe cutaneous adverse reactions (SCARs), which can be life-threatening or fatal, have been reported very rarely with treatment with this medicine. These usually manifest as:

- Stevens-Johnson syndrome (SJS), a widespread rash with blisters and peeling, especially around the mouth, nose, eyes, and genitals
- Toxic Epidermal Necrolysis (TEN), a more severe form that causes excessive peeling of the skin
- Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS) consists of flu-like symptoms with rash, fever, swollen glands, and abnormal blood test results (including increased white blood cells (eosinophilia) and liver enzymes).
- Acute Generalized Exanthematous Pustulosis (AGEP), small blisters filled with pus
- Erythema Multiforme (EM), itchy red irregular mottled skin rash

If you experience these symptoms, stop using GYREX® and contact your doctor immediately. Please contact us or get medical support.

Weight gain

GYREX® Weight gain was observed in patients taking it. You and your doctor should monitor your weight regularly. You should check as.

Children and adolescents

GYREX® is not used in children and adolescents under 18 years of age.

If these warnings apply to you, even at any time in the past, please consult your doctor.

Use of GYREX® with food and drinks

You can take GYREX® with or without food.

Be careful how much alcohol you drink. Because the combined effects of GYREX® and alcohol can make you drowsy.

Do not drink grapefruit juice while receiving GYREX® treatment. It may change the way the drug works.

Pregnancy

Consult your doctor or pharmacist before using the medicine.

If you think you are pregnant or planning to become pregnant, consult your doctor before taking GYREX®. You should not take GYREX® during pregnancy without consulting your doctor.

Newborns exposed to antipsychotic drugs (effective in the treatment of psychiatric diseases such as schizophrenia and psychotic depression) in the last three months of pregnancy are at risk of abnormal muscle movements and/or drug withdrawal symptoms, which may vary in severity following birth. These symptoms include restlessness, excessive muscle tension, loss of muscle

tension, tremors, sleepiness, breathing difficulties or nutritional disorders. If your baby develops any of these symptoms, you should contact your doctor.

If you notice that you are pregnant during your treatment contact your doctor or pharmacist immediately.

Breastfeeding

Consult your doctor or pharmacist before using the medicine.

Do not breastfeed your baby while you are using the medicine.

Driving and using machines

This medicine you use may make you sleepy. Do not drive or use machines until you know how these tablets affect you.

Important information about the excipients in GYREX®

GYREX® It contains bovine-sourced lactose monohydrate, which is a type of sugar. If you have been told by your doctor that you have an intolerance to certain sugars, contact your doctor before taking this medication..

Taking with other medicines

Do not use GYREX® with the following medications

- Some drugs used in the treatment of AIDS (HIV), such as HIV protease inhibitors (e.g., didanosine, lopinavir, ritonavir)
- Azole class drugs used for the treatment of fungal infections (e.g., ketoconazole, fluconazole, itraconazole)
- Erythromycin or clarithromycin (used for the treatment of infections)
- Antidepressants like nefazodone

If you are using the following medications, please contact your doctor:

- Antiepileptic drugs (such as phenytoin or carbamazepine)
- Antihypertensive medications (for high blood pressure)
- Barbiturates (used for treating insomnia)
- Thioridazine or lithium (other antipsychotic medications)
- Medications that affect your heart rate: For example, diuretics (which can cause electrolyte imbalances such as low potassium and magnesium levels in the blood) or certain antibiotics (used for treating infections)
- Medications that can cause constipation
- Some medications used to treat medical conditions that affect nerve cell function (anticholinergics)

Before stopping any of your medications, please consult your doctor.

If you are currently using or have recently used any prescription or over-the-counter medications, please inform your doctor or pharmacist about them.

Drug Testing in Urine

If you are undergoing a drug test, please be aware that the use of GYREX® may lead to a positive result for methadone or tricyclic antidepressants (TCA), even if you are not taking these substances. If such a result occurs, more specific tests may be required to confirm the results..

3. How to use GYREX®?

Instructions for appropriate use and dose/frequency:

Always follow your doctor's instructions precisely when using GYREX®. If you are unsure about anything, consult your doctor or pharmacist.

Your doctor will determine the starting dose. The maintenance dose (daily dose) depends on your condition and needs, but it will typically range between 150 mg and 800 mg.

Method and route of administration:

You will take your tablets once a day at bedtime or twice a day, depending on your disease.

Swallow your tablets whole with some water.

You can take your tablets while fasting or with food.

Do not drink grapefruit juice while using GYREX®. It may affect the way the medicine works.

Do not stop taking your tablets without your doctor telling you, even if you feel well.

Different age groups:

Use in children:

GYREX® is not recommended for use in children and adolescents under 18 years of age.

Use in elderly patients:

If you are elderly, your doctor may change your dose.

Special usage conditions

Kidney impairment:

No dosage adjustment is required in patients with renal impairment.

Liver impairment:

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

If you have the impression that the effect of GYREX® is too strong or too weak, consult your doctor or pharmacist..

If you take more GYREX® then you should have:

If you have taken more GYREX® than you should, consult a doctor or pharmacist immediatly.

If you have taken more GYREX® than your doctor has prescribed for you, you may experience drowsiness, drowsiness, and abnormal heartbeats. Contact your doctor and go directly to the nearest hospital. Take your GYREX® tablets with you.

If you forget to take GYREX®:

Do not take a double dose to make up for forgotten doses.

Take the forgotten tablet as soon as you remember, unless it is very close to the time of your next dose.

Effects when stopping treatment with GYREX®:

If you suddenly stop using GYREX®, you might experience difficulty sleeping (insomnia) or feel unwell (nausea), or develop symptoms such as headache, diarrhea, vomiting, dizziness, or agitation.

Your doctor may advise you to gradually reduce the dose before stopping the treatment.

If you have any other questions about using this medication, please ask your doctor or pharmacist.

4. Possible side effects

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

Stop using GYREX® and IMMEDIATELY inform your doctor or go to the nearest emergency department if any of the following occur:

- Serious allergic reactions (anaphylactic reactions), which may cause difficulty breathing or shock.
- Allergic reactions, including skin blisters, skin swelling and swelling around the mouth.
- Sudden blistering of the skin, usually swelling around the eyes, lips and throat (angioedema).

These are all very serious side effects. If you have one of these, it means you have a serious allergy to GYREX®. You may need emergency medical attention or hospitalization.

These side effects are rare. Side effects are classified as follows:

Very Common: May occur in at least 1 in 10 patients.

Common: May occur in less than 1 in 10 but more than 1 in 100 patients.

Uncommon: May occur in less than 1 in 100 but more than 1 in 1,000 patients.

Rare: May occur in less than 1 in 1,000 but more than 1 in 10,000 patients.

Very Rare: May occur in less than 1 in 10,000 patients

Unknown: cannot be estimated from the available data.

Other side effects of GYREX® include:

Very Common:

- Dizziness (may cause fainting), headache, dry mouth,
- Decrease in hemoglobin,
- Drowsiness (may pass over time as you continue to take GYREX®) (may cause a fall),
- Discontinuation symptoms (symptoms when you stop using GYREX®); these include not being able to sleep (insomnia), feeling sick (nausea), headache, diarrhea, feeling sick (vomiting), dizziness, and restlessness. It is recommended to discontinue the medication gradually over a period of at least 1 to 2 weeks.
- Weight gain,
- Abnormal muscle movements. These include difficulty initiating muscle movements, tremors, discomfort, or painless muscle stiffness.
- Changes in the amount of some fats (triglycerides and total cholesterol).

Common:

- Increased heart rate (tachycardia),
- Feeling like the heart is beating too hard, beating too fast, or skipping between heartbeats,
- Constipation, stomach upset (indigestion),
- Feeling of weakness and weakness,
- Swelling in arms or legs,

- A decrease in blood pressure when standing up (orthostatic hypotension) and a resulting feeling of dizziness or fainting (may cause a fall),
- Increased blood sugar,
- Blurred vision,
- Abnormal dreams and nightmares,
- Feeling of hunger (increased appetite),
- The state of being hypersensitive to stimuli,
- Difficulty in speaking and pronunciation,
- Increase in depression and suicidal thoughts,
- Shortness of breath,
- Vomiting (especially in the elderly),
- Fever,
- Changes in the amount of thyroid hormones in the blood,
- Decreases in the number of some blood cell types,
- Increases in the amount of liver enzymes measured in the blood,
- Increases in the amount of prolactin hormone in the blood. Elevated levels of the hormone prolactin can, in rare cases, lead to:
 - Breast swelling and unexpected milk discharge in men and women.
 - Women's menstrual cycle or irregular menstruation.

Uncommon:

- Seizures,
- Allergic reactions including skin blisters, skin swelling and swelling around the mouth,
- Feeling of restlessness in the legs (also called restless legs syndrome),
- Difficulty in swallowing,
- Involuntary movements, especially in the face and tongue,
- Disorder in sexual activity,
- Diabetes mellitus,
- Change in the electrical activity of the heart seen on the ECG (QT prolongation),
- A slower than normal heart rate may occur when treatment is started and may be associated with low blood pressure and fainting,
- Difficulty urinating,
- Fainting (may cause a fall),
- Stuffy nose,
- Decrease in the amount of red blood cells,
- Decrease in the amount of sodium in the blood,
- Decrease in the number of neutrophils, one of the white blood cells,
- Worsening of pre-existing diabetes (diabetes),
- State of mental confusion,
- Decrease in thrombocyte (blood platelets) numbers,
- Decrease in blood hormone levels (decrease in free T3, hypothyroidism),
- Increased serum aspartate aminotransferase (AST) levels (an enzyme test often used to diagnose heart and liver diseases).

Rare:

- A combination of fever, sweating, stiff muscles, feeling very sleepy, or fainting (a disorder called "neuroleptic malignant syndrome")
- Yellowing of the skin and eyes (jaundice),
- Liver inflammation (hepatitis),

- Priapism (prolonged and painful erection),
- Swelling of the breasts and unexpected production of breast milk (galactorrhea),
- Menstrual irregularity,
- Blood clot, especially in the leg veins, that travels along the blood vessels towards the lungs, causing chest pain and difficulty breathing (symptoms of swelling, pain and redness in the legs). If any of these symptoms occur, contact your doctor immediately.
- Walking, talking, eating and doing other activities while asleep,
- Decrease in body temperature (hypothermia),
- Inflammation of the pancreas,
- A condition that is a combination of three or more of the following (also called metabolic syndrome): Increased abdominal fat, decrease in “good cholesterol” (HDL-C), increase in a type of fat in the blood called triglycerides, high blood pressure, and increased blood sugar. ,
- A condition called agranulocytosis; low white blood cell count with fever, flu-like symptoms, sore throat or other infection,
- Intestinal obstruction,
- Increased blood levels of creatine phosphokinase (a substance in the muscles),
- Stopping breathing for short periods during normal night sleep (sleep apnea).

Very rare:

- Severe diaper rash, swelling and red bumps on the skin,
- Serious allergic reaction (anaphylaxis) that may cause breathing difficulties or shock.
- Sudden blistering of the skin, usually around the eyes, lips and throat (angioedema),
- Severe peeling of the skin, mouth, eyes and genital areas (Stevens-Johnson syndrome),
- Inappropriate secretion of the hormone that regulates urine volume,
- Destruction of muscle fibers and pain in the muscles (rhabdomyolysis)

Unknown:

- Skin rash with irregular red spots (erythema multiforme), Rapid appearance of areas of red skin filled with small pustules (small blisters filled with white/yellow fluid called Acute Generalized Exanthematous Pustulosis (AGEP)),
- Serious, sudden allergic reaction (toxic epidermal necrolysis) with symptoms such as fever, blisters on the skin and peeling of the skin.
- Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS), which consists of flu like symptoms with rash, fever, swollen glands, and abnormal blood test results (including increased white blood cells (eosinophilia) and liver enzymes).
- Drug withdrawal symptoms in newborn babies due to GYREX[®] use by pregnant women
- Paralysis
- Heart muscle disorder (cardiomyopathy)
- Inflammation of the heart muscle (myocarditis)
- Inflammation of blood vessels (Vasculitis), skin rash often with small red or purple bumps

The group of drugs that GYREX[®] belongs to can cause serious and fatal heart rhythm disorders.

Some side effects may only be seen when a blood test is done. These include changes in the amount of some fats (triglycerides and total cholesterol) and sugar in the blood, changes in the amount of thyroid hormones in the blood, an increase in liver enzymes, a decrease in the number of some blood cells, a decrease in the amount of red blood cells, an increase in the amount of creatine phosphokinase (a substance in the muscles) and prolactin in the blood. Including an increase in the amount of the hormone. Increases in the hormone prolactin may rarely cause the following conditions:

- Swollen breasts and unexpected production of breast milk in men and women
- Lack of monthly periods or irregular periods in women

Additional side effects in children and adolescents

The same side effects that can be seen in adults can also be seen in children and adolescents.

The following side effects occur more frequently in children and adolescents or do not occur in adults:

Very Common:

- Increase in the amount of the hormone called prolactin in the blood. In rare cases, prolactin hormone
The increase may be followed by:
 - Swollen breasts and unexpected production of breast milk in boys and girls
 - Girls do not have monthly periods or have irregular periods
- Increased appetite,
- Vomiting,

- Abnormal muscle movements. These include difficulty initiating muscle movements, tremors, discomfort, or painless muscle stiffness.
- Increased blood pressure.

Common:

- Feeling weak (may cause fainting),
- Stuffy nose,
- Feeling restless.

Reporting of side effects

Talk to your doctor, pharmacist or nurse if you experience any side effects listed or not listed in this leaflet. Also reporting suspected adverse reactions after authorization of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the national reporting system.

5. Storage of GYREX®

Keep GYREX® in its packaging and out of sight and reach of children.
Store at room temperature below 30°C.

Use in accordance with the expiration date.

Do not use GYREX® after the expiration date stated on the packaging.

Do not dispose of expired or unused medication in the trash! Dispose of them according to the collection system established by the Ministry of Environment and Urbanization.

Marketing Authorization Holder:

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This leaflet has been approved <{DD month YYYY}>. [To be completed nationally]