Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986
This medicine is dispensed with a doctor's prescription only

Geodon® 20 mg Capsules
Geodon® 40 mg Capsules
Geodon® 60 mg Capsules
Geodon® 80 mg Capsules

Each capsule contains:
ziprasidone (as hydrochloride monohydrate) 20 mg, 40 mg, 60 mg, 80 mg

Inactive ingredients and allergens in this medicine: See section 2 under "Important information about some of this medicine's ingredients" and section 6 "Further information".

Read the entire leaflet carefully before using this medicine. This leaflet contains concise information about this medicine. If you have any further questions, consult your doctor or pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar to yours.

This medicine is not intended for treatment of children and adolescents under 18 years of age.

Important information that you should know:

Geodon is not intended for the treatment of patients with dementia-related psychosis. Elderly patients with dementia-related psychosis, who are being treated with antipsychotics, are at high risk of death.

1. WHAT IS THIS MEDICINE INTENDED FOR?

An antipsychotic medicine for treatment of schizophrenia in adults, for treatment of manic episodes that are part of bipolar disorder (bipolar mania) in adults, as well as for maintenance treatment of bipolar disorder, in combination with lithium or valproate in adults.

Therapeutic group:
Atypical antipsychotics – antagonists for D_2 dopamine and $5HT_{2A}$ serotonin receptors in the brain.

2. BEFORE USING THIS MEDICINE

Do not use this medicine if:

- You are sensitive (allergic) to the active ingredient or to any of the other ingredients contained in the medicine (see section 6).
- You are suffering or have recently suffered from severe dysfunction of the heart, such as QT interval prolongation syndrome, a recent heart attack, severe heart failure, or certain heart rhythm disorders (discuss this with your doctor).
- You are taking medicines that should not be taken in combination with Geodon that prolong the QT interval, such as dofetilide, sotalol, quinidine and other antiarrhythmic drugs for treatment of heart rate disorders (from class Ia or III), mesoridazine, thioridazine, chlorpromazine, droperidol, pimozide, sparfloxacin, gatifloxacin, moxifloxacin, halofantrine, mefloquine, pentamidine, arsenic trioxide, levomethadyl acetate, dolasetron mesylate, probucol or tacrolimus.
- Do not use the medicine in elderly patients suffering from dementia-related psychosis.

Special warnings regarding use of the medicine:
Before treatment with Geodon, tell the doctor if:

- You are suffering, or have suffered in the past, from any problem with the way your heart beats or from impaired function of the heart.
- You have a known family history of heart disease, including a recent heart attack.
- You are suffering, or have suffered in the past, from fainting or dizziness.
- You are suffering, or have suffered in the past, from impaired liver function.

- You are sensitive to certain medicines.
- You are taking, or have taken in the past, certain prescription medicines.
- You are taking non-prescription medicines or dietary supplements.
- You are suffering, or have suffered in the past, from an imbalance in blood electrolyte levels, such as low levels of potassium or magnesium (the levels of these electrolytes must be stabilized before beginning treatment).
- You are suffering, or have suffered in the past, from diabetes (or if you have a family history of diabetes).
- You are suffering, or have suffered in the past, from obesity, seizures, breast cancer, a low white blood cell count.
- You are suffering from an illness manifested by diarrhea, vomiting or any other illness that involves loss of fluids.
- You are pregnant, may be pregnant or are planning to become pregnant.
- You are breastfeeding or planning to breastfeed.

Additional warnings regarding use of the medicine:

- Use of the medicine may cause side effects in the cardiovascular system including stroke in elderly patients suffering from dementia-related psychosis.
- As with other antipsychotics, use of this medicine may cause neuroleptic malignant syndrome (NMS), whose symptoms include very high fever, rigid muscles, shaking, confusion, sweating, increased heart rate and blood pressure. This syndrome is rare but serious and may be fatal. Therefore, report to the doctor if you experience any of these symptoms.
- A delayed-onset reaction to the medicine, called drug reaction with eosinophilia and systemic symptoms (DRESS), may occur while using this medicine. Signs of this reaction (DRESS) may include rash, fever and enlarged lymph nodes. Other severe cutaneous adverse reactions may occur during the course of treatment with Geodon, such as Stevens-Johnson syndrome whose symptoms may include rash with blisters, ulcers in the mouth, skin peeling, fever and appearance of target-like spots on the skin. These reactions may sometimes be life-threatening; therefore, inform the doctor immediately if you notice these symptoms.
- There have been a number of reports of high blood sugar levels (hyperglycemia) or diabetes in patients who have taken Geodon. It is not known if Geodon is associated with these effects. Signs of hyperglycemia should be followed up and monitored during the course of treatment with atypical antipsychotic medicines.
- Use of the medicine may cause dizziness due to a drop in blood pressure, especially when first starting to use the medicine or when the dose is increased; therefore, be careful when standing up from a lying or sitting position (stand up slowly). Report this effect to the doctor.
- Use of this medicine may affect the ability to regulate body temperature; therefore, it is preferable to avoid exposure to a high temperature or to humidity.
- Atypical antipsychotic medicines have been associated with metabolic changes including high blood sugar levels (hyperglycemia), high blood lipid levels (dyslipidemia) and weight gain.

Children and adolescents
There is not enough information regarding the safety and effectiveness of using this preparation in children and adolescents.
This medicine is not intended for treatment of children and adolescents under 18 years of age.

Tests and follow up
Your potassium and magnesium levels should be monitored.
During the course of treatment with atypical antipsychotic medicines, signs of increased blood sugar levels (hyperglycemia) should be followed up and monitored.
If you are suffering from an illness that is manifested by diarrhea, vomiting or any condition where there is a risk of fluid loss, it is possible that your doctor will refer you for blood tests to monitor levels of salts in the blood.

Drug interactions
If you are taking, or have recently taken, other medicines, including nonprescription medicines and dietary supplements, tell the doctor or pharmacist.
Particularly if you are taking:

- Medicines that prolong the QT interval, such as: dofetilide, sotalol, quinidine and other antiarrhythmic drugs for treatment of heart rate disorders (from class Ia or III), mesoridazine, thioridazine, chlorpromazine, droperidol, pimozide, sparfloxacin, gatifloxacin, moxifloxacin, halofantrine, mefloquine, pentamidine, arsenic trioxide, levomethadyl acetate, dolasetron mesylate, probucol or tacrolimus (see section 2 ”Do not use this medicine if“).
- Medicines that affect the central nervous system (e.g., sedatives, hypnotics, medicines for Parkinson’s disease, medicines for epilepsy).
- Ketoconazole, an antifungal medicine.

Using this medicine and food
Take the medicine with meal in order to achieve optimal efficacy of the medicine.

Using this medicine and alcohol consumption
It is recommended to avoid consuming alcoholic beverages while taking the medicine.

Pregnancy and breastfeeding
If you are pregnant, may be pregnant or are planning to become pregnant, do not start treatment with the medicine without consulting your doctor.
Do not use this medicine if you are breastfeeding or are planning to breastfeed.

Driving and using machines
Use of this medicine may impair alertness and cause sleepiness, and therefore, caution must be exercised when driving a car, operating dangerous machinery and when engaging in any activity that requires alertness.

Important information about some of this medicine’s ingredients
The capsule contains lactose monohydrate – if you have been told by your doctor that you have an intolerance to some sugars, consult the doctor before taking the medicine.

3. HOW TO USE THIS MEDICINE?

Always use this medicine according to your doctor's instructions.
Check with the doctor or pharmacist if you are uncertain about the dosage and treatment regimen of the medicine.
The dosage and treatment regimen will be determined by your doctor only.

Do not exceed the recommended dose.

The optimal effect of the medicine may be manifested after a few weeks of treatment.
Take this medicine at the same time every day.

Swallow the capsule whole. Do not open and disperse the contents of the capsule, as the effect of this form of administration has not been tested.

If you have taken an overdose, or if a child has accidentally swallowed some medicine, immediately see a doctor or go to a hospital emergency room and bring the medicine package with you.

If you forget to take the medicine at the scheduled time, take a dose as soon as you remember, unless it is already time for your next dose. In this case, do not take a double dose. Take the next dose at the usual time and consult your doctor.

Adhere to the treatment as recommended by your doctor.
Even if your health improves, do not stop taking this medicine without consulting your doctor.

Do not take medicines in the dark! Check the label and dose <u>each time</u> you take medicine. Wear glasses if you need them.
If you have any further questions about using this medicine, consult your doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Geodon may cause side effects in some users. Do not be alarmed by this list of side effects; you may not experience any of them.

Stop taking this medicine and contact your doctor immediately in case of:

- fainting or loss of consciousness
- a sensation of a change in the rate of heart beats (palpitations).

Side effects that occur frequently and that should be reported to the doctor if they occur:

- Feeling unusually tired or sleepy
- Nausea or gastrointestinal disorders
- Constipation
- Dizziness
- Restlessness
- Abnormal muscle movements, including tremor, shuffling, and uncontrolled involuntary movements
- Diarrhea
- Rash
- Increased cough and runny nose

Common side effects – Effects occurring in at least 1 in 100 users:
Abdominal pain, flu-like symptoms, fever, falls, face edema, chills, photosensitivity (sensitivity to light), flank pain, hypothermia, rapid heartbeat, hypertension, orthostatic hypotension, anorexia, vomiting, muscle pain, agitation, tremor, disturbances in muscle movement, hostility, twitching, paresthesia, confusion, dizziness (vertigo), walking disturbance, oculogyric crisis, decreased sensation or sense of touch, speech disturbance, memory loss, rigid muscles, low or high muscle tone, delirium, double vision, lack of coordination, neuropathy, breathing difficulties, fungal skin inflammation.

Uncommon side effects – Effects occurring in 1 out of 100 to 1 out of 1000 users:
Slow pulse, angina pectoris, atrial fibrillation, rectal hemorrhage, difficulties swallowing, tongue edema, anemia, subcutaneous bleeding, changes in blood count (increase or decrease in the number of white blood cells), enlarged lymph nodes, thirst, an increase in liver enzymes, peripheral edema, hyperglycemia (high blood sugar level), increase in creatine phosphokinase level, increase in alkaline phosphatase level, increase in cholesterol level, dehydration, increase in lactate dehydrogenase level, albumin in the urine, low blood potassium level, ”trigger finger“ (tenosynovitis), paralysis, pneumonia, nosebleed, skin reactions such as rash, urticaria, eczema, dermatitis, hair loss, dry eyes, conjunctivitis, blepharitis, tinnitus, cataract, impotence, ejaculation problems, sexual dysfunction in men, sugar in the urine, blood in the urine, amenorrhea, excessive menstrual bleeding, secretion of milk from the nipple, urinary retention, excessive urination, bleeding between periods, difficulty in reaching sexual satisfaction.

Rare side effects – Effects occurring in less than 1 in 1000 users
Blockage of cardiac conduction, phlebitis, pulmonary embolism, heart enlargement, stroke or cerebral infarct, venous thrombosis, inflammation of the heart muscle, gum hemorrhage, jaundice, bloody vomit, hepatitis, enlarged liver, a disease of oral mucous membrane (leukoplakia), fatty liver, black stools, hypo/hyperthyroidism, inflammation of the thyroid gland (thyroiditis), changes in blood count, low platelet count (thrombocytopenia) or high platelet count (thrombocythemia), increased blood urea and creatinine, changes in lipid homeostasis (increase in lipids, such as triglycerides, decrease in cholesterol) and in the levels of essential body salts (increase in potassium level, increase/decrease in chloride level, decrease in sodium level, decrease in calcium level, decrease in magnesium level), decrease in protein level in the body, increase in blood uric acid, decreased glucose tolerance, hypoglycemia, gout, ketosis, respiratory alkalosis, myopathy, increased reflexes, involuntary eye movement, torticollis (stiff neck), numbness around the mouth, opisthotonos, lockjaw, spitting blood, spasm of the throat muscles, eye hemorrhage, visual field disturbance, keratitis, keratoconjunctivitis, breast enlargement in men (gynecomastia), vaginal bleeding, nocturia, low urine output, uterine hemorrhage, sexual dysfunction in women.

Additional side effects reported after marketing:
Rapid heart rate, arrhythmias (Torsades de pointes type) in the presence of multiple risk factors, swollen tongue, galactorrhea – production of breast milk irrespective of giving birth or breastfeeding, prolonged erection (priapism), facial droop, serotonin syndrome (alone or in combination with

serotonergic medicines), neuroleptic malignant syndrome, tardive dyskinesia, insomnia, mania/hypomania, allergic reaction (skin rash, allergic dermatitis, subcutaneous edema, urticaria, edema of the face and mouth), skin reaction with systemic symptoms to treatment with the medicine (DRESS), enuresis, urinary incontinence, orthostatic hypotension, fainting.

If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.

You can report side effects to the Ministry of Health by following the link 'Reporting Side Effects of Drug Treatment' on the Ministry of Health home page (www.health.gov.il) which links to an online form for reporting side effects or by using the link: https://sideeffects.health.gov.il.

5. HOW TO STORE THE MEDICINE?

- Prevent poisoning! This and any other medicine should be kept in a closed place, out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by a doctor.
- Do not use the medicine after the expiry date (exp. date) which is stated on the package. The expiry date refers to the last day of that month.
- Store below 30˚C.

6. FURTHER INFORMATION

In addition to the active ingredient, this medicine also contains:

Lactose monohydrate, pregelatinized maize starch and magnesium stearate.
Hard gelatin locking capsules shell contains: titanium dioxide (E171), indigotin (E132) – blue capsules, sodium dodecylsulfate, gelatin and TekPrint SW-9008 black ink.

The medicine contains lactose monohydrate:
Geodon 20 mg capsules: 66.098 mg
Geodon 40 mg capsules: 87.83 mg
Geodon 60 mg capsules: 131.745 mg
Geodon 80 mg capsules: 175.66 mg

What the medicine looks like and contents of the pack:
Geodon 20 mg capsules: a blue/white capsule with "PFIZER" and "ZDX 20" imprinted on it.
Geodon 40 mg capsules: a blue capsule with "PFIZER" and "ZDX 40" imprinted on it.
Geodon 60 mg capsules: a white capsule with "PFIZER" and "ZDX 60" imprinted on it.
Geodon 80 mg capsules: a blue/white capsule with "PFIZER" and "ZDX 80" imprinted on it.

The pack of the medicine contains 14, 20, 30, 50, 56, 60 or 100 capsules.

Not all pack sizes may be marketed.

Registration holder and address:
Pfizer PFE Pharmaceuticals Israel Ltd., 9 Shenkar St., Herzliya Pituach 46725

Registration numbers of the medicine in the National Drug Registry of the Ministry of Health:
Geodon 20 mg capsules: 124.82.30181
Geodon 40 mg capsules: 124.79.30182
Geodon 60 mg capsules: 124.80.30183
Geodon 80 mg capsules: 124.81.30184

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