



**Patient package insert according to Pharmacists' Regulations (Preparations) – 1986**

This medicine can be sold with a physician'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 the medicine – see section 6 "Additional information" and in section 2 "Important information about some of the ingredients of the medicine".

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

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

**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 the 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<sub>2</sub> dopamine and 5HT<sub>2A</sub> serotonin receptors in the brain.

**2. Before using the medicine**

**Do not use the medicine if:**

- You are hypersensitive (allergic) to the active ingredient (ziprasidone), or to any of the other ingredients this medicine contains (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 rhythm 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.
- You are taking a monoamine oxidase inhibitor (MAOI, including the linezolid and intravenous methylene blue) or have stopped taking an MAOI in the last 14 days.

### **Special warnings regarding the use of the medicine**

#### **Before the 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 taking, or have taken in the past, certain prescription medicines.
- You are taking non-prescription medicines or nutritional supplements.
- You are suffering, or have suffered in the past, from impaired liver function.
- 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 the 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, think you may be pregnant or are planning to become pregnant.
- You are breastfeeding or are planning to breastfeed.
- You are sensitive to certain medicines.

#### **Additional warnings regarding the 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 or increased heartbeat and blood pressure. This syndrome is rare but serious and could be fatal. Therefore, report to the doctor if you notice these symptoms.
- A delayed-onset reaction to **Geodon**, 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 treatment with **Geodon**, such as Stevens-Johnson syndrome, whose symptoms may include rash with blisters, ulcers in the mouth, skin shedding, 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 treatment with atypical antipsychotic medicines.
- The use of **Geodon** may cause dizziness due to a drop in blood pressure, especially at the starting of using the medicine or when the dose is increased. Therefore, be careful and not stand up too quickly and report the phenomenon to your doctor.
- Use of this medicine may affect the ability of the body to adjust to heat; therefore, it is best to avoid exposure to a high temperature or humidity.
- Atypical antipsychotic medicines have been associated with metabolic changes including high blood sugar levels (hyperglycemia), high blood lipid levels (dyslipidemia) and weight gain.
- **Geodon** may lead to the development of a serotonin syndrome, a potentially life-threatening condition (see in section 2 "Do not use the medicine if", "Drug interactions" and section 4 "Side effects").

### **Children and adolescents**

There is not enough information regarding the safety and effectiveness of using **Geodon** in children and adolescents.

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

### **Tests and follow up**

Potassium and magnesium levels should be monitored.

During the treatment with atypical antipsychotic medicines signs of increased blood sugar levels (hyperglycemia) should be monitored.

If you are suffering from an illness manifested by diarrhea, vomiting or any condition where there is a risk of fluid loss, your doctor may refer you for a blood test to monitor salts levels in the blood.

### **Drug interactions**

**If you are taking or have recently taken other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist.**

Especially if you are taking:

- Medicines that prolong the QT interval, such as: dofetilide, sotalol, quinidine and other antiarrhythmic drugs for treatment of heart rhythm 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 in section 2 "Do not use the medicine if").
- Medicines that affect the central nervous system (e.g., sedatives, hypnotics, for the treatment of Parkinson's disease and epilepsy).
- Medicines for lowering blood pressure
- Ketoconazole, an antifungal medicine.
- Serotonin syndrome can occur during treatment with **Geodon**, especially when the following medicines are taken simultaneously:
  - Medicines for treatment of depression, for example: selective serotonin reuptake inhibitors (SSRIs), serotonin norepinephrine reuptake inhibitors (SNRIs), tricyclic antidepressants or medicines containing lithium
  - Triptans (for migraine treatment)
  - Medicines containing opioids such as: fentanyl, meperidine (for relief of severe pain)
  - Medicines containing methadone (for treatment of addiction to opioids or treatment of severe pain)
  - Medicines containing tramadol (analgesic)
  - Medicines containing tryptophan (for sleep problems and depression)
  - Buspirone (for anxiety treatment)
  - Medicines containing amphetamines (for treatment of attention deficit hyperactivity disorder (ADHD), narcolepsy and obesity)
  - Medicines containing St. John's Wort (also called hypericum perforatum, a herbal remedy used for the treatment of mild depression)
  - MAO inhibitors (for the treatment of depression, infections or high levels of methaemoglobin in the blood. See in section 2 "Do not use the medicine if").

### **Use of the medicine and food**

Take the medicine with meal to achieve optimal efficacy of the medicine.

### **Use of the medicine and alcohol consumption**

It is recommended to avoid consuming alcoholic beverages while taking **Geodon**.

### **Pregnancy and breastfeeding**

Do not start treatment with this medicine without consulting the doctor if you are pregnant, think you may be pregnant or are planning to become pregnant.

Do not use this medicine without consulting the doctor if you are breastfeeding or are planning to breastfeed. **Geodon** can pass into breast milk.

### **Driving and using machines**

The use of **Geodon** can cause sleepiness, and therefore requires caution when driving and operating machinery.

### **Important information about some of the ingredients of the medicine**

**Geodon** contains lactose. If you have been told by the doctor that you have an intolerance to some sugars, contact the doctor before taking this medicine.

This medicine contains less than 1 mmol sodium (23 mg) per capsule, that is to say, essentially "sodium-free".

## **3. How to use the medicine?**

Always use the medicine according to the doctor's instructions. Check with the doctor or pharmacist if you are not sure about the dosage and the manner of treatment with the medicine.

The dosage and manner of treatment will be determined by the doctor only.

### **Do not exceed the recommended dose.**

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.

Take this medicine with food.

Take this medicine at the same time every day.

The optimal effect of the medicine may be manifested after a few weeks of treatment.

### **If you have accidentally taken a higher dosage**

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

### **If you forgot to take the medicine**

If you forgot to take this medicine at the designated 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 the doctor.

Continue with the treatment as recommended by the doctor.

Even if there is an improvement in your health, do not stop taking this medicine without consulting the doctor.

**Do not take medicines in the dark! Check the label and the dose each time you take a medicine. Wear glasses if you need them.**

**If you have further questions on the use of this medicine, consult the doctor or pharmacist.**

## **4. Side effects**

Like any medicine, the use of **Geodon** may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

**Stop taking this medicine and refer to the doctor immediately with the occurrence of:**

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

You should contact your doctor if you experience any of the following signs and symptoms of serotonin syndrome: agitation, hallucinations, coma or mental status changes; rapid heartbeat, high or low blood pressure; coordination problems or muscle contraction; nausea, vomiting or diarrhea; sweating or fever; muscle rigidity, shaking, seizures.

**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 that occur in 1-10 out of 100 users):**

Abdominal pain, flu-like symptoms, fever, falls, facial swelling (edema), chills, photosensitivity (sensitivity to light), flank pain, hypothermia, rapid heartbeat, high blood pressure (hypertension), orthostatic hypotension (a fall in blood pressure on standing), loss of appetite, vomiting, muscle pain, agitation, shaking, disturbances in muscle movement, hostility, twitching, numbness (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 that occur in 1-10 out of 1,000 users):**

Slow heartbeat, chest pain, atrial fibrillation, rectal bleeding, difficulties swallowing, swelling of the tongue, anemia, subcutaneous bleeding, changes in blood count (increase or decrease in the number of white blood cells), enlarged lymph nodes, thirst, swelling of the ankles, feet or fingers, hyperglycemia (high blood sugar level), increase in liver enzymes, increase in creatine phosphokinase level, increase in alkaline phosphatase level, increase in lactate dehydrogenase level, increase in cholesterol level, dehydration, albumin in the urine, low blood potassium level, tendon sheath inflammation (tenosynovitis), paralysis, pneumonia, nosebleed, skin reactions such as rash, hives, eczema, dermatitis, hair loss, dry eyes, conjunctivitis, blepharitis, cataract, light intolerance (photophobia), ringing in the ears, impotence, ejaculation problems, sexual dysfunction in men, difficulty in reaching sexual satisfaction, sugar in the urine, blood in the urine, urinary retention, excessive urination, absence of menstrual periods, excessive menstrual bleeding, bleeding between periods, milk secretion from the nipple.

**Rare side effects (effects that occur in 1-10 out of 10,000 users):**

Blockage of cardiac conduction, phlebitis, blood clot in the lungs, heart enlargement, stroke or cerebral infarct, thrombophlebitis, inflammation of the heart muscle, gum bleeding, yellowing of the skin or whites of the eyes, fecal impaction, elevated gamma-glutamyl transferase (GGT) level, vomiting of blood, cholestasis, hepatitis, enlarged liver, a disease of oral mucous membrane (leukoplakia), fatty liver, black stools, under/overactive thyroid gland, inflammation of the thyroid gland (thyroiditis), changes in blood count, low platelet count (thrombocytopenia) or high platelet count (thrombocythemia), lymphedema,

increased blood urea and creatinine, increase in lipids, decrease in cholesterol, change 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 blood, increase in blood uric acid, decreased glucose tolerance, hypoglycemia, gout, ketosis, respiratory alkalosis, pain or weakness in muscles, increased reflexes, involuntary eye movement, twisted neck (torticollis), numbness around the mouth, opisthotonos, lockjaw, spitting blood, spasm of the throat muscles, eye bleeding, visual field disturbance, keratitis, keratoconjunctivitis, breast enlargement in men (gynecomastia), vaginal bleeding, nocturia, low urine output, uterine bleeding, sexual dysfunction in women.

**Additional side effects reported after marketing:**

Rapid heartbeat, irregular heart rhythm (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 (with or without combination of the medicine with drugs that inhibit serotonin reuptake), neuroleptic malignant syndrome, uncontrollable movements of mouth, tongue and limbs, difficulty in sleeping, feeling elated or over-excited, which causes unusual behaviour (mania/hypomania), sleepwalking, allergic reaction (allergic dermatitis, swelling of the face, mouth, tongue, throat, hands or feet, difficulty swallowing or breathing, hives, edema of the face and mouth), rash, drug reaction with eosinophilia and systemic symptoms (DRESS, see symptoms in section 2 “Additional warnings regarding the use of the medicine”), bedwetting, urinary incontinence, orthostatic hypotension (a fall in blood pressure on standing), fainting.

**If a side effect occurs, if one of the side effects worsens or if you suffer from a side effect not mentioned in this leaflet, consult the doctor.**

Side effects can be reported to the Ministry of Health by clicking the link "דיווח על תופעות לוואי עקב טיפול תרופתי" found on the homepage of the Ministry of Health website ([www.health.gov.il](http://www.health.gov.il)) directing to the online form for reporting side effects or via the link: <https://sideeffects.health.gov.il>

**5. How to store the medicine?**

- Avoid poisoning! This medicine and any other medicine must be stored 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 the doctor.
- Do not use the medicine after the expiry date (EXP) stated on the package. The expiry date refers to the last day of that month.
- **Storage conditions:** store below 30°C.

**6. Additional information**

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

Lactose monohydrate, gelatin, pregelatinized maize starch, magnesium stearate, titanium dioxide (E171), sodium dodecyl sulfate, black ink (shellac, black iron oxide (E172), propylene glycol, ammonium hydroxide, potassium hydroxide).

Geodon 20, 40, 80mg capsules contain also indigotin (E132).

**What the medicine looks like and what the package contains:**

GEODON 20 MG CAPSULES: a blue/white capsule with "VTRS" and "ZDX 20" imprinted on it.

GEODON 40 MG CAPSULES: a blue capsule with " VTRS " and "ZDX 40" imprinted on it.

GEODON 60 MG CAPSULES: a white capsule with " VTRS " and "ZDX 60" imprinted on it.  
GEODON 80 MG CAPSULES: a blue/white capsule with " VTRS " and "ZDX 80" imprinted on it.

Approved package sizes: 14, 20, 30, 50, 56, 60 or 100 capsules.  
Not all package sizes may be marketed.

Revised in March 2025 according to MOH guidelines.

**Drug registration numbers at 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

**Manufacturer and registration holder:** Dexcel Ltd., 1 Dexcel St., Or Akiva 3060000, Israel