

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: **S5**

GEODON® 20 mg Capsules

GEODON® 40 mg Capsules

GEODON® 60 mg Capsules

GEODON® 80 mg Capsules

Ziprasidone hydrochloride

Contains sugar (lactose monohydrate)

Each 20 mg capsule contains 66,10 mg lactose monohydrate.

Each 40 mg capsule contains 87,83 mg lactose monohydrate.

Each 60 mg capsule contains 131,74 mg lactose monohydrate.

Each 80 mg capsule contains 175,66 mg lactose monohydrate.

Read all of this leaflet carefully before you start taking GEODON

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- GEODON has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

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

6. Contents of the pack and other information

1. What GEODON is and what it is used for

GEODON is a type of prescription medicine called an antipsychotic. Antipsychotics are medicines used to treat symptoms of schizophrenia.

2. What you need to know before you take GEODON

Do not take GEODON:

- If you are hypersensitive (allergic) to ziprasidone or any of the other ingredients of GEODON (listed in section 6).
- If you have certain heart diseases, for example, a long QT interval syndrome, a recent heart attack, heart failure, or irregularities of heart rhythm (discuss the specifics with your doctor).
- If you are taking any of the following medicines: dofetilide, sotalol, quinidine, mesoridazine, thioridazine, chlorpromazine, droperidol, pimozide, sparfloxacin, gatifloxacin, moxifloxacin, halofantrine, mefloquine, pentamidine, arsenic trioxide, levomethadyl acetate, dolasetron mesylate, probucol or tacrolimus.
- If you are pregnant, might be pregnant, or plan to get pregnant.
- If you are breastfeeding.
- If you are under the age of 18 years.

Warnings and precautions

Take special care with GEODON:

- If you have ever had problems with your heart, especially if you have a history of dysrhythmia (a problem with the rate or rhythm of the heartbeat). You must inform your doctor if you are taking any medicines that are known to affect the heart's rhythm.
- If you have any previous problems with blood clotting.
- If you have ever had a reaction to GEODON called neuroleptic malignant syndrome (NMS), which includes symptoms such as high fever associated with muscle stiffness/pain/weakness, tiredness, confusion and sweating.
- If you develop a rash or other signs or symptoms of hypersensitivity such as fever or enlargement

of lymph nodes, you should tell your doctor immediately as this may be an indication of a serious medical event.

- If you have ever had a reaction to GEODON called tardive dyskinesia, which involves involuntary twitching or movements of the face and tongue, as well as of the arms and legs.
- GEODON may cause sleepiness, dizziness, fall in blood pressure when standing up and gait disturbances, which may lead to falls. Caution should be taken, particularly if you are an elderly patient or have some debility.
- If you have had seizures.
- If you are over 65 years old, and especially if you have a condition known as “dementia-related psychosis”, GEODON should not be used.
- If you are experiencing a painful and long-lasting erection.
- If you are experiencing milk flow from the breast, an absence of menstrual period or impotence.
- If you are diabetic or have a family history of diabetes, as GEODON can cause high blood sugar episodes.

Your doctor may want you to get additional laboratory tests to see if GEODON is an appropriate treatment for you.

Other medicines and GEODON

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

GEODON sometimes affects the action of other medicines and sometimes the effect of GEODON is affected by other medicines.

- GEODON should not be used in combination with medicines used to control heart rhythm – check with your doctor-
- Caution should be used when GEODON is used together with:
 - Ketoconazole (a medicine used to treat fungal infections).
 - Carbamazepine (a medicine used to control seizures).
 - Rifampicin (a medicine used to treat tuberculosis infections).
 - St. John’s Wort (a herbal remedy used to treat depression).
 - Other centrally acting medicines including selective serotonin reuptake inhibitors (SSRIs) (used

to treat depression).

GEODON with food, drink and alcohol

GEODON should be taken with food.

Caution should be used when GEODON is taken in combination with alcohol.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding your baby, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

You should not take GEODON if you are pregnant.

If you are a woman of childbearing potential, an appropriate method of contraception should be used.

You should not take GEODON if you are breastfeeding your baby.

Driving and using machines

GEODON can cause sleepiness. Be advised not to drive a car or operate potentially dangerous machinery until it is known that GEODON does not affect your ability to engage in these activities.

It is not always possible to predict to what extent GEODON may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which GEODON affects them.

GEODON capsules contain lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. HOW TO TAKE GEODON

Do not share medicines prescribed for you with any other person.

Always take GEODON exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Swallow the capsules whole with plenty of water. The capsules should be taken with food and swallowed whole without chewing, crushing or opening beforehand because it may affect the absorption of the medicine. Try to take the capsules at the same time every day.

Use in adults

The amount of GEODON needed varies from person to person. Most people need 40 mg twice a day.

The daily dose may be adjusted by your doctor to 80 mg twice a day.

You should not alter the dose yourself without your doctor's advice.

Your doctor will tell you how long your treatment with GEODON will last. Do not stop taking GEODON unless told to do so by your doctor. Should you need to stop taking GEODON, your doctor will decide which the best method is for you.

If you have the impression that the effect of GEODON is too strong or too weak, tell your doctor or pharmacist.

Use in children

Safety and effectiveness in children under the age of 18 years has not been determined.

If you take more GEODON than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre. You may feel unusually sleepy or tired, anxious or experience abnormal muscle movements. Always take the GEODON package with you, whether there are any capsules left or not.

If you forget to take GEODON

If you forget to take a capsule, take it as soon as you remember unless it is time for the next dose. Do not take a double dose to make up for forgotten individual doses. If you forget to take GEODON for more than one week, call your doctor before taking any more GEODON.

4. Possible side effects

GEODON can have side effects.

Not all side effects reported for GEODON are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking GEODON, please consult your health care provider for advice.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- Involuntary/unusual movements, especially in your face or tongue (tardive dyskinesia).
- Fast or irregular heartbeat, dizziness on standing up which may indicate abnormal functioning of the

heart. These could be symptoms of a condition known as orthostatic hypotension.

- Swelling in the face, lips, tongue or throat, swallowing or breathing problems, a nettle rash. These could be symptoms of a serious allergic reaction such as angioedema.
- Feel a change in the way that your heart beats (palpitations) such as fast irregular heartbeat and fainting. These could be symptoms of a life-threatening condition known as Torsades de Pointes.
- Fever, faster breathing, sweating, muscle stiffness, shaking, difficulty swallowing and reduced consciousness. These could be symptoms of a condition known as neuroleptic malignant syndrome.
- Skin reactions, in particular rash, fever and swollen lymph nodes which could be symptoms of a condition called drug reaction with eosinophilia and systemic symptoms (DRESS). These reactions could be life-threatening.
- If you develop a skin rash that causes blistering (this can affect the mouth, tongue and eyes). This potentially life-threatening skin rash is often accompanied by flu-like symptoms. The rash may progress to widespread blistering or peeling of the skin. These may be signs of a condition known as Stevens-Johnson syndrome.
- Confusion, agitation, high temperature, sweating, lack of muscle co-ordination, muscle twitching. These could be symptoms of a condition known as serotonin syndrome.
- Persistent abnormal and painful erection of the penis.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects

- Difficulty sleeping.
- Sleepiness.
- Headache.
- Restlessness.
- Anxiety.
- Abnormalities of movement including involuntary movements, muscular rigidity, slowness of movements.
- Tremor.

- Dizziness.
- Blurred or impaired vision.
- Nausea, vomiting, constipation, indigestion, dry mouth, increased salivation.
- Male sexual problems.
- Abnormal physical weakness or lack of energy.

Less frequent side effects

- Increased appetite.
- Nightmares.
- Nervousness.
- Decreased sexual desire.
- Seizures, drooling, clumsiness, speech disorder, reduced ability to concentrate, excessive daytime sleepiness, numbness, pins and needles sensation, a lack of energy and enthusiasm.
- Palpitations.
- Involuntary eyes movements into a fixed position.
- Sensitivity to light.
- Sensation of spinning (vertigo), buzzing in the ears.
- High blood pressure.
- Difficulty breathing.
- Sore throat.
- Diarrhoea, stomach pain or discomfort, tongue disorder, wind.
- Itchy skin rash, acne.
- Unusual position of the head.
- Muscle discomfort or cramp.
- Stiff or swollen joints.
- Breast enlargement in men.
- Chest discomfort, abnormal walk, pain, thirst.
- Abnormal liver function test results.
- Runny nose.

- Decrease in calcium levels in the blood.
- Panic attack, feeling depressed.
- Slowed thinking, lack of emotions feeling flat.
- Reduced orgasm.
- Weakness or partial paralysis, absence of movement.
- Restless legs syndrome.
- Decrease in white blood cells (in blood test).
- Partial or complete loss of vision in one eye (lazy eye), disturbances in vision, itchy or dry eyes.
- Ear pain.
- Difficulty speaking, hiccups.
- Acid reflux, loose stools.
- Patches of raised and inflamed red skin covered by a white scale known as psoriasis.
- Dermatitis, skin irritations.
- Hair loss.
- Swollen face.
- Inability to open mouth (lockjaw).
- Difficulty emptying bladder, pain or difficulty urinating.
- Erectile dysfunction or increased erection.
- Abnormal breast milk production.
- Fever or feeling hot.
- Abnormal liver function or blood test results.

Frequency not known

- Hypersensitivity.
- High levels of prolactin in the blood.
- Abnormally high mood energy, feeling agitated.
- Fainting.
- Facial weakness or facial droop.
- Sedation.

- 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.
- Difficulty swallowing, swollen or thick tongue.
- Loss of bladder control, especially at night.
- Absence of menstruation.
- Tiredness.
- Weight loss or gain.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the “**6.04 Adverse Drug Reactions Reporting Form**”, found online under SAHPRA’s publications: <https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of GEODON.

5. How to store GEODON

Store all medicines out of reach of children.

Store at or below 30 °C.

Store in the original package. Keep the container in the outer carton. Keep the container tightly closed.

Protect from light and moisture. Do not store in a bathroom.

Do not use after the expiry date stated on the label.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What GEODON capsules contain

The active substance is ziprasidone hydrochloride.

The content of the capsules is lactose monohydrate, magnesium stearate and pregelatinised starch.

The capsule shells contain gelatine and titanium dioxide.

The printing ink contains indigotin/indigo carmine (20 mg, 40 mg and 80 mg).

What GEODON look like and contents of the pack

GEODON 20 mg: No. 4 blue/white locking type hard gelatine capsule, imprinted in black with “Pfizer” and “ZDX 20”.

GEODON 40 mg: No. 4 blue locking type hard gelatine capsule, imprinted in black with “Pfizer” and “ZDX 40”.

GEODON 60 mg: No. 3 white locking type hard gelatine capsule, imprinted in black with “Pfizer” and “ZDX 60”.

GEODON 80 mg: No. 2 blue/white locking type hard gelatine capsule, imprinted in black with “Pfizer” and “ZDX 80”.

GEODON is available in the following containers:

Blister strips (PVC/foil) containing 14, 20, 30, 50, 56, 60 or 100 capsules.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

Upjohn South Africa (Pty) Ltd

85 Bute Lane

Sandton

2196

South Africa

Tel.: +27(0)11 320 6000 / 0860 734 937 (Toll-free South Africa)

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