Package leaflet: Information for the user

GEODON™
20 mg/ml powder and solvent for solution for injection
Ziprasidone

Read all of this leaflet carefully before you start using 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 and will be given to you by a doctor or a nurse.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist. 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 Geodon Injection is and what it is used for

Geodon belongs to a group of medicines called antipsychotics.

Geodon for injection is used to quickly control agitation (anxiety) in the treatment of schizophrenia in adults - a mental disorder characterised by the following symptoms: to hear, see and feel things that do not exist, to believe in something not true, to feel unusual suspicions, to be absent and have difficulty in establishing social relationships, nervousness, depression or anxiety.

Geodon for injection can be used for a maximum of three consecutive days.

2. What you need to know before you use Geodon Injection

You may have been given Geodon in an emergency so you may be reading this leaflet after having been given it. Your doctor will have considered the following points but check them yourself in case you need to be given Geodon again.

Do not use Geodon
- if you are allergic to ziprasidone or any of the other ingredients of this medicine (listed in Section 6). Signs of an allergic reaction include; rash, itching, swelling in the face, or lips, difficulty in breathing.
- if you suffer or have suffered from heart problems or have recently had a heart attack.

- if you use medicines for heart rhythm problems or that may affect the heart's rhythm.

Also refer to the section "Other medicines and Geodon Injection" below.

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Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking Geodon Injection

- if 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 liver problems
- if you suffer or have suffered from seizure or epilepsy
- if you are elderly (over 65 years old) and suffer from dementia and are at risk of having a stroke
- if you have a low resting heart-rate and/or you know that, you may have salt depletion as a result of prolonged severe diarrhoea and vomiting (being sick) or usage of diuretics (water tablets)
- if you experience a fast or irregular heartbeat, fainting, collapse or dizziness on standing up which may indicate abnormal functioning of the heart rate

Contact your doctor immediately if you experience any of the following:

- Severe skin reactions such as rash with blisters which could include ulcers in the mouth, skin shedding, fever and target-like spots on the skin that could be symptoms of Stevens-Johnson syndrome. These skin reactions could potentially be life-threatening
- Persistent abnormal and painful erection of the penis, also known as priapsim

Tell your doctor that you are having Geodon before you have a laboratory test (such as blood, urine, liver function, heart rate etc) because it may alter the results of the test.

Other medicines and Geodon Injection

Tell your doctor or pharmacist if you are using or have recently used or might use any other medicines, including medicines obtained without a prescription.

Do not use Geodon Injection if you use medicines for heart rhythm problems or medicines that may affect the heart's rhythm, such as:

- Class IA and III antiarrhythmics, arsenic trioxide, halofantrine, levomethadyl acetate, mesoridazine, thioridazine, pimozide, sparfloxacin, gatifloxacin, moxifloxacin, dolasetron mesilate, mefloquine, sertindole or cisapride. These medicines affect the heart rhythm by prolonging the QT interval. If you have any further questions about this you should speak to your doctor.

Talk to your doctor or pharmacist before taking Geodon Injection

Please tell your doctor or pharmacist if you are using or have recently used medicines for the treatment of:

- skin and fungal infections such as ketoconazole;
- mood swings (ranging from depressive mood to euphoria), agitation and irritation; these are known as mood stabilising medicines e.g. lithium, carbamazepine, valproate;

- depression, including certain serotonergic medicines e.g. Selective serotonin reuptake inhibitors (SSRI's) such as fluoxetine, paroxetine, sertraline;
- epilepsy e.g. phenytoin, phenobarbital, carbamazepine, ethosuximide;
- Parkinson's disease e.g. levodopa, bromocriptine, ropinirol, pramipexole.

Also refer to the section "Do not use Geodon" above.

Taking Geodon with food and drink

You should not drink alcohol during treatment with this medicine, as this may increase the risk of side effects.

Pregnancy and breast-feeding

Pregnancy
Do not use Geodon during pregnancy unless you are told otherwise by your doctor because there is a risk that this medicine may harm your baby. Always use effective contraception. Tell your doctor immediately if you become pregnant or are planning to become pregnant whilst using this medicine.

The following symptoms may occur in newborn babies, of mothers that have used antipsychotics 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 should contact your doctor.

Breast-feeding
Do not breast-feed if you are using Geodon. This is because small amounts may pass into the mother's milk. If you are planning to breast-feed talk to your doctor before taking this medicine.

Ask your doctor or pharmacists for advice before using any medicine.

Driving and using machines
Taking Geodon may make you feel drowsy after receiving this medicine. If you experience this symptom, do not drive or use tools or machinery until the drowsiness disappears.

Geodon Injection contains sodium.
This medicinal product contains less than 20 mg of sodium in each dose and therefore is essentially sodium-free.

3. How to use Geodon Injection

Adults
Geodon for injection is given into a muscle. Your doctor or pharmacist will decide how much medicine you should receive. The recommended dose is 10 mg but some people may need 20 mg as their first dose. If the dose of your first injection is 10 mg,

you may be given another injection two hours later. If your first dose is 20 mg, you may be given another injection four hours later.

Your doctor may adjust the amount of medicine you are given so that your symptoms are adequately controlled.

Geodon for injection will be given to you for a maximum of three consecutive days. If you need further treatment your doctor may decide to continue your treatment using Geodon capsules or Geodon oral suspension.

Geodon must not be injected into a blood vessel.

Children and adolescents
Children and adolescents under the age of 18 should not be given Geodon for injection.

Elderly (over 65 years old)
The use of Geodon is not recommended.

Patients with liver problems
If you have liver problems you will usually be given a lower dose of this medicine. Your doctor will work out the correct dose for you.

Patients with kidney problems
Tell your doctor if you have kidney problems as this may affect the dose your doctor prescribes for you.

If you think you have been given more Geodon than you should
If you think you have been given more medicine than you should, inform your doctor or nurse immediately.

If you have received too much of this medicine, you may experience drowsiness, shaking, fits, feeling more anxious and uncontrollable movements of the head and neck.

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. However, most side effects are transient. It may often be difficult to distinguish the symptoms of your disease from those of side effects.

STOP using Geodon and contact your doctor immediately if you experience any of the following serious side effects:

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

- 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 postural hypotension.
- Involuntary/unusual movements, especially in your face or tongue.

Not known (frequency cannot be estimated from the available data):

- 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.
- 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 potentially life-threatening.
- Confusion, agitation, high temperature, sweating, lack of muscle co-ordination, muscle twitching. These could be symptoms of a condition known as serotonin syndrome.
- Fast, irregular heartbeat, fainting which could be symptoms of a life-threatening condition known as Torsades de Pointes.

You may experience any of the following side effects listed below. These potential side effects generally are mild to moderate and may resolve with time. However, if the side effect is severe or persistent, you should contact your doctor.

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

- restlessness
- abnormalities of movement including involuntary movements, muscular stiffness and rigidity, slowness of movements, shaking
- sleepiness
- headache
- dizziness
- high blood pressure
- low blood pressure
- nausea, vomiting
- muscle rigidity
- feeling weak and or loss of strength
- burning and/or pain at the site of injection

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

- decreased appetite
- feeling agitated or anxious, increased difficulty in social relationships, seeing or hearing things that are not there
- difficulty in sleeping
- difficulty in controlling movements or making involuntary sounds such as throat clearing, sniffing, or grunting, difficulty and/or not being able to move parts of your body, clumsiness
- feeling dizzy and/or problems with your balance when standing or walking

- speech disorder
- slow and/or irregular heart rate, increased heart rate
- loss of balance, light-headedness
- feeling light-headedness or dizzy when you suddenly stand up, low blood pressure
- feeling flushed
- throat tightness, difficulty in swallowing
- stomach problems such as constipation, diarrhoea
- dry mouth
- increased and/or excessive sweating
- increase in liver enzymes
- increased tiredness, having flue like illness
- discomfort, redness at the injection site
- drug withdrawal syndrome

Rare side effects (may affect up to 1 in 1,000 people):
- urinary incontinence, pain or difficulty urinating

Not known (frequency cannot be estimated from the available data):
- mania and or hypomania symptoms include extremely high mood energy, strange thinking patterns and hyperactivity
- facial droop/sagging of the face
- dizziness, loss of consciousness
- 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
- involuntary urinating

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, Earlsfort Terrace, IRL-Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; e-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Geodon Injection

Keep this medicine out of the sight and reach of children.

Do not store above 30°C. Keep the container in the outer carton. Do not freeze.

Do not use this medicine after the expiry date, which is stated on the carton and vial 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 protect the environment

6. Contents of the pack and other information

What Geodon for injection contains

- The active substance is ziprasidone. Each vial contains 20 mg ziprasidone as ziprasidone mesilate.
- The other ingredients are sulphobutyl ether beta-cyclodextrin sodium and water for injections.

What Geodon looks like and contents of the pack
Geodon for injection is provided as a white to off-white powder for solution for injection and a clear and colourless solvent for solution for injection. Each carton contains 1 vial (powder) and 1 ampoule (solvent).

The vials are made of flint glass, sealed with rubber stoppers and flip-off aluminium seals. The ampoules are made of flint glass.

Marketing Authorisation Holder:
Pfizer Limited,
Sandwich
Kent CT13 9NJ
United Kingdom

Manufacturer:

Fareva Amboise
Zone Industrielle
29 route des Industries
37530 Pocé-sur-Cisse
France

or

Pfizer Ireland Pharmaceuticals
Pottery Road
Dun Laoghire
County Dublin
Ireland

You can also telephone the following national helplines for more advice on schizophrenia:
Schizophrenia Ireland: 01 860 1620
Mental Health Association of Ireland: 01 284 1166

This medicinal product is authorised in the Member States of the EEA under the following names:

EU COUNTRIES	**INTRAMUSCULAR**
Austria, Denmark, Finland, Germany, Iceland, Italy, Norway, Portugal, Spain,	ZELDOX

Sweden	
Greece, Ireland	GEODON

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Health Care Professional: Please read and detach before handing leaflet to patient.

METHOD OF PREPARATION AND ADMINISTRATION OF GEODON 20 mg/ml POWDER AND SOLVENT FOR SOLUTION FOR INJECTION

Preparation

- Aseptic technique must be used for the preparation of the final intramuscular solution as no preservative or bacteriostatic agent is included in the product.
- Each vial of GEODON powder should be reconstituted by the introduction of 1.2 ml of the supplied Water for Injection solvent to achieve a final concentration of 20 mg ziprasidone per ml and shaking for approx 1/2 - 1 minute until all the contents have completely dissolved.
- Only the supplied Water for Injections solvent should be used to reconstitute GEODON 20mg/ml Injection.
- As the vials are for single use only, any unused portion of the solution should be discarded.
- Prior to administration, carefully inspect the vial visually for particles and discoloration.
  Discard vials containing discoloured solution or visible particulate matter.

Administration

- Withdraw the appropriate volume (0.5 or 1 ml) of solution from the vial of reconstituted solution and administer by intramuscular injection

Compatibility and Stability

- Additives or other medication should not be added to GEODON 20 mg/ml Injection. If GEODON 20mg/ml Injection is to be given at the same time as another drug, each drug should be given separately according to the manufacturer's recommended dosage and route of administration.
- GEODON 20 mg/ml Injection has been shown to be stable after reconstitution for up to 24 hours at 25°C or for up to 7 days when refrigerated at 2 - 8°C.
- After reconstitution, the solution should be protected from light and from a microbiological point of view should be used immediately.
- When reconstituted as directed, a fill volume of 1.5 ml is created (50% overfill) containing a total of 30 mg ziprasidone. This overfill facilitates the withdrawal of 1 ml to provide 20 mg of ziprasidone.
- After withdrawal of the dose, discard any unused solution.

- Do not store above 30°C
- Keep the container in the outer carton.
- Do not freeze.