PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S5

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM:

GEODON IM 20 mg/ml Powder for Solution for Injection (vials)

Read this leaflet carefully before you start to take this medicine

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or pharmacist.
- GEODON Injection 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.

1. WHAT GEODON INJECTION CONTAINS:

The active ingredient of GEODON Injection is ziprasidone mesylate.

GEODON Injection is supplied with WATER FOR INJECTIONS. The GEODON powder is mixed with the WATER FOR INJECTIONS. After mixing, each ml contains 20 mg ziprasidone.

Other ingredients: Sulphobutyl ether β-cyclodextrin sodium.

2. WHAT GEODON INJECTION IS USED FOR:

GEODON is a type of prescription medicine called an antipsychotic. GEODON Injection is used in emergency situations to quickly relieve the symptoms of what is known as an acute schizophrenic episode.

3. BEFORE YOU TAKE GEODON INJECTION:

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

GEODON Injection should not be taken if:

- You have ever had an allergic reaction to ziprasidone or any of the other ingredients of GEODON Injection. An allergic reaction may be recognised as a rash, itching, a swollen face, swollen lips, or shortness of breath. Tell your doctor if this has ever happened to you.
- You have ever had any problems with your heart like a recent heart attack, severe heart failure, or certain irregularities of heart rhythm (discuss the specifics with your doctor).

Only your doctor can decide if GEODON INJECTION is right for you. Be sure to tell your doctor if you:

- Are taking any other medicines prescribed by a doctor, or that you may have bought. In particular, any medicines for anxiety, depression, epilepsy or Parkinson's disease or medicines that are known to affect the heart's rhythm.
- Have had liver problems.
- Have had kidney problems.
- Have had seizures (fits).
- Have ever had problems with your heart.
- Are pregnant, might be pregnant, or plan to get pregnant.
- Are breastfeeding.
- Are allergic to any medicines.
- Are under 18 or over 65 years old.

Pregnancy and breastfeeding:

Pregnancy:

GEODON Injection should be avoided if you are pregnant or think you may be, unless your doctor considers GEODON Injection to be essential for you.

Breastfeeding:

GEODON Injection must not be taken during breastfeeding.

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machinery:

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

Taking other medicines with GEODON INJECTION:

GEODON sometimes affects the action of other medicines and sometimes GEODON is affected by other medicines. Always tell your pharmacist you are taking GEODON when you buy medicines, including over-the-counter medicines and herbal remedies. If you require an operation or will visit your dentist or doctor, let them know that you are taking GEODON.

Caution should be used when it is taken in combination with other centrally acting agents, including alcohol.

4. HOW TO RECEIVE GEODON INJECTION?

GEODON injection is given by injection into a muscle. Your doctor will decide how much GEODON injection you should receive.

Adults:

The usual dose is 10 mg, but some patients may need 20 mg as their first dose. After a 10 mg injection, you may be given another one 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 GEODON Injection you are given so you get the right amount to control your symptoms.

GEODON Injection may be given for up to three days in a row. After using GEODON injection, your doctor may prescribe GEODON capsules which you swallow.

5. POSSIBLE SIDE EFFECTS:

As with all medicines, side effects are reported with the use of GEODON Injection. Tell your doctor if any side-effects worry you or are particularly severe.

The most common side effects of GEODON which patients may experience are injection site pain, nausea, dizziness and sleepiness.

Other common side effects include the following and should also be discussed with your doctor if they occur:

Weakness, headache, higher blood pressure, feeling dizzy when you stand up, restlessness.

Other uncommon side effects include, flu-like symptoms, slower or faster heartbeat, lower blood pressure, loss of appetite, dry mouth, vomiting, unusual movements, agitation, sleeplessness, problems

with speech, vertigo (dizziness in high places), sweating.

Severe skin reactions that could lead to death have been reported.

Not all side effects reported for this medicine are included in this leaflet. Also, tell your doctor if any other effects occur while you are taking GEODON Injection.

6. STORING AND DISPOSING OF GEODON INJECTION:

Keep all medicines out of reach and sight of children. Store at or below 30 °C. Protect from light. Keep the container in the outer carton. Do not freeze.

DO NOT use GEODON Injection after the expiry date which is printed on the label. Return all unused medicine to your pharmacist. DO NOT dispose of unused medicine in drains or sewerage systems (e.g. toilets).

7. PRESENTATION OF GEODON INJECTION:

GEODON is available in the following packaging:

A carton containing 1 clear glass vial of GEODON IM 20 mg/ml powder for solution for injection, and 1 clear glass ampoule of WATER FOR INJECTIONS.

8. IDENTIFICATION OF GEODON INJECTION:

GEODON 20 mg/ml Powder for Solution for Injection: A vial containing a white to off-white powder. The reconstituted product is a clear and practically particle-free solution.

WATER FOR INJECTIONS: A clear colourless solvent.

9. REGISTRATION NUMBER / REFERENCE NUMBER:

GEODON IM 20 mg/ml: 36/2.6.5/0478

PFIZER WATER FOR INJECTIONS: 36/34/0479

10. NAME AND ADDRESS OF REGISTRATION HOLDER:

Pfizer Laboratories (Pty) Ltd

85 Bute Lane

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South Africa

11. DATE OF PUBLICATION OF THE PATIENT INFORMATION LEAFLET:

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