

Pharma Ltd.





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LEAFLET

CIT-20 TABLETS (CITALOPRAM TABLETS BP 20 MG)

Composition:

Each Film coated tablet contains: Citalopram Hydrobromide BP Eq. to Citalopram 20 mg

Category: Antidepressant Drug

Clinical Pharmacology:

Citalogram selectively inhibit the reuptake of serotonin

(5-hydroxytryptamine,5-HT).

Citalopram hydrobromide acts as an antidepressant by potentiating the serotonergic activity in the central nervous system (CNS). Multiple studies in the past confirmed that citalopram hydrobromide is a selective serotonin reuptake inhibitor (SSRI) and that it does not have any effect on norepinephrine or dopamine reuptake. It has a low affinity for muscarinic acetylcholine receptors, but no significant effect on alpha- or beta-adrenergic receptors or dopamine-1, dopamine-2, histamine, 5HT1A, 5HT1B, gamma-aminobutyric, acid, opioid, or benzodiazepine receptors.

The onset of action for depression is about 1 to 4 weeks. However, the full response may take 8 to 12 weeks after initiation of treatment.

Bioavailability is 80%: Tablets and oral solution are bioequivalent Half-life is 24 to 48 hours (average: 35 hours); however, half-life significantly increases in patients with hepatic impairment, mild-tomoderate renal impairment, in elderly patients (60 years or older), and in poor CYP2C19 metabolizes.

Indications:

Alcoholism

Depressive illness

Coronary arteriosclerosis

Obsessive-compulsive disorder

Panic disorder

Postmenopausal flushing

Premenstrual dysphoric disorder

Dosage and Administration:

The usual dose is (By mouth as tablets):

Adults: The usual dose is 20 mg per day. This may be increased

by your doctor to a maximum of 40 mg/day.

Elderly patients (>65 years of age): The starting dose should be decreased to half of the recommended dose, e.g. 10-20 mg per day. Elderly patients should not usually receive more than 20 mg per day. Use in children and adolescents: Citalopram should not be used in the treatment of children and adolescents under 18 years of age.

Liver problems: Patients with mild to moderate liver problems should receive a starting dose of 10 mg per day. Patients with liver complaints should not receive more than 20 mg per day. Such patients should be clinically monitored. Caution and extra careful dosing is advised in patients with severe liver problems.

* Always take this medicine exactly as your doctor has told you. Do not stop taking Citalopram even if you begin to feel better, unless you are told to do so by the doctor. Never change the dose of your medicine without talking to your doctor first.

Precautions and Warning:

For people with heart problems: Don't take citalogram if you have a heart problem, including a condition called congenital long QT



AGOG Pharma Ltd.





(WHO - GMP CERTIFIED - GOVT RECOGNISED EXPORT HOUSE)

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syndrome. Taking citalopram may put you at higher risk of a serious heart rhythm change called QT prolongation, which can cause sudden death. People with slow heart rate, recent heart attack, or severe heart failure should also not take citalopram

For people with low Potassium & Magnesium levels: Don't take citalopram if you have low potassium & Magnesium levels. It may put you at higher risk of a serious heart rhythm change called QT prolongation, which can cause sudden death.

For people with kidney disease: Talk to your doctor before using citalopram if you have kidney disease. This drug may build up and cause more side effects in people with severe kidney disease. For people with liver disease: Citalopram is processed by the liver. If you have liver disease, the levels of this drug in your body might increase, and may have more side effects. People with liver disease shouldn't take more than 20 mg of citalopram per day.

For pregnant women: Citalopram is a category C pregnancy drug. Talk to your doctor if you're pregnant or planning to become pregnant. This drug should be used only if the potential benefit justifies the potential risk to the fetus.

For women who are breastfeeding: Citalopram passes into breast milk and may cause side effects in a child who is breastfed. Talk to your doctor if you breastfeed your child.

Contraindication:

Citalopram is contraindicated in patients with a history of hypersensitivity to the drug or components. It is also contraindicated with monoamine oxidase inhibitors, including linezolid or IV methylene blue and also pimozide.

Do not start citalopram within 14 days of discontinuing an MAOI due to increased risk of serotonin syndrome.

SSRIs should be used with caution in patients with epilepsy

Adverse Reactions/Side Effects: If you experience any of the following symptoms immediately seek medical advice.

- Thoughts of suicide and suicidal behavior
- Extrapyramidal disorder (e.g. involuntary movements, muscle rigidity and muscle contraction. Common adverse effects are greater than 10%:
- CNS: Drowsiness, insomnia, dizziness, headache
- Dermatologic: Diaphoresis
- Gastrointestinal (GI): Nausea, vomiting, constipation, and diarrhea Serotonin syndrome has been reported in patients treated with this type of antidepressant (SSRI). Tell your doctor if you experience high fever, trembling, muscle twitches and anxiety because these symptoms may indicate the development of this condition. Treatment with Citalopram should be discontinued immediately.

STORAGE:

Store under normal storage condition.(15°C to 30°C).

Protect from light.

Keep all medicines out of reach of children.

PRASENTATION:

A Bulk pack of 100's Tablets.



Manufactured in India by:

AGOG PHARMA LTD.

Plot No. 33, Sector II, The Vasai Taluka Indl. Co-op. Estate Ltd., Vasai (E), Dist. Thane. INDIA.