LeCital®

Citalopram

Citalopram
A selective and potent serotonin reuptake inhibitor (SSRI).

Composition
LeCital® 20: Each tablet contains citalopram hydrobromide corresponding to 20 mg citalopram.

LeCital® 40: Each tablet contains citalopram hydrobromide corresponding to 40 mg citalopram.

LeCital® Syrup: Each 5 ml contains citalopram hydrobromide corresponding to 10 mg citalopram.

PHARMACOLOGICAL INFORMATION:

Pharmacological effects and mode of action
LeCital® is a potent and the most selective inhibitor of serotonin uptake with antidepressant effect.
LeCital® has no or very low affinity for a series of receptors including muscarine cholinergic receptors, histamine receptors and adrenoceptors. This absence of effects on receptors could explain why citalopram produces fewer of the traditional adverse effects of tricyclic antidepressants such as dry mouth, blurred vision, sedation, cardiotoxicity and orthostatic hypotension. Unlike other available SSRIs, *LeCital®* is only a very weak inhibitor of the Cytochrome P450 II D6 metabolic pathway with a consequent reduction in potential for adverse events and interactions.
The antidepressant effect usually sets in after 2 to 4 weeks.
LeCital® does not affect the cardiac conduction system or blood pressure. This is particularly important for elderly patients. In addition *LeCital®* does not affect the haematological, hepatic or renal systems. The low frequency of side effects and the minimal sedative properties of *LeCital®* make it especially useful in long-term treatment. Moreover, *LeCital®* neither causes weight gain nor potentiates the effect of alcohol.

Pharmacokinetics:
The oral bioavailability of citalopram is about 80%. Maximum citalopram plasma levels are reached 2 to 4 hours after dosing. The protein binding is below 80%. Metabolism proceeds by demethylation, deamination and oxidation. Unchanged citalopram is the predominant compound in plasma. The kinetics is linear. Steady-state conditions are achieved in 1-2 weeks. The biological half-life is about 1 ½ days. Excretion is via urine and faeces.

CLINICAL INFORMATION:

Therapeutic indications:
Treatment of depression.

Dosage and administration:
LeCital® is administered as a single daily dose. *LeCital®* tablets can be taken any time of the day without regard to food intake.

Adult:
LeCital® should be administered as a single oral dose of 20 mg daily. Dependent on individual patient response and severity of depression the dose may be increased to a maximum of 60 mg daily.

Elderly (above 65 years):
The recommended daily dose is 20 mg. Dependent on individual patient response and severity of depression the dose may be increased to a maximum of 40 mg daily.

Children:
Not recommended, as safety and efficacy have not been established in this population.

Reduced hepatic function:
Dosage should be restricted to the lower end of the dose range.

Reduced renal function:
Dosage adjustment is not necessary in cases of mild or moderate renal impairment. No information is available in cases of severe renal impairment.

Duration of treatment:
A treatment period of at least 6 months is usually necessary to minimize potential for relapse.

Contraindications:
Hypersensitivity to Citalopram.

Produced by:
JOSWE® medical
Jordan Sweden Medical and Sterilization Co
Na'ur - Jordan
الأردنية السويدية للمنتجات الطبية والتعقيم م.م. ناعور - الأردن
www.joswe.com

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Special warnings and special precautions for use:
As with other SSRIs, Citalopram should not be given to patients receiving Monoamine Oxidase Inhibitors (MAOIs), or for 14 days after their discontinuation. Treatment with MAOIs may be introduced 7 days after discontinuation of Citalopram.
Should the patient enter a manic phase Citalopram should be discontinued and appropriate treatment with a neuroleptic (e.g. zuclopenthixol) instituted.
As with all antidepressant treatment the possibility of suicide in depressed patients remains until significant remission occurs because release of inhibition may precede the antidepressant action.

Interaction with other drugs:
Simultaneous administration of Citalopram and MAO inhibitors may cause hypertensive crises (serotonin syndrome).
Sumatriptan's serotonergic effects are suspected to be enhanced by SSRIs. Until further evidence is available it is advised not to use citalopram simultaneously with sumatriptan. Pharmacokinetic interaction studies have shown that during Citalopram treatment only a weak inhibition of the sparteine oxygenase (CYP2D6) was indicated whilst the mephenytoin oxygenase was not influenced by Citalopram treatment.
Cimetidine caused a moderate increase in the average steady-state levels of Citalopram. It is therefore advised to exercise caution at the upper end of the dose range of Citalopram when it is used concomitantly with high doses of cimetidine.
There was no interaction with lithium or alcohol and no pharmacokinetic interactions of clinical importance with phenothiazines or tricyclic antidepressants.
No pharmacodynamic interactions have been found in clinical studies in which Citalopram has been given concomitantly with benzodiazepines, neuroleptics, analgesics, lithium, antihistamines, antihypertensive drugs, betablockers and other cardiovascular drugs.
There is little clinical experience of concurrent use of Citalopram and ECT.

Use during pregnancy and lactation:
The safety of Citalopram during human pregnancy and lactation has not been established. Therefore it is recommended that pregnant or lactating women are not treated with Citalopram unless the potential clinical benefit outweighs the theoretical risk.
Animal studies have not shown any evidence of teratogenic potential and Citalopram does not affect reproduction or perinatal conditions. Citalopram appears in milk in very low concentrations.

Effects on ability to drive or use machines:
Citalopram does not impair intellectual function and psychomotor performance. However, patients who are prescribed psychotropic medication may be expected to have some impairment of general attention and concentration either due to the illness itself, the medication or both and should be cautioned about their ability to drive a car and operate machinery.

Undesirable effects:
Adverse effects observed with Citalopram are in general mild and transient. They are most prominent during the first one or two weeks of treatment and usually attenuate as the depressive state improves.
The most commonly observed adverse events associated with the use of Citalopram and not seen at an equal incidence among placebo-treated patients were: dry mouth, nausea, somnolence, increased sweating and tremor. The incidence of each in excess over placebo is low (1< 10%).
In comparative clinical trials with tricyclic antidepressants the incidence of adverse events occurring with Citalopram was found to be lower in all cases.
In exceptional cases seizures have occurred.
Citalopram may cause a small reduction in heart rate which normally is without clinical importance. However, in patients with pre-existing low heart rate this may lead to bradycardia.

Overdose effects:
Symptoms:
When Citalopram has been taken alone recorded symptoms/signs were: somnolence, coma, stiffened expression, episode of grand mal convulsion, sinus tachycardia, occasional nodal rhythm, sweating, nausea, vomiting, cyanosis, hyperventilation. No case was fatal. The clinical picture was inconsistent.

Treatment:
There is no specific antidote. Treatment is symptomatic and supportive. Gastric lavage should be carried out as soon as possible after oral ingestion. Medical surveillance is advisable.

PHARMACEUTICAL INFORMATION:

Dosage forms /Description of product:
LeCital® 20 Tablet: Blistered pack of 30 tablets

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LeCital® Syrup: 120 ml amber glass bottle.

Storage conditions:
LeCital® should be stored at room temperature (below 30° C). Each pack has an expiry date.

Keep out of reach of children.