

SUMMARY OF PRODUCT CHARACTERISTICS

1. TRADE NAME OF MEDICINAL PRODUCT

Oropram® 10 mg, 20 mg or 40 mg.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Citalopram hydrobromide, equivalent to citalopram 10 mg, 20 mg or 40 mg.

List of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Tablet, film-coated.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Depression.

Panic disorder (alarm) with or without fear of open spaces (agoraphobia).

4.2 Posology and method of administration

Dosage for adults:

The medicine should be given once a day; doses may vary.

Depression: The initial dose is 20 mg per day, and may be increased to 40 mg per day if required. Larger doses than 60 mg per day are not recommended. For patients older than 65 years, the recommended daily dose is one half of the aforementioned doses, i.e. 10-30 mg per day, and a maximum of 40 mg per day.

It is important to administer the medicine for at least 2-3 weeks before the effects of the drug are assessed.

The period of treatment is 4-6 months depending on the reaction of the patient.

Panic attacks: Low doses are used at the start of the treatment to reduce the possibility of the exacerbation of the condition. Thus, the recommended initial dose is 10 mg per day. After one week's treatment the dose is increased to 20 mg per day. The usual maintenance dose is 20-30 mg per day. If the patient's reaction is unsatisfactory, the dose may be increased, but the maximum daily dose should not exceed 60 mg. In the treatment of panic attacks, maximum therapeutic benefit is reached in about 3 months, and is lasting with continued treatment.

Dosage for children:

The drug is not intended for children.

4.3 Contraindications

Hypersensitivity to citalopram or to any of the excipients.

Simultaneous use of MAO inhibitors.

4.4 Special warnings and special precautions for use

Care should be taken in the administration of the drug to patients with impaired hepatic or renal function.

Depression is accompanied by risk of suicide; at the start of the treatment, some antidepressants may increase this risk.

4.5 Interaction with other medicinal products and other forms of interaction

Citalopram and MAO inhibitors must not be administered simultaneously; at least 14 days should have passed between the administration of these two drugs, unless the MAO inhibitor's half life is very short.

The metabolism of citalopram is only in part dependent on the cytochrome P450 isoenzyme CYP 2D6, and unlike some other specific inhibitors of re-uptake, citalopram is a very mild inhibitor of this enzyme system (cytochrome P450) which takes part in the metabolism of many drugs. Citalopram's protein binding is relatively small (80%). Due to these characteristics of citalopram, its possibilities to cause clinically-significant adverse events are small.

4.6 Pregnancy and lactation.

Experience with the administration of the drug to pregnant women is very limited, and animal testing does not indicate foetal-damaging effects. Until further experience with

the use of citalopram for pregnant women has been gained, it should only be administered after careful consideration.

It is not known whether the drug is excreted in breast milk, and in animal testing, small amounts of the drug have been found in the milk.

4.7 Effects on ability to drive and use machines

Citalopram does not have any effects on intellectual functions or sensory motor functions. However, a patient using psychotropic drugs may expect impairment of his/her general attention and concentration abilities, either due to the disease itself, the medication or both. Patients should be warned that their ability to drive or operate machinery may be impaired.

4.8 Undesirable effects

Undesirable effects caused by citalopram are, in general, mild and temporary and pass even though the treatment is continued.

The most common adverse effect is nausea in up to 7% of cases.

Common (>1%):

Systemic: Headache, increased perspiration, fatigue, malaise, tremors, weight change and vertigo.

Vascular system: Palpitations.

Central nervous system: Sleep disturbances, perception disorder and agitation.

Digestive system: Nausea, constipation, diarrhoea, dyspepsia and dry mouth.

Urinary system: Difficulty in micturition.

Eyes: Accommodation difficulties.

Rare (0.1-1.0%):

Systemic: General indisposition, yawning.

Central nervous system: Agitation, confusion, difficulties in concentration, decreased sex drive and interrupted ejaculation.

Digestive system: Increased salivation.

Skin: Rash.

Respiratory system: Nasal congestion.

Eyes: Enlarged pupil.

Very rare (< 0.1%):

Central nervous system: Mania.

4.9 Overdose

In the event of an overdose of citalopram, adverse reactions may be amplified. Palpitations and impaired consciousness have also been observed.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Category by effects: ATC category: N 06 AB 04

Citalopram is a dicyclic phthalide derivative, and is effective against depression and anxiety attacks. The effect of the drug is due to a specific inhibition of the re-uptake of serotonin in the brain. The drug has no effect on the re-uptake of noradrenalin, dopamine or GABA. The drug and its metabolites have no antidopamine, antiadrenergic, antiserotonin, antihistaminic or anticholinergic effects. Even with long-term use, the drug does not have any effect on the number of receptors for chemical mediators in the central nervous system. The drug does not affect the cardiac conduction system nor blood pressure and it does not increase the effects of alcohol. Citalopram has a mild sedative effect.

5.2 Pharmacokinetic properties

The absorption of citalopram is very high, and independent of food consumption. Bioavailability after intake is higher than 80%. Maximum concentration in blood is reached after 1-6 hours and the steady state concentration in blood is reached after 1-2 weeks. Protein binding is about 14 l/kg and the half-life is about 36 hours, (possibly longer for the elderly). The drug is metabolized before it is excreted; about 30% in urine. The metabolites have similar though milder effects than the citalopram.

5.3 Preclinical safety data

Not applicable.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Microcrystalline cellulose, mannitol, magnesium stearate, silicon dioxide, hypromellose, macrogol and titanium dioxide colouring agent (E171).

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years.

6.4 Special precautions for storage

Store at (15-25°C) in closed containers.

6.5 Nature and contents of container

Plastic tablet container with sealed plastic cover.

Oropram 10 mg tablets : White, film-covered, round and convex with a diameter of 6 mm.

Package sizes: 28 tablets and 100 tablets

Oropram 20 mg: White, film-covered, round and convex with a diameter of 8 mm, with a division groove.

Package sizes: 28 tablets, 56 tablets and 100 tablets.

Oropram 40 mg: White, film-covered, round and convex with a diameter of 10 mm, with a cross-shaped groove.

Package sizes: 28 tablets, 56 tablets and 100 tablets.

6.6 Instructions for use, handling and disposal

Not applicable.

7. MARKETING AUTHORIZATION HOLDER

Actavis hf.

Reykjavíkurvegi 76-78

220 Hafnarfjörður

Iceland

8. MARKETING AUTHORIZATION NUMBERS

Oropram 10 mg: MT No. 990322 (IS)

Oropram 20 mg: MT No. 990323 (IS)

Oropram 40 mg: MT No. 990324 (IS)

9. DATE OF FIRST AUTHORIZATION

Oropram 10 mg: Authorization first granted on 1st November 2000.

Oropram 20 mg: Authorization first granted on 1st November 2000.

Oropram 40 mg: Authorization first granted on 1st November 2000.

10. DATE OF REVISION OF THE TEXT

9 February 2005.