



Opsonil®

Chlorpromazine Hydrochloride BP

Description

Chlorpromazine (Opsonil®) is a potent neuroleptic drug and exerts a relatively selective action on those part of the central nervous system concerned with alertness and performance. Chlorpromazine is also valuable as an antiemetic, potentiator of analgesic and disrupter of conditional avoidance reactions.

Mode of action

Chlorpromazine (Opsonil®) exerts its activities by blocking dopamine, alpha-adreno, muscarinic, serotonin and histamine-H1 receptor and helps in the management of psychotic and manic-depressive conditions including excitement, agitation and different psychomotor disturbances in schizophrenic patients.

Pharmacokinetics

The peak plasma level of Chlorpromazine has been reached in 1-4 hours for oral administration and 15-30 min for intramuscular injection. It is highly protein bound (90-99%). This drug is completely metabolized by liver and less than 1% unchanged drug has been excreted through urine.

Composition

Opsonil® 50 mg Tablet: Each film-coated tablet contains Chlorpromazine Hydrochloride BP 50 mg.

Opsonil® 100 mg Tablet: Each film-coated tablet contains Chlorpromazine Hydrochloride BP 100 mg.

Opsonil® Injection: Each 2 ml ampoule contains Chlorpromazine Hydrochloride BP 50 mg.

Indications

Schizophrenia and other psychoses (especially paranoid) mania and hypomania, Anxiety, psychomotor agitation, excitement, violent or dangerously impulsive behavior, Intractable hiccup, Nausea and vomiting of terminal illness where other drugs have failed or are not available), Childhood schizophrenia and autism.

Dosage & administration

Adult

Oral: Initially 25 mg 3 times daily increased by daily amount of 25 mg for maintenance dose. The usual range is 75-300 mg daily but some patients may require up to 1000 mg daily.

IM: 25-50 mg 6-8 hourly.

Children (1-5 years)

Oral: 0.5 mg/kg body weight every 4-6 hours. Maximum 40 mg daily.

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Children (6-12 years)

Oral: 8.3 mg daily. Maximum 75 mg daily.

IM: 0.5 mg/kg body weight every 6-8 hours. Maximum 75 mg daily.

Contraindications

Known hypersensitivity to chlorpromazine or to any of the excipients, bone marrow depression.

Side effects

Extrapyramidal symptoms (which can be reversed by dose reduction or anticholinergic agents) and on, prolonged administration, occasionally tardive dyskinesia; hypothermia, drowsiness, apathy, pallor, nightmares, insomnia, depression and more rarely agitation anticholinergic symptoms e.g. dry mouth, constipation, difficulty with micturition and blurred vision; hypotension, cardiac arrhythmias.

Use in pregnancy & lactation

USFDA pregnancy category C. Not recommended during pregnancy and lactation.

Precautions

Chlorpromazine should be avoided in patients with hepatic or renal dysfunction, parkinson's disease, hypothyroidism, cardiac failure, phaeochromocytoma, myasthenia gravis and prostate hypertrophy. It should be avoided in patients known to be hypersensitive to phenothiazines or with a history of narrow angle glaucoma or agranulocytosis. It should be used with caution in the elderly, particularly during very hot or cold weather. The elderly is particularly susceptible to postural hypotension. Close monitoring is required in patients with epilepsy or a history of seizures, as phenothiazines may lower the seizure threshold.

Drug interactions

Antacids slow the absorption, barbiturates increase clearance, ciprofloxacin and oral contraceptives increase plasma concentration of this drug. Benzodiazepines, anesthetic drugs, opioids increase the depressant action. Thiazide diuretics may cause orthostatic hypotension. Interaction with MAOIs may lead to additive hypotension.

Overdosage

Symptoms of chlorpromazine overdosage include drowsiness or loss of consciousness, hypotension, tachycardia, ECG changes, ventricular arrhythmia and hypothermia. Severe extrapyramidal dyskinésias may occur. Generalized vasodilation may result in circulatory collapse; raising the patient's legs may suffice. In severe cases, volume expansion by intravenous fluids may be needed; infusion fluids should be warmed before administration in order not to aggravate hypothermia.

Storage

Store in a cool and dry place, protected from light.

Packaging

Opsonil® 50 mg Tablet: Each carton contains 10X10 tablets in blister pack.

Opsonil® 100 mg Tablet: Each carton contains 10X10 tablets in blister pack.

Opsonil® Injection: Each carton contains 5X5 ampoules in blister pack.

Manufactured by
Opsonil Pharma Limited
Rupatali, Barishal, Bangladesh.
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