

Colon-S

Tablets



Composition:

Each Colon-S 50 Tablet contains: Sulpiride 50 mg.
Each Colon-S Fort Tablet contains: Sulpiride 200 mg.

Mechanism of Action:

Sulpiride is a member of the group of substituted benzamides. It is a selective antagonist of central dopamine (D_1 , D_2 and D_4) receptors. One of the unique characteristics of sulpiride is its bimodal activity, as it has both antidepressant and neuroleptic properties.

Pharmacokinetics:

Peak sulpiride serum levels are reached 3-6 hours after an oral dose. The plasma half-life in human is approximately 8 hours. Approximately 40% sulpiride is bound to plasma proteins. 95% of the compound is excreted in the urine and faeces as unchanged sulpiride. The elimination half-life is about 3-10 hours.

Indications:

Colon-S is indicated in the treatment of psychosis, obsessive-compulsive neurosis and digestive disorders.

Contraindications:

- Hypersensitivity to sulpiride or to any of the excipients.
- Phaeochromocytoma and acute porphyria.
- Concomitant prolactin-dependent tumours e.g., pituitary gland prolactinomas and breast cancer.
- Severe renal and hepatic impairment.
- Concomitant use with levodopa or antiparkinsonian drugs.

Warnings & Precautions:

- Extrapyramidal effects, principally akathisia have been reported in a small number of cases.
- Cases of venous thromboembolism (VTE) have been reported with antipsychotic drugs.
- Colon-S should be used with caution in the following situations:
 - In elderly people, particularly if they have dementia, hypertension or risk factors for stroke.
 - A history of blood clots since antipsychotic drugs can cause blood clots.
 - Patients with glaucoma, absence of intestinal transit, congenital stenosis of the gastrointestinal tract, urinary retention, or prostatic hypertrophy.
 - A history of breast cancer, due to the possible onset of hyperprolactinemia. Sulpiride may increase prolactin levels.

Pregnancy & Lactation:

Pregnancy: Colon-S is not recommended during pregnancy and in women of childbearing potential not using effective contraception.

Lactation: You should not breast-feed during therapy with Colon-S. You should consult the doctor about the best way to feed your baby if you are taking Colon-S.

Drug Interactions:

- Levodopa, antiparkinsonian drugs: reciprocal antagonism of effects between these drugs and neuroleptics.
- Alcohol: Enhances the sedative effects of neuroleptics.

- Combination with the following medications could induce arrhythmia (torsades de pointes) or prolong the QT interval: β -blockers, some Ca channel blockers (e.g. diltiazem, verapamil); diuretics, stimulant laxatives, amphotericin B; Class IA antiarrhythmic drugs (e.g. quinidine, disopyramide); Class III antiarrhythmic drugs (e.g. amiodarone, sotalol); pimozide, haloperidol, imipramine, antidepressants.

- Antacids or sucralate: The absorption of sulpiride is decreased after co-administration.

- Lithium: Increased risk of extrapyramidal effects.

- Antihypertensive drugs: enhanced antihypertensive effect.

Side Effects:

Common side effects are hyperprolactinemia, insomnia, sedation or drowsiness, extrapyramidal effects (these symptoms are generally reversible upon administration of antiparkinsonian medication), parkinsonism, tremor, akathisia, constipation, hepatic enzyme increased, maculo-papular rash, breast pain, galactorrhea and weight gain.

Driving & Using Machines:

This medicine can cause drowsiness. Caution should be exercised while driving or using machinery.

Dosage & Administration:

Adults: Dosage is individualised according to patient response and the predominant symptoms manifested.

- In patients with mainly positive symptoms: starting dosage, 400 mg twice a day, increased as necessary. Max: 1200 mg twice a day.

- In patients with mainly negative symptoms: 200-400 mg twice a day. Max: 800 mg daily.

- In patients with mixed positive and negative symptoms (neither predominating): 400-600 mg twice a day.

Children: Clinical experience in children under 14 years of age is insufficient to permit specific recommendations.

Overdose:

Symptoms: Restlessness, decrease in consciousness, extrapyramidal symptoms, agitation, confusion, low blood pressure, coma.

Treatment: Follow symptomatic and supportive treatment procedures. Sulpiride may be partially removed by haemodialysis or treated with alkaline osmotic diuresis. May administer anti-parkinsonian drugs, if necessary. If severe extrapyramidal symptoms occur, anticholinergics should be administered.

Storage:

Keep out of reach of children. Store below 25 °C.

Packaging:

Each Colon-S 50 carton box contains 20 Tablets in two blister strips.

Each Colon-S Fort carton box contains 10 Tablets in a blister strip.

- A medicament is a product which affects your health, and it's consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist experts in medicine, it's benefits and risks.
- Do not repeat the same prescription without consulting your doctor.
- KEEP THE MEDICAMENTS OUT OF REACH OF CHILDREN
- Council of Arab Health Ministries, Union of Arab Pharmacies

Reva Pharma for Pharmaceutical Industries - Idlib - Syria

POT008 / 002

