

Abbreviated prescribing information

Please consult the entire SPC

Name: Serdolect® sertindole.

Presentation: Tablets of 4, 12, 16 or 20 mg. **Indication:** Treatment of schizophrenia. Due to cardiovascular safety concerns, sertindole should only be used for patients intolerant to at least one other antipsychotic agent. Not for urgent relief of symptoms in acutely disturbed patients. **Switching from other antipsychotics:** Treatment can be initiated according to the recommended titration schedule concomitantly with cessation of other oral antipsychotics, or in place of the next depot injection. **ECG monitoring:** Mandatory prior to and during treatment with Serdolect®. ECG monitoring should be conducted at baseline, upon reaching steady state after approximately 3 weeks or when reaching 16 mg and again after 3 months of treatment. During maintenance therapy an ECG is required every 3 months. **Dosage and administration:** Once daily with or without meals. In patients where sedation is required, a benzodiazepine may be co-administered. **Adults:** All patients should be started on sertindole 4 mg/day. The dose should be increased by increments of 4 mg after 4-5

days on each dose until the optimal daily maintenance dose within the range of 12-20 mg is reached. Only in exceptional cases should the maximum dose of 24mg be considered. **Elderly (> 65 years):** Treatment should only be initiated after a thorough cardiovascular examination. Slower titration and lower maintenance doses may be appropriate. **Children and adolescents (< 18 years):** Not recommended. **Re-titration:** Not required if patients have been without Serdolect® for less than a week. Otherwise the recommended titration schedule should be followed. **Contraindications:** Prescribing physicians should comply fully with the required safety measures. Hypersensitivity to sertindole or any of the excipients. Known uncorrected hypokalaemia or hypomagnesaemia. History of clinically significant cardiovascular disease, congestive heart failure, cardiac hypertrophy, arrhythmia, or bradycardia (<50 beats per minute). Congenital long QT syndrome (or family history of this disease), or known acquired QT interval prolongation. Pregnancy. Severe hepatic impairment. **Drugs known to significantly prolong the QT interval:** e.g. class I a and III antiarrhythmics, antipsychotics, macrolides, antihistamines, quinolone antibiotics, cisapride, and lithium. **Drugs known to potentially inhibit hepatic cytochrome P450 3A enzymes:** e.g. 'azole' antifungal agents (systemic treatment), macrolide anti-










biotics, HIV protease inhibitors, calcium channel blockers, and cimetidine. **Special precautions:** Mild/moderate hepatic dysfunction. Risk of significant electrolyte disturbances: e.g. experiencing vomiting or diarrhoea, potassium depleting diuretic use. Parkinson's disease. Elderly > 65 years. Known poor metabolisers of CYP2D6. History of seizures. Breast-feeding. Dopamine agonists. Some SSRIs: e.g. fluoxetine, paroxetine (potent CYP2D6 inhibitors). Agents known to induce CYP isozymes: e.g. rifampicin, carbamazepine, phenytoin, phenobarbital. **Adverse events:** >10%: Rhinitis/nasal congestion. 1-10%: Decreased ejaculatory volume, dizziness, dry mouth, postural hypotension, weight gain, peripheral oedema, dyspnoea, paraesthesia, and prolonged QT interval. **Overdose:** Symptoms have included somnolence, slurred speech, tachycardia, hypotension, and transient prolongation of the QTc interval. Cases of Torsade de Pointes have been observed, often in combination with other drugs known to induce TdP. **Treatment:** There is no specific antidote to sertindole, and it is not dialysable, therefore appropriate supportive measures should be instituted. Adrenaline and dopamine should be used with caution (may worsen hypotension).

Serdolect[®]

Dosage Guide



Serdolect® dose titration

| | | | | |
|------------------|----------|-----------|---|-------|
| titration dose | Day 1-4 | 1 tablet |  | 4 mg |
| | Day 5-8 | 2 tablets |   | 8 mg |
| | Day 9-12 | 3 tablets |    | 12 mg |
| maintenance dose | | 1 tablet |  | 12 mg |
| | | 1 tablet |  | 16 mg |
| | | 1 tablet |  | 20 mg |

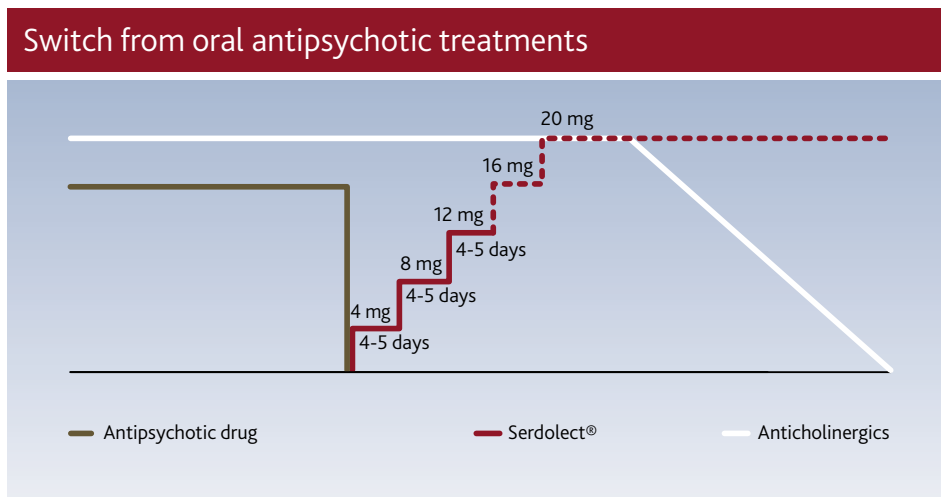
- Serdolect® should be titrated by increments of 4 mg after 4-5 days on each dose until the optimal daily maintenance dose is reached. ECG monitoring is mandatory prior to and during treatment with Serdolect (please consult the entire SPC).
- The defined dose is 16 mg/day but it may be increased to 20 mg/day or decreased to 12 mg/day depending on individual patient response. Only in exceptional cases should the maximum dose of 24 mg/day be considered.
- For the elderly, slower dose titration and lower maintenance dose should be considered. Patients with moderately reduced liver function: slower dose titration and lower maintenance dose.
- Blood pressure should be monitored during the initial dose titration phase and early in the maintenance phase.
- Patients who have stopped taking Serdolect® for less than a week can resume the maintenance dose immediately.
- Patients who have stopped taking Serdolect® for more than a week should follow the dose titration guidelines including a new ECG.

Tablet strengths and pack sizes

- 4 mg: 30 or 100 tablets
- 12 mg: 28 or 100 tablets
- 16 mg: 28 or 100 tablets
- 20 mg: 28 or 100 tablets



Switching to Serdolect®



- If anti-EPS medication has been used in conjunction with the previous antipsychotic drug, it should be continued for a month after starting Serdolect® to prevent possible rebound effects from the previous treatment.
- When switching from depot injection, including Acutard®/Acuphase®, Serdolect® should be titrated in the usual way, starting from the day the next injection would otherwise have been given.
- It's recommended to switch from clozapine in a stepwise manner. Down titrating clozapine while up-titrating Serdolect® in an overlapping fashion according to local clinical practise.

Sedation

Serdolect® is non-sedating.
If sedation is necessary, Serdolect® can be administered with a benzodiazepine without risk.