

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. *Chil-*

dren 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 antibiotics, 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).

H Lundbeck A/S: Ottiliavej 9, DK-2500 Valby, Copenhagen, Denmark. www.serdolect.com, www.lundbeck.com, date: 2006-03-03.

References:

1. Summary of Product Characteristics (SPC)
2. Azorin et al. Int Clin Psychopharmacol 2006; 21: 49-56
3. Zimbroff et al. Am J Psychiatry 1997; 154: 782-91
4. Tamminga et al. Int Clin Psychopharmacol 1997; 12 (Suppl 1): S29-S35
5. Lublin et al. Int Clin Psychopharmacol 2005; 20: 183-98
6. Serdolect Product Monograph, www.serdolect.com
7. Peuskens et al. CNS Drugs 2004; 18 (Suppl 2): 1-43
8. Kasper et al. Int J Psych Clin Pract 2002; 5 (Suppl 1): S1-S35
9. Hale et al. Int J Psych Pract 2000; 4: 55-62
10. Hale et al. Int J Psych Pract 2000; 4: 47-54

Serdolect® Prescribing Aid



Lundbeck  Serdolect
sertindole

Lundbeck  Serdolect
sertindole

Patients are likely to benefit from switching to Serdolect®¹⁻¹⁰

- If positive/negative symptoms are not controlled
- If sedation or EPS are present
- If they experience excessive weight gain
- If their cognitive functioning is impaired
- If they are experiencing anticholinergic side effects
- If their sexual functioning is disturbed

Check the following before prescribing Serdolect®

- Serdolect® is indicated for the treatment of schizophrenia in patients who are intolerant to at least one other antipsychotic agent.
- ECG monitoring is mandatory before 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.

- Please advise other relevant physicians (e.g. GPs) seen by the patients, to pay attention to contraindications and precautions.
- Please consult Serdolect® prescribing information for further details.

Contraindications

If you tick any of these boxes, you should **not** prescribe Serdolect® to your patient.

Does your patient currently have any of the following medical conditions or do any of the circumstances shown apply?	<input checked="" type="checkbox"/>
Hypersensitivity to Serdolect® or any of the excipients	<input type="checkbox"/>
Known uncorrected hypokalaemia or hypomagnesaemia	<input type="checkbox"/>
History of clinically significant cardiovascular disease, congestive heart failure, cardiac hypertrophy, arrhythmia, or bradycardia (<50 bpm)	<input type="checkbox"/>
Congenital long QT syndrome (or family history of this disease) or known acquired QT interval prolongation	<input type="checkbox"/>
Pregnancy	<input type="checkbox"/>
Severe hepatic impairment	<input type="checkbox"/>

Is your patient currently receiving any of the following medications?

Is your patient currently receiving any of the following medications?	<input checked="" type="checkbox"/>
Drugs known to significantly prolong the QT interval: e.g. class Ia or III antiarrhythmics, antipsychotics, macrolides, antihistamines, quinolone antibiotics, cisapride, lithium	<input type="checkbox"/>
Drugs known to potentially inhibit hepatic cytochrome P450 3A (CYP3A) enzymes: e.g. 'azole' antifungal agents (systemic treatment), macrolide antibiotics, HIV protease inhibitors, calcium channel blockers, cimetidine	<input type="checkbox"/>

Special precautions:

If you tick any of these boxes, Serdolect® should only be prescribed with caution.

Does your patient currently have any of the following medical conditions or do any of the circumstances shown apply?	<input checked="" type="checkbox"/>
Mild / moderate hepatic dysfunction	<input type="checkbox"/>
Risk of significant electrolyte imbalances: e.g. experiencing vomiting or diarrhoea, potassium-depleting diuretic use	<input type="checkbox"/>
Parkinson's disease	<input type="checkbox"/>
Age >65 years	<input type="checkbox"/>
Known poor metabolizer of CYP2D6	<input type="checkbox"/>
History of seizures	<input type="checkbox"/>
Breast feeding	<input type="checkbox"/>

Is your patient currently receiving any of the following medications?

Is your patient currently receiving any of the following medications?	<input checked="" type="checkbox"/>
Dopamine agonists	<input type="checkbox"/>
Some SSRIs: e.g. fluoxetine, paroxetine (potent CYP2D6 inhibitors)	<input type="checkbox"/>
Agents known to induce CYP isozymes: e.g. rifampicin, carbamazepine, phenytoin, phenobarbital	<input type="checkbox"/>