

**“The only voice I hear now is my own”**

## THE POWER TO TREAT POSITIVE SYMPTOMS

- The ability to reduce positive symptoms is a prerequisite for all antipsychotic treatments
- Serdolect's efficacy has been established in 5 pivotal double-blind randomised parallel group studies involving over 1600 patients<sup>1, 2, 3, 4, 5</sup>

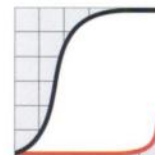
In addition to this SERDOLECT demonstrates:

- EFFICACY AGAINST NEGATIVE SYMPTOMS<sup>1, 6, 7, 8</sup>
- EPS AT PLACEBO LEVEL<sup>1</sup>
- SEDATION AT PLACEBO LEVEL<sup>2</sup>
- LACK OF ANTICHOLINERGIC SIDE EFFECTS<sup>1</sup>



sertindole

*Success is a long-term achievement*



### SERDOLECT: ABBREVIATED PRESCRIBING INFORMATION

**Presentation:** Tablets of 4mg, 12mg, 16mg or 20mg sertindole. **Indications:** Treatment of schizophrenia. Not for urgent relief of symptoms in acutely disturbed patients. **Dosage and administration:** Tablets should be taken orally once daily without regard for food. Adults: All patients should be started on 4mg/day. The dose should be increased by 4mg increments after 4-5 days on each dose to the optimum daily maintenance dose range of 12-20mg. The dose may be increased to a maximum of 24mg. Re-titration is necessary if dosing is suspended for more than one week. Children: Not recommended. Mild to moderate hepatic impairment: Slower titration and lower maintenance dose. Elderly: Slower titration and lower maintenance doses may be required. **Contraindications:** Known prolongation of QT interval or combined use of drugs known to prolong QT interval. Clinically significant cardiac disease or uncorrected hypokalaemia. Combined use of drugs that may induce hypokalaemia. Diuretic therapy may be initiated if required but a potassium-sparing agent must be used. Combined use of quinidine or systemic ketoconazole or itraconazole. Severe hepatic impairment. Hypersensitivity to Serdolect. **Pregnancy and lactation:** Safety during human pregnancy and lactation has not been established and Serdolect should not be used during pregnancy. Nursing mothers should not breast-feed if they are taking Serdolect. **Precautions:** Serdolect is not sedative, however, patients should be advised not to drive or operate machinery until their individual susceptibility is known. History of diabetes, seizures, Parkinson's disease. Symptoms of orthostatic hypotension may occur and blood pressure should be monitored during initial dose titration and in early maintenance phase. In common with other antipsychotic drugs, Serdolect lengthens the QT interval in some patients (<1.7% of patients). Electrolyte imbalance or combined use of other drugs that inhibit Serdolect metabolism can increase the risk of occurrence of prolonged QT interval. An ECG should be performed prior to use with periodic ECG monitoring during treatment. Serdolect should not be initiated or should be discontinued if the QTc<sub>2</sub> interval exceeds 520 msec. Hypokalaemia and hypomagnesaemia should be corrected and maintained within normal limits during treatment. If signs and symptoms of tardive dyskinesia appear, consider dose reduction or discontinuation. **Drug interactions:** (see also contraindications). Combined use of agents known to inhibit hepatic isoenzymes may necessitate lower maintenance doses. Combined use of agents known to induce hepatic isoenzymes may necessitate lower maintenance doses toward the upper dose range. **Adverse events:** Most commonly (>1% of patients): nasal

congestion, decreased ejaculatory volume, dizziness, dry mouth, postural hypotension, weight gain, peripheral oedema, dyspnoea, paraesthesia and prolonged QT interval. Incidence of EPS adverse events similar to placebo. Overdosage: Symptoms have included somnolence, slurred speech, tachycardia, hypotension and transient prolongation of QT interval. There is no specific antidote. Treatment is supportive and symptomatic. Epinephrine and dopamine should not be used (may exacerbate hypotension). Cardiovascular monitoring recommended. Administration of activated charcoal and laxative should be considered. **Package quantities and basic NHS price:** 4mg tablets, £36.63 for 30 tablet pack, 12mg tablets, £102.55 for 28 tablet calendar pack, 16mg tablets, £102.55 for 28 tablet calendar pack, 20mg tablets, £102.55 for 28 tablet calendar pack. Legal category: POM. **Product Licence numbers:** 4mg: 13761/0001, 12mg: 13761/0003, 16mg: 13761/0004, 20mg: 13761/0005. **Date of last review:** April 1997. Further information is available on request from Lundbeck Limited, Sunningdale House, Caldecotte Lake Business Park, Caldecotte, Milton Keynes, MK7 8LF. Serdolect<sup>®</sup> is a registered trademark of H. Lundbeck A/S.

### REFERENCES

1. Zimbroff DL et al. Am J Psychiatry 1997;154:782-791.
2. Data on file, H. Lundbeck A/S
3. Zborowski J et al. Poster at 148th APA Meeting, 1995, Miami
4. McEvoy J et al. Schizophr Res 1993;9(2,3):244
5. van Kammen DP et al. Psychopharmacology 1996;124:168-175
6. Krystal J et al. Poster at 35th ANCP Meeting, December 1996, Puerto Rico
7. Hale A et al. Poster presented at CINP Meeting, June 1996, Melbourne
8. Wehnert A et al. Poster presented at 6th World Congress of Biological Psychiatry, 1997, Nice





Prescribe  
97% of psychiatrists

http://doi.org/10.1197/50007125000151918 Published online by Cambridge University Press



# Fast Response

Can start to improve symptoms within seven days<sup>1</sup>



**LUSTRAL**™ 50mg  
sertraline

## A first choice antidepressant



### Abbreviated Prescribing Information:

#### Lustral (sertraline)

**Presentation:** Tablets containing 50mg or 100mg sertraline. **Indications:** Treatment of symptoms of depressive illness, including accompanying symptoms of anxiety. Prevention of relapse or recurrence of depressive episodes, including accompanying symptoms of anxiety. **Dosage:** Lustral should be given as a single daily dose. The initial dose is 50mg and the usual therapeutic dose is 50mg daily.

Dosage can be further increased, if appropriate, to a maximum of 200mg daily. Patients should be maintained on the lowest effective dose and doses of 150mg or more should not be used for periods exceeding 8 weeks. **Use in children:** Not recommended. **Use in the elderly:** Usual adult dose. **Contra-indications:** Hypersensitivity to Lustral. Hepatic insufficiency. Do not use with, or within two weeks of treatment with, MAOIs. At least 14 days should

elapse before starting with MAOIs. **Use during pregnancy:** Lustral should be used only if clearly needed. **Lactation:** Not recommended. **Precautions, warnings:** Renal insufficiency, unstable epilepsy, ECT, driving. Lustral should be discontinued in a patient who develops seizures. Lustral should not be administered to patients concurrently being treated with tranquillizers who drive or operate machinery. Patients should be closely supervised for the possibility of suicide attempt or activation of mania/hypomania. Bleeding abnormalities. **Drug interactions:** Caution with other centrally active medication and with drugs known to affect platelet function. Serotonergic drugs including tryptophan, sumatriptan and fenfluramine should not be used with Lustral. Lithium levels should be monitored. Although Lustral has been shown to have no adverse interaction with alcohol, concomitant use with alcohol is not recommended. Interactions with other highly protein bound drugs should be borne in mind. The potential of Lustral to interact with e.g. warfarin, diazepam, tolbutamide and cimetidine have not been fully

evaluated. **Side effects:** Nausea, anorexia, diarrhoea/loose stools, sexual dysfunction (principally, ejaculatory delay), tremor, increased sweating, dyspepsia, dizziness, insomnia and somnolence. Vomiting, abdominal pain, abnormal LFTs, jaundice, serious liver events, pancreatitis, arthralgia, myalgia, malaise, rash (including rare reports of erythema multiforme, photosensitivity), angioedema, tachycardia. Seizures (see precautions, warnings). Movement disorders, menstrual irregularities, hyperprolactinaemia and galactorrhoea. Hyponatraemia. As with all psychoactive medicines, possible side effects on discontinuation. **Legal Category:** POM. **Basic NHS Cost:** 50mg tablet (PL57/0308) Calendar pack of 28, £26.51; 100mg tablet (PL 57/0309) Calendar pack of 28, £39.77. Further information on request. Pfizer Limited, Sandwich, Kent. Date revised: September 1997 **Reference:** 1. Lustral SPC.

