Chear®

Sertraline

Presentation
Chear® 25mg Tablet: Round shaped, brown, film-coated tablet; each tablet contains 25mg Sertraline as Sertraline Hydrochloride lNN.

Chear® 50mg Tablet: Oblong shaped, brown, film-coated tablet with break-line on one side; each tablet contains 50 mg Serlraline as Sedraline Hydrochloride INN

Uses
Chear® is indicated for the treatment oJ sympioms of depressive illness, including accompanying symptoms of anxiety. Following satisfactory response, continuation with Chear® therapy is effective in preventing relapse of the initial episode of depression or recurrence of further depressive episodes, including accompanying symptoms of anxiety.

Dosage & administration
Adult: Chear® should be given as a single daily dose. Chear® tablets can be administered with or without food. The starting dose is 50 mg daily and the usual therapeutic dose is 50 mg daily. ln some patients doses higher than 50 mg daily may be required. ln patients with incomplete response but good toleration at lower doses, dosage adlustments should be made in 50 mg increments over a period of weeks to a maximum of 200mg daily.
Chear® tablets are for oral administration only.

Use in patients with renal or hepatic impairment: As with many other medications, sertraline should be used with caution in patients with renal and hepatic impairment.

Use in children: The use of Chear® in children is not recommended as safety and efficacy has not been established.

Use in the etderly: No special precautions are required. The usual adult dose is recommended. Several hundred elderly patients have participated in clinical studies with Sertraline. The pattern and incidence of adverse reaction in the elderly is similar to that in younger patients.

Contra-indications, warnings, etc.
Contra-indications: Sertraline is contra-indicated in patients with a known hypersensitivity to sertraline.
Concomitant use in-patients taking monoamine oxid-ase inhrbitols (MAOls) is contra-indicated.
Use in hepatic impairment: sertraline is extensively metabolised by the liver. A single dose pharmacokinetic study in subjects with mild, stable cinhosis demonstrated AUC in comparison to normal subjects.

Special warnings and special precautions for use: Monoamine oxidase inhibitors: Cases of serious reactions have been reported in patients receiving sertraline in combination with a monoamine oxidase inhibitor (MAOI), including the selective MAOI selegiline and the reversible MAOI (reversible inhibitor monoamine oxidase RIMO), moclobemide. Some cases presented with features, resembling the serotonin syndrome. Similar cases, sometimes fatal, have been reported with other anti-depressants during combined treatment with a

MAOI and in patients who have recently discontinued an anti-depressant drug and have been staded on a MAOI. Symptoms of a drug interaction between an SSRI and a MAOI include: hyperthermia, rigidity, myoclonus, autonomic instability with possible rapid fluctuations of vital signs, mental status changes that include confusion, initability and extreme agitation progressing to delirium and coma. Therefore, sertraline should not be used in combination with a MAOI or within 14 days of discontinuing treatment with a MAOI. Similarly, at least 14 days should elapse after discontinuing sertraline treatment before staning a MAOI.

Electroconvulsive therapy (ECl: fhere are no clinical studies establishing the risks or benefits of the combined use of ECT and seftraline.

Activation of mania / hypomania: As with other antidepressants, activation of mania/ hypomania has been reported in a small proportion of patients.

Seizures: Seizures are a potential risk with antidepressant drugs. Sertraline should be avoided in patients with unstable epilepsy and patients with controlled epilepsy should be carefully monitored. The drug should be discontinued in any patient who develops seizures.

Suicide: Since the possibility o1 a suicide attempt is inherent in depression and may persist until significant remission occurs, patients should be closely supervised during the early course of therapy.

Use in renal insufficiency: Since sertraline is extensively metabolised, excretion of unchanged drug in urine is a minor route of elimination. ln patients with mild to moderate renal impairment (creatinine clearance 20-50 ml/min), or severe renal impairment (creatinine clearance <20 ml/min) single dose pharmacokinetic parameters were not significantly different compared with controls. However, steady state pharmacokinetics of senraline has not been adequately studied in this patient population and caution is advised when treating patienis with renal impairment.

Use in the elderly: Several hundred elderly patients have pafticipated in clinical studies with sertraline. The pattern and incidence ol adverse reactions in the elderly is similar to that in younger patients.

Drug interaction: Centrally active medicationi Caution is advised if sertraline is administered with other centrally active medication.

Alcohol: ln 11 healthy subjects administered sertraline (200 mg daily) for 9 days, there was no adverse effect on cognitive or psychomotor performance relative to placebo, following a single dose of 500 mg/kg alcohol.
However, the concomitant use of sertraline and alcohol in depressed patients is not recommended.

Serotonergic drugs: There is limited controlled experience regarding the optimal timing of switching from other
antidepressant drugs to sertraline. Care and prudent medical judgment should be exerctsed when switching particularly irom long-acting agents. The duration of washout period which should intervene before switching from one selective serotonin re-uptake inhibitor (SSRI) to another has not been established.

Other drug interactions: Since sertraline is bound to plasma proteins, the potential of sertraline to interact with other plasma protein bound drugs should be borne in mind.

Co-administration of sertraline (200 mg daily) with warfarin resulted a small but statistically significant increase in prothrombin time, the clinical signiticance of which is unknown.
Accordingly, prothrombin time should be carefully monitored when sertraline therapy is initiated or stopped. Sertraline (200 mg daily) did not potentiate the effects of carbamazepine, haloperidol or phenytoin on cognitive and psychomotor pedormance in healthy subjects.
Use in pregnancy: Reproduction studies have been performed in rats and rabbits at doses up to approximately 20 times and 10 times the maximum daily human dose, respectively. There was no evidence of teratogenicity or embryotoxicity at any dose level. At the dose level corresponding to approximately 2.5 to 10 times the maximum daily human dose, however, sertraline was associated with delayed ossification in foetuses, probably secondary to effects on the dams.
There was decreased neonatal survival following maternal administratioh of sertraline at doses approximately 5 times the maximum human dose. Similar effects on neonatal sulival have been described for other antidepressant drugs. The clinical significance of these effects is unknown. There are no adequate and well-controlled studies in pregnant women. Since animal reproduction siudies are not always predictive of human response, sertraline should be used during pregnancy only if the perceived benefits outweigh the risks. Women of childbearing potential should employ an adequate method of contraception if taking sertraline.

Use during lactation: Limited data concerning sertraline levels in breast milk are available, hence use in nursing mothers is not recommended.

Effects on ability to drive and use machines: Since antidepressanrdrugs may impair the abilities required, to perform potentially hazardous tasks such as driving a car or operating machinery, the patient should be cautioned accordingly, Serlraline should not be administered with benzodiazepines or other tranqullizers in patients who drive or operate machinery.

Side-effects: ln multiple dose studies involving dose escalation based on the patients' response, side-effects which occurred significantly more lrequently with sedraline than placebo were: nausea, diarrhoea / loose stools, dyspepsia, tremor, dizziness, insomnia, somnolence, increased sweating, dry mouth and male sexual dysfunction (principally ejaculatory delay). Spontaneous reports of malaise and rash (including rare reports of erythema multiforme) have been reported with sertraline.

Asymptomatic elevations in serum transaminases (AST and ALT) have been reported infrequently (approximately 0.8%) in association with sertraline administration. The abnormalities usually occurred within the first 1 to I weeks of drug treatment and promptly diminished upon drug discontinuation.

Seizures: There have been isolated reports ol movement disorders, such as edrapyramidal symptoms and gait abnormalities, with sertraline and their association with the drug is not proven. Most of these have occurred in patients on concomitant neuroleptic medication or with pre-existing movement disorder. There have been isolated reports of hyperprolactinaemia, galactorrhoea and menstrual irregularities with sertraline. Association with the drug is not proven. Rare cases of hyponatraemia have been reported and appeared to be reversible when sertraline was discontinued. Some cases were possrbly due to the syndrome of inappropriate antidiuretic hormone secretion. The majority of reports were associated with older patients and patients taking diuretics or other medications. Rare cases of withdrawal reaction have been reported.

Overdose:
On the evidence available, sertraline has a wide margin of safety in overdose. Overdoses of sedraline alone of up to 8 g have been reported. Deaths involving overdoses of sertraline in combination with other drugs and / or alcohol have been reported. Therefore, any overdosage should be treated aggressively, No specific therapy is recommended and there are no specific antidotes to sertraline. Establish and maintain
an airway, ensure adequate oxygenation and ventilation. Activated charcoal, which may be used with sorbitol, may be as or more effective than emesis or lavage, and should be considered in treating overdose. Cardiac and vital signs monitoring is recommended along with, general symptomatic and supportive measures. Due to the large volume of distribution of sertraline, forced diuresis, dialysis, haemoperfusion and exchange
transfusion are unlikely to be of benefit.

Pharmaceutical precautions
Store in a cool dry place, protected from light.

Package quantities

Chear® 25mg tablet	: Cartons of 10 X10 tablets in strips
Chear® 50 mg tablet	: Cartons of 5 X 10 tablets in strips
Chear® 100 mg tablet	: Cartons of 3 X 10 tablets in strips

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