Pharmacode position may change as per Supplier's m/c requirement & additional small pharma code may appear on the front / back panel

Aurasert 50 (Sertraline Tablets 50mg)
Aurasert 100 (Sertraline Tablets 100mg)

Description and Composition:
Aurasert 50
White coloured, biconvex, capsule shaped, film coated tablets debossed with 'A' on one side and with a score line in between '8' and '1' on the other side.
Each film-coated tablet contains: Sertraline hydrochloride equivalent to sertraline 50mg

Aurasert 100
White coloured, biconvex, capsule shaped film coated tablets debossed with 'A' on one side and '82' on the other side.
Each film-coated tablet contains: Sertraline hydrochloride equivalent to sertraline 100mg

Pharmacodynamics:
Sertraline is a potent and selective inhibitor of neuronal serotonin (5-HT) reuptake. It has only a weak effect on Neuronal uptake of nor-epinephrine and dopamine. Sertraline's inhibition of serotonin reuptake enhances serotonergic transmission. *In vitro* studies have shown that sertraline has no significant affinity for adrenergic, muscarinic, cholinergic, gamma aminobutyric acid (GABA), dopaminergic, serotonergic (5HT1A, 5HT1B, 5HT2) histaminergic or benzodiazepine receptors.

Pharmacokinetics
The gastrointestinal absorption of sertraline is slow but consistent. Sertraline undergoes extensive first pass metabolism in the liver. The bioavailability is slightly increased if sertraline is taken with food. Mean peak plasma concentrations of about 20-55 mcg/l occur between 4.5-8.4 hours after administration of a single 100mg dose. Sertraline is approximately 98% bound to plasma proteins. Both sertraline and its metabolites are extensively distributed into tissues. The metabolite n-desmethylsertraline exhibits only about 1/8 of its activity. It does not contribute to the antidepressant activity or toxicity of the parent compound. Both sertraline and its metabolite undergo oxidative deamination and subsequent reduction, hydroxylation and glucuronide conjugation. Only 0.2% of the unchanged drug is excreted through the kidneys. The elimination half-life of sertraline is 24 to 26 hours. The pharmacokinetics of sertraline in elderly patients is similar to younger adults.
Sertraline pharmacokinetics have been evaluated in a group of 61 paediatric patients (29 aged 6-12 years, 32 aged 13-17 years) with a DSM-III-R diagnosis of depression or obsessive- compulsive disorder. During 42 days of chronic sertraline dosing, sertraline was titrated up to 200mg/day and maintained at that dose for a minimum of 11 days. Relative to the adults, both the 6–12-year-olds and 13-17 years old showed about 22% lower AUC (0-24 hours) and Cmax values when plasma concentration was adjusted for weight. These data suggest that paediatric patients metabolize sertraline with slightly greater efficiency than adults.
Nevertheless, lower doses may be advisable for paediatric patients given their lower body weights, especially in very young patients, in order to avoid excessive plasma levels.

Indications
Aurasert is indicated for the treatment of symptoms of depressive illness including accompanying symptoms of anxiety. It is also indicated in preventing relapse of the initial episode of depression or recurrence of further depressive episodes including accompanying symptoms of anxiety.
Aurasert is indicated in the treatment of obsessions and compulsions in patients with obsessive compulsive disorder.
Aurasert is indicated for the treatment of panic disorder with or without agorahophobia

Dosage and administration
Dosage for adults *Depression*:
Initially 50mg per day as a single daily dose. The dose may be increased after several weeks with increments of 50mg made at intervals of at least 1week, as needed and tolerated, up to a maximum dose of 200 mg once daily. In elderly individuals, a lower initiation dose (12.5 to 25mg) may be used.

Obsessive-compulsive disorder:
Aurasert should be administered at a dose of 50mg. The daily dose may be increased if required at intervals of at least one week, up to 200mg.

Panic disorder:
Aurasert treatment should be initiated with a dose of 25mg once daily. After one week, the dose should be increased to 50 mg once daily. Further increments may be made up to a dose of 200 mg/d.
Doses of 150 mg or more should not be used for periods exceeding 5 weeks.

Aurasert tablets should be administered once daily, either in the morning or evening.

Mode of administration:
Aurasert tablets should be administered once daily, either in the morning or evening.

Special warnings and precautions for use:
Serotonin Syndrome (SS) or Neuroleptic Malignant Syndrome (NMS)
The development of potentially life-threatening syndromes like serotonin syndrome (SS) or Neuroleptic Malignant Syndrome (NMS) has been reported with SSRIs, including treatment with sertraline. The risk of SS or NMS with SSRIs is increased with concomitant use of other serotonergic drugs (including other serotonergic antidepressants, amphetamines, triptans), with drugs which impair metabolism of serotonin (including MAOIs e.g., methylene blue), antipsychotics and other dopamine antagonists, and with opiate drugs. Patients should be monitored for the emergence of signs and symptoms of SS or NMS syndrome.

Switching from Selective Serotonin Reuptake Inhibitors (SSRIs), antidepressants or anti- obsessional drugs
There is limited controlled experience regarding the optimal timing of switching from SSRIs, antidepressants or anti-obsessional drugs to sertraline. Care and prudent medical judgment should be exercised when switching, particularly from long-acting agents such as fluoxetine.

Other serotonergic drugs e.g., tryptophan, fenfluramine and 5-HT agonists
Co-administration of sertraline with other drugs which enhance the effects of serotonergic neurotransmission such as amphetamines, tryptophan or fenfluramine or 5-HT agonists, or the herbal medicine, St John's Wort (Hypericum perforatum), should be undertaken with caution and avoided whenever possible due to the potential for a pharmacodynamic interaction.

QTc Prolongation/Torsade de Pointes (TdP)
Cases of QTc prolongation and Torsade de Pointes (TdP) have been reported during post- marketing use of sertraline. The majority of reports occurred in patients with other risk factors for QTc prolongation/TdP. Therefore, sertraline should be used with caution in patients with risk factors for QTc prolongation such as cardiac disease, hypokalaemia or hypomagnesemia, familial history of QTc prolongation, bradycardia and concomitant use of medications which prolong QTc interval.

Activation of hypomania or mania
Manic/hypomanic symptoms have been reported to emerge in a small proportion of patients treated with marketed antidepressant and anti-obsessional drugs, including sertraline. Therefore, sertraline should be used with caution in patients with a history of mania/hypomania. Close surveillance by the physician is required. Sertraline should be discontinued in any patient entering a manic phase.

Schizophrenia
Psychotic symptoms might become aggravated in schizophrenic patients.

Seizures
Seizures may occur with sertraline therapy: sertraline should be avoided in patients with unstable epilepsy and patients with controlled epilepsy should be carefully monitored. Sertraline should be discontinued in any patient who develops seizures.

Suicide/suicidal thoughts/suicide attempts or clinical worsening
Depression is associated with an increased risk of suicidal thoughts, self-harm and suicide (suicide related events). This risk persists until significant remission occurs. As improvement may not occur during the first few weeks or more of treatment, patients should be closely monitored until such improvement occurs. It is general clinical experience that the risk of suicide may increase in the early stages of recovery.

Other psychiatric conditions, for which sertraline is prescribed, can also be associated with an increased risk of suicide related events. In addition, these conditions may be co-morbid with major depressive disorder. The same precautions observed when treating patients with major depressive disorder should therefore be observed when treating patients with other psychiatric disorders.

Patients with a history of suicide-related events, or those exhibiting a significant degree of suicidal ideation prior to commencement of treatment are known to be at greater risk of suicidal thoughts or suicide attempts and should receive careful monitoring during treatment. A meta-analysis of placebo-controlled clinical trials of antidepressant drugs in adult patients with psychiatric disorders showed an increased risk of suicidal behaviour with antidepressants compared to placebo in patients less than 25 years old.

Close supervision of patients and in particular those at high risk should accompany drug therapy especially in early treatment and following dose changes. Patients (and caregivers of patients) should be alerted about the need to monitor for any clinical worsening, suicidal behaviour or thoughts and unusual changes in behaviour and to seek medical advice immediately if these symptoms present.

Sexual dysfunction
Selective serotonin reuptake inhibitors (SSRIs) may cause symptoms of sexual dysfunction. There have been reports of long-lasting sexual dysfunction where the symptoms have continued despite discontinuation of SSRIs.

Paediatric population
Sertraline should not be used in the treatment of children and adolescents under the age of 18 years, except for patients with obsessive compulsive disorder aged 6-17 years old. Suicide-related behaviours (suicide attempt and suicidal thoughts), and hostility (predominantly aggression, oppositional behaviour and anger) were more frequently observed in clinical trials among children and adolescents treated with antidepressants compared to those treated with placebo. If, based on clinical need, a decision to treat is nevertheless taken; the patient should be carefully monitored for appearance of suicidal symptoms. In addition, only limited clinical evidence is available concerning, long-term safety data in children and adolescents including effects on growth, sexual maturation and cognitive and behavioural developments. A few cases of retarded growth and delayed puberty have been reported post-marketing. The clinical relevance and causality are yet unclear. Physicians must monitor paediatric patients on long term treatment for abnormalities in growth and development.

Suicidality in Children and Adolescents
- Antidepressants increase the risk of suicidal thinking and behaviour (suicidality) in children and adolescents with major depressive disorder (MDD) and other psychiatric disorders.
- Anyone considering the use of an antidepressant in a child or adolescent for any clinical use must balance the risk of increased suicidality with the clinical need.
- Patients who are started on therapy should be observed closely for clinical worsening, suicidality, or unusual changes in behaviour.
- Families and caregivers should be advised to closely observe the patient and to communicate with the prescriber.
- The indication(s) approved in paediatric for the particular drug should be clearly stated / included.

Abnormal bleeding/Haemorrhage
There have been reports of bleeding abnormalities with SSRIs including cutaneous bleeding (ecchymoses and purpura) and other haemorrhagic events such as gastrointestinal or gynaecological bleeding, including fatal haemorrhages. Caution is advised in patients taking SSRIs, particularly in concomitant use with drugs known to affect platelet function (e.g anticoagulants, atypical antipsychotics and phenothiazines, most tricyclic antidepressants, acetylsalicylic acid and nonsteroidal anti-inflammatory drugs (NSAIDs)) as well as in patients with a history of bleeding disorders.

Hyponatraemia
Hyponatraemia may occur as a result of treatment with SSRIs or SNRIs including sertraline. In many cases, hyponatraemia appears to be the result of a syndrome of inappropriate antidiuretic hormone secretion (SIADH). Cases of serum sodium levels lower than 110 mmol/L have been reported.

Elderly patients may be at greater risk of developing hyponatraemia with SSRIs and SNRIs. Also, patients taking diuretics or who are otherwise volume-depleted may be at greater risk (see Use in elderly). Discontinuation of sertraline should be considered in patients with symptomatic hyponatraemia and appropriate medical intervention should be instituted. Signs and symptoms of hyponatraemia include headache, difficulty concentrating, memory impairment, confusion, weakness and unsteadiness which may lead to falls. Signs and symptoms associated with more severe and/or acute cases have included hallucination, syncope, seizure, coma, respiratory arrest, and death.

Withdrawal symptoms seen on discontinuation of sertraline treatment
Withdrawal symptoms when treatment is discontinued are common, particularly if discontinuation is abrupt. In clinical trials, among patients treated with sertraline, the incidence of reported withdrawal reaction was 23% in those discontinuing sertraline compared to 12% in those who continued to receive sertraline treatment.

The risk of withdrawal symptoms may be dependent on several factors including the duration and dose of therapy and the rate of dose reduction. Dizziness, sensory disturbances (including paraesthesia), sleep disturbances (including insomnia and intense dreams), agitation or anxiety, nausea and/or vomiting, tremor and headache are the most commonly reported reactions. Generally, these symptoms are mild to moderate; however, in some patients they may be severe in intensity. They usually occur within the first few days of discontinuing treatment, but there have been very rare reports of such symptoms in patients who have inadvertently missed a dose. Generally, these symptoms are self-limiting and usually resolve within 2 weeks, though in some individuals they may be prolonged (2-3 months or more). It is therefore advised that sertraline should be gradually tapered when discontinuing treatment over a period of several weeks or months, according to the patient's needs.

Akathisia/psychomotor restlessness
The use of sertraline has been associated with the development of akathisia, characterised by a subjectively unpleasant or distressing restlessness and need to move often accompanied by an inability to sit or stand still. This is most likely to occur within the first few weeks of treatment. In patients who develop these symptoms, increasing the dose may be detrimental.

Hepatic impairment
Sertraline is extensively metabolised by the liver. A multiple dose pharmacokinetic study in subjects with mild, stable cirrhosis demonstrated a prolonged elimination half-life and approximately three-fold greater AUC and Cmax in comparison to normal subjects. There were no significant differences in plasma protein binding observed between the two groups. The use of sertraline in patients with hepatic disease must be approached with caution. If sertraline is administered to patients with hepatic impairment, a lower or less frequent dose should be considered. Sertraline should not be used in patients with severe hepatic impairment.

Renal impairment
Sertraline is extensively metabolised, and excretion of unchanged drug in urine is a minor route of elimination. In studies of patients with mild to moderate renal impairment (creatinine clearance 30-60 ml/min) or moderate to severe renal impairment (creatinine clearance 10-29 ml/min), multiple-dose pharmacokinetic parameters (AUC0- 24 or Cmax) were not significantly different compared with controls. Sertraline dosing does not have to be adjusted based on the degree of renal impairment.

Use in elderly
Over 700 elderly patients (>65 years) have participated in clinical studies. The pattern and incidence of adverse reactions in the elderly was similar to that in younger patients. SSRIs or SNRIs including sertraline have however been associated with cases of clinically significant hyponatraemia in elderly patients, who may be at greater risk for this adverse event.

Diabetes
In patients with diabetes, treatment with an SSRI may alter glycaemic control. Insulin and/or oral hypoglycaemic dosage may need to be adjusted.

Electroconvulsive therapy
There are no clinical studies establishing the risks or benefits of the combined use of ECT and sertraline.

Grapefruit juice
The administration of sertraline with grapefruit juice is not recommended.

Interference with urine screening tests
False-positive urine immunoassay screening tests for benzodiazepines have been reported in patients taking sertraline. This is due to lack of specificity of the screening tests. False- positive test results may be expected for several days following discontinuation of sertraline therapy. Confirmatory tests, such as gas chromatography/mass spectrometry, will distinguish sertraline from benzodiazepines.

Angle-Closure glaucoma
SSRIs including sertraline may have an effect on pupil size resulting in mydriasis. This mydriatic effect has the potential to narrow the eye angle resulting in increased intraocular pressure and angle-closure glaucoma, especially in patients predisposed. Sertraline should therefore be used with caution in patients with angle-closure glaucoma or history of glaucoma.

Interactions with other medicinal products and other forms of interaction
Contraindicated
Monoamine Oxidase Inhibitors (Irreversible MAOIs (e.g., selegiline)
Sertraline must not be used in combination with irreversible MAOIs such as selegiline. Sertraline must not be initiated for at least 14 days after discontinuation of treatment with an irreversible MAOI. Sertraline must be discontinued for at least 7 days before starting treatment with an irreversible MAOI.

Reversible, selective MAO-A inhibitor (moclobemide)
Due to the risk of serotonin syndrome, the combination of sertraline with a reversible and selective MAOI, such as moclobemide, should not be given. Following treatment with a reversible MAO-inhibitor, a shorter withdrawal period than14 days may be used before initiation of sertraline treatment. It is recommended that sertraline should be discontinued for at least 7 days before starting treatment with a reversible MAOI.

Reversible, non-selective MAOI (linezolid)
The antibiotic linezolid is a weak reversible and non-selective MAOI and should not be given to patients treated with sertraline.
Severe adverse reactions have been reported in patients who have recently been discontinued from an MAOI (e.g. Methylene blue) and started on sertraline, or have recently had sertraline therapy discontinued prior to initiation of an MAOI. These reactions have included tremor, myoclonus, diaphoresis, nausea, vomiting, flushing, dizziness, and hyperthermia with features resembling neuroleptic malignant syndrome, seizures, and death.

Pimozide
Increased pimozide levels of approximately 35% have been demonstrated in a study of a single low dose pimozide (2mg). These increased levels were not associated with any changes in EKG. While the mechanism of this interaction is unknown, due to the narrow therapeutic index of pimozide, concomitant administration of sertraline and pimozide is contraindicated.

Co-administration with sertraline is not recommended
CNS depressants and alcohol
The co-administration of sertraline 200 mg daily did not potentiate the effects of alcohol, carbamazepine, haloperidol, or phenytoin on cognitive and psychomotor performance in healthy subjects; however, the concomitant use of sertraline and alcohol is not recommended.

Other serotonergic drugs
Caution is also advised with fentanyl (used in general anaesthesia or in the treatment of chronic pain), other serotonergic drugs (including other serotonergic antidepressants, amphetamines, triptans), and with other opiate drugs.

Special Precautions
Drugs that Prolong the QT Interval
The risk of QTc prolongation and/or ventricular arrhythmias (e.g., TdP) may be increased with concomitant use of other drugs which prolong the QTc interval (e.g., some antipsychotics and antibiotics).

Lithium
In a placebo-controlled trial in normal volunteers, the co-administration of sertraline with lithium did not significantly alter lithium pharmacokinetics, but did result in an increase in tremor relative to placebo, indicating a possible pharmacodynamic interaction. When co- administering sertraline with lithium, patients should be appropriately monitored.

Phenytoin
A placebo-controlled trial in normal volunteers suggests that chronic administration of sertraline 200 mg/day does not produce clinically important inhibition of phenytoin metabolism. Nonetheless, as some case reports have emerged of high phenytoin exposure in patients using sertraline, it is recommended that plasma phenytoin concentrations be monitored following initiation of sertraline therapy, with appropriate adjustments to the phenytoin dose. In addition, co-administration of phenytoin may cause a reduction of sertraline plasma levels. It cannot be excluded that other CYP3A4inducers, e.g. phenobarbital, carbamazepine, St John´s Wort, rifampicin may cause a reduction of sertraline plasma levels.

Triptans
There have been rare post-marketing reports describing patients with weakness, hyperreflexia, in coordination, confusion, anxiety and agitation following the use of sertraline and sumatriptan. Symptoms of serotonergic syndrome may also occur with other products of the same class (triptans). If concomitant treatment with sertraline and triptans is clinically warranted, appropriate observation of the patient is advised.

Warfarin
Co-administration of sertraline 200 mg daily with warfarin resulted in a small but statistically significant increase in prothrombin time, which may in some rare cases unbalance the INR value.
Accordingly, prothrombin time should be carefully monitored when sertraline therapy is initiated or stopped.

Other drug interactions, digoxin, atenolol, cimetidine
Co-administration with cimetidine caused a substantial decrease in sertraline clearance. The clinical significance of these changes is unknown. Sertraline had no effect on the beta- adrenergic blocking ability of atenolol. No interaction of sertraline 200 mg daily was observed with digoxin.

Drugs affecting platelet function
The risk of bleeding may be increased when medicines acting on platelet function (e.g. NSAIDs, acetylsalicylic acid and ticlopidine) or other medicines that might increase bleeding risk are concomitantly administered with SSRIs, including sertraline.

Neuromuscular Blockers
SSRIs may reduce plasma cholinesterase activity resulting in a prolongation of the neuromuscular blocking action of mivacurium or other neuromuscular blockers.

Drugs Metabolized by Cytochrome P450
Sertraline may act as a mild-moderate inhibitor of CYP 2D6. Chronic dosing with sertraline 50 mg daily showed moderate elevation (mean 23%-37%) of steady-state desipramine plasma levels (a marker of CYP 2D6 isozyme activity). Clinically relevant interactions may occur with other CYP 2D6 substrates with a narrow therapeutic index like class 1C antiarrhythmics such as propafenone and flecainide, TCAs and typical antipsychotics, especially at higher sertraline dose levels.

Sertraline does not act as an inhibitor of CYP 3A4, CYP 2C9, CYP 2C19, and CYP 1A2 to a clinically significant degree. This has been confirmed by *in-vivo* interaction studies with CYP3A4 substrates (endogenous cortisol, carbamazepine, terfenadine, alprazolam), CYP2C19 substrate diazepam, and CYP2C9 substrates tolbutamide, glibenclamide and phenytoin. *In vitro* studies indicate that sertraline has little or no potential to inhibit CYP 1A2.

Intake of three glasses of grapefruit juice daily increased the sertraline plasma levels by approximately 100% in a cross-over study in eight Japanese healthy subjects. Therefore, the intake of grapefruit juice should be avoided during treatment with sertraline.

Based on the interaction study with grapefruit juice, it cannot be excluded that the concomitant administration of sertraline and potent CYP3A4 inhibitors, e.g., protease inhibitors, ketoconazole, itraconazole, Posaconazole, voriconazole, clarithromycin, telithromycin and nefazodone, would result in even larger increases in exposure of sertraline. This also concerns moderate CYP3A4 inhibitors, e.g., aprepitant, erythromycin, fluconazole, verapamil and diltiazem. The intake of potent CYP3A4 inhibitors should be avoided during treatment with sertraline.

Sertraline plasma levels are enhanced by about 50% in poor metabolizers of CYP2C19 compared to rapid metabolizers (see section 5.2). Interaction with strong inhibitors of CYP2C19, e.g. omeprazole, lansoprazole, pantoprazole, rabeprazole, fluoxetine, fluvoxamine cannot be excluded.

Fertility, pregnancy and lactation
Pregnancy
There are no well controlled studies in pregnant women. However, a substantial amount of data did not reveal evidence of induction of congenital malformations by sertraline. Animal studies showed evidence for effects on reproduction probably due to maternal toxicity caused by the pharmacodynamic action of the compound and/or direct pharmacodynamic action of the compound on the foetus.

Use of sertraline during pregnancy has been reported to cause symptoms, compatible with withdrawal reactions, in some neonates, whose mothers had been on sertraline. This phenomenon has also been observed with other SSRI antidepressants. Sertraline is not recommended in pregnancy, unless the clinical condition of the woman is such that the benefit of the treatment is expected to outweigh the potential risk.

Neonates should be observed if maternal use of sertraline continues into the later stages of pregnancy, particularly the third trimester. The following symptoms may occur in the neonate after maternal sertraline use in later stages of pregnancy: respiratory distress, cyanosis, apnoea, seizures, temperature instability, feeding difficulty, vomiting, hypoglycaemia, hypertonia, hypotonia, hyperreflexia, tremor, jitteriness, irritability, lethargy, constant crying, somnolence and difficulty in sleeping. These symptoms could be due to either serotonergic effects or withdrawal symptoms. In a majority of instances, the complications begin immediately or soon (<24 hours) after delivery.

Epidemiological data have suggested that the use of SSRIs in pregnancy, particular in late pregnancy, may increase the risk of persistent pulmonary hypertension in the new born (PPHN). The observed risk was approximately 5 cases per1000 pregnancies. In the general population 1 to 2 cases of PPHN per 1000 pregnancies occur.

Breast-feeding
Published data concerning sertraline levels in breast milk show that small quantities of sertraline and its metabolite

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		Aurasert	Leaflet	P1538561	08.01.2025 & 11.10 am
		Country	Version No.	Reason of Issue	Reviewed / Approved by
		Malaysia_U3	00	Commercial	
Team Leader	Kiran K	Dimensions (mm)	Colours: 01		
Initiator	Shirisha N	A/s : 280 x 540 mm			
Artist	Advnt (Kiran)	Pharma Code: 38561	38561		
Additional Information: Supersede code: P1514158					

N-desmethylsertraline are excreted in milk. Generally negligible to undetectable levels were found in infant serum, with one exception of an infant with serum levels about 50% of the maternal level (but without a noticeable health effect in this infant). To date, no adverse effects on the health of infants nursed by mothers using sertraline have been reported, but a risk cannot be excluded. Use in nursing mothers is not recommended unless, in the judgment of the physician, the benefit outweighs the risk.

Fertility
Animal data did not show an effect of sertraline on fertility parameters.
Human case reports with some SSRI's have shown that an effect on sperm quality is reversible.
Impact on human fertility has not been observed so far.

Side effects
Nausea is the most common undesirable effect. In the treatment of social anxiety disorder, sexual dysfunction (ejaculation failure) in men occurred in 14% for sertraline vs 0% in placebo. These undesirable effects are dose dependent and are often transient in nature with continued treatment.
The undesirable effects profile commonly observed in double-blind, placebo-controlled studies in patients with OCD, panic disorder, PTSD and social anxiety disorder was similar to that observed in clinical trials in patients with depression.
Table 1 displays adverse reactions observed from post-marketing experience (frequency not known) and placebo-controlled clinical trials (comprising a total of 2542 patients on sertraline and 2145 on placebo) in depression, OCD, panic disorder, PTSD and social anxiety disorder.
Some adverse drug reactions listed in Table 1 may decrease in intensity and frequency with continued treatment and do not generally lead to cessation of therapy.

Table 1: Adverse Reactions
Frequency of adverse reactions observed from placebo-controlled clinical trials in depression, OCD, panic disorder, PTSD and social anxiety disorder. Pooled analysis and post-marketing experience.

System Organ Class	Very Common	Common	Uncommon	Rare	Frequency Not Known
Infections and infestations		upper respiratory tract infection, pharyngitis, rhinitis	gastroenteritis, otitis media	Diverticulitis§	
Neoplasms benign, malignant and unspecified (including cysts and polyps)			neoplasm		
Blood and lymphatic system disorders				lymphadenopathy thrombocytopenia*§ leukopenia*§	
Immune system disorders			hypersensitivity* seasonal allergy*	anaphylactoid reaction*	
Endocrine disorders			hypothyroidism*	hyperprolactinaemia*§ inappropriate antidiuretic hormone secretion*§	
Metabolism and nutrition disorders		Decreased appetite, increased appetite*		hypercholesteroleaemia, diabetes mellitus* ,hypoglycaemia* ,hyperglycaemia*§ ,hyponatraemia*§	
Psychiatric disorders	insomnia	anxiety* depression* agitation* libido decreased* nervousness, depersonalisation, nightmare, bruxism*	Suicidal ideation/behaviour, psychotic disorder* Thinking abnormal, apathy, hallucination* aggression* euphoric mood* paranoia	Conversion disorder*§ paroniria*§ drug dependence, sleepwalking, premature ejaculation	
Nervous system disorders	dizziness, headache* somnolence	tremor, movement disorders (including extrapyramidal symptoms such as hyperkinesia, hypertonia, dystonia, teeth grinding or gait abnormalities paraesthesia* , hypertonia* , disturbance inattention, dysgeusia	amnesia, hypoaesthesia* , muscle contractions involuntary* syncope* hyperkinesia* migraine* convulsion* dizziness postural, coordination abnormal, speech disorder	coma*, akathisia, dyskinesia, hyperaesthesia, cerebrovascular spasm (including reversible cerebral vasoconstriction syndrome and Call-Fleming syndrome) *§ psychomotor restlessness*§, sensory disturbance, choreoathetosis§ also reported were signs and symptoms associated with serotonin syndrome* or neuroleptic malignant syndrome: In some cases, associated with concomitant use of serotonergic drugs that included agitation, confusion, diaphoresis, diarrhoea, fever, hypertension, rigidity and tachycardia§	
Eye disorders		Visual disturbance*	mydriasis*	scotoma, glaucoma, diplopia,	maculopathy
				photophobia, hyphaema*§, pupils unequal*§ vision abnormal§, lacrimal disorder	
Ear and labyrinth disorders		tinnitus*	ear pain		
Cardiac disorders		palpitations*	tachycardia*, cardiac disorder	myocardial infarction*§, Torsade de Pointes*§ bradycardia, QTc prolongation*	
Vascular disorders		hot flush*	abnormal bleeding (such as gastrointestinal bleeding) * hypertension* flushing, haematuria*	peripheral ischaemia	
Respiratory, thoracic and Mediastinal disorders		yawning*	dyspnoea, epistaxis* bronchospasm*	hyperventilation, interstitial lung disease*§ laryngospasm, dysphonia, stridor*§ hypoventilation, hiccups	
Gastrointestinal disorders	nausea, diarrhoeadry mouth	dyspepsia, constipation* abdominal pain* vomiting* flatulence	melaena, tooth disorder oesophagitis, glossitis, haemorrhoids, salivary hypersecretion dysphagia, eructation, tongue disorder	mouth ulceration, pancreatitis*§ haematochezia, tongue ulceration, stomatitis	Colitis microscopic*
Hepatobiliary disorders				hepatic function abnormal, serious liver events (including hepatitis, jaundice and hepatic failure)	
Skin and subcutaneous tissue disorders		hyperhidrosis, rash*	periorbital oedema* urticaria* alopecia* pruritus* purpura* dermatitis, dry skin, face oedema, cold sweat	rare reports of severe cutaneous adverse reactions (SCAR): e.g. Stevens-Johnson syndrome* and epidermal necrolysis*§ skin reaction*§ photosensitivity§, angioedema, hair texture abnormal, skin odour abnormal, dermatitis bullous, rash follicular	

Table 1: Adverse Reactions
Frequency of adverse reactions observed from placebo-controlled clinical trials in depression, OCD, panic disorder, PTSD and social anxiety disorder. Pooled analysis and post-marketing experience.

System Organ Class	Very Common	Common	Uncommon	Rare	Frequency Not Known
Musculoskel etal and connective tissue disorders		back pain, arthralgia*, myalgia	osteoarthritis, muscle twitching, muscle cramps*, muscular weakness	rhabdomyolysis*§, bone disorder	trismus*
Renal and urinary disorders			pollakiuria, micturition disorder, urinary retention, urinaryincontinence* polyuria, nocturia	urinary hesitation* oliguria	
Reproductive system and breast disorders	ejaculation failure	Menstruation irregular* erectile dysfunction	sexual dysfunction, menorrhagia, vaginal haemorrhage, female sexual dysfunction	galactorrhoea*, atrophic vulvovaginitis, genital discharge, balanoposthitis*§ gynaecomastia* priapism*	
General disorders and administration site conditions	fatigue*	malaise* chest pain* asthenia* pyrexia*	oedema peripheral* chills, gait disturbance* thirst	hernia, drug tolerance decreased	
Investigations		weight increased*	Alanine Aminotransferase increased* aspartate aminotransferase increased* weight decreased*	blood cholesterol increase* abnormal clinical laboratory results, semen abnormal, altered platelet function*§	
Injury, poisoning and procedural complications		injury			
Surgical and Medical procedures				vasodilation procedure	

*ADR identified post-marketing
§ ADR frequency represented by the estimated upper limit of the 95% confidence interval using "The Rule of 3"

Withdrawal symptoms seen on discontinuation of sertraline treatment Discontinuation of sertraline (particularly when abrupt) commonly leads to withdrawal symptoms. Dizziness, sensory disturbances (including paraesthesia), sleep disturbances (including insomnia and intense dreams), agitation or anxiety, nausea and/or vomiting, tremor and headache are the most commonly reported. Generally, these events are mild to moderate and are self-limiting; however, in some patients they may be severe and/or prolonged. It is therefore advised that when sertraline treatment is no longer required, gradual discontinuation by dose tapering should be carried out.

Elderly population
SSRIs or SNRIs including sertraline have been associated with cases of clinically significant hyponatraemia in elderly patients, who may be at greater risk for this adverse event.

Paediatric population
In over 600 paediatric patients treated with sertraline, the overall profile of adverse reactions was generally similar to that seen in adult studies. The following adverse reactions were reported from controlled trials
Very common: Headache, insomnia, diarrhoea and nausea.

Common: Chest pain, mania, pyrexia, vomiting, anorexia, affect lability, aggression, agitation, nervousness, disturbance in attention, dizziness, hyperkinesia, migraine, somnolence, tremor, visual disturbance, dry mouth, dyspepsia, nightmare, fatigue, urinary incontinence, rash, acne, epistaxis, flatulence.

Uncommon: ECG QT prolonged, suicide attempt, convulsion, extrapyramidal disorder, paraesthesia, depression, hallucination, purpura, hyperventilation, anaemia, hepatic function abnormal, alanine aminotransferase increased, cystitis, herpes simplex, otitis externa, ear pain, eye pain, mydriasis, malaise, haematuria, rash pustular, rhinitis, injury, weight decreased, muscle twitching, abnormal dreams, apathy, albuminuria, pollakiuria, polyuria, breast pain, menstrual disorder, alopecia, dermatitis, skin disorder, skin odour abnormal, urticaria, bruxism, flushing.
Frequency not known: enuresis

Class effects
Epidemiological studies, mainly conducted in patients 50 years of age and older, show an increased risk of bone fractures in patients receiving SSRIs and TCAs. The mechanism leading to this risk is unknown.

Overdosage
Toxicity
Sertraline has a margin of safety dependent on patient population and/or concomitant medication. Deaths have been reported involving overdoses of sertraline, alone or in combination with other drugs and/or alcohol. Therefore, any overdosage should be medically treated aggressively.

Symptoms
Symptoms of overdose include serotonin-mediated side effects such as somnolence, gastrointestinal disturbances (e.g. nausea and vomiting), tachycardia, tremor, agitation and dizziness. Coma has been reported although less frequently.
QTc prolongation/Torsade de Pointes has been reported following sertraline overdose; therefore, ECG-monitoring is recommended in all ingestions of sertraline overdoses.

Management
There are no specific antidotes to sertraline. It is recommended to establish and maintain an airway and, if necessary, ensure adequate oxygenation and ventilation. Activated charcoal, which may be used with a cathartic, may be as, or more effective than lavage, and should be considered in treating overdose. Induction of emesis is not recommended. Cardiac (e.g. ECG) and vital sign monitoring is also 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.

Effects on Ability to Drive and Use Machines
Clinical pharmacology studies have shown that sertraline has no effect on psychomotor performance. However, as psychotropic drugs may impair the mental or physical abilities required for the performance of potentially hazardous tasks such as driving a car or operating machinery, the patient should be cautioned accordingly.

Storage
Store at or below 30°C

Shelf life
36 months

Presentation:
Aurasert 50 and 100mg:
Blister strip of 10's & 14's tablets, Box of 10 x 10's & 2 x 14's

Manufactured by:

AUROBINDO
Aurobindo Pharma Limited
Unit - III, Sy.No.313 and 314, Bachupally Village,
Bachupally Mandal, Medchal-Malkajgiri District,
Pincode 500090, Telangana State,India.

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