LUVOX®
Fluvoxamine Maleate

NAME OF THE MEDICINAL PRODUCT
Luvox®, film-coated tablets, 50 mg
Luvox®, film-coated tablets, 100 mg

QUALITATIVE AND QUANTITATIVE COMPOSITION
Active ingredient: fluvoxamine maleate
Each tablet contains 50 mg or 100 mg of fluvoxamine maleate.
For a full list of excipients, see Section List of Excipients.

PHARMACEUTICAL FORM
Film-coated tablets 50mg
Round, biconvex, scored, white to off-white film coated tablets for oral administration.
The tablets can be divided into equal halves.
Film-coated tablets 100mg
Oval, biconvex, scored, white to off-white film coated tablets for oral administration.
The tablets can be divided into equal halves.

CLINICAL PARTICULARS
Therapeutic Indications
- Treatment of depressive illness and symptoms of depressive disorder.
- Treatment of Obsessive Compulsive Disorder (OCD)

Posology and Method of Administration
Depressive illness and symptoms of depressive disorder
The recommended starting dose is 50 or 100 mg, given as single dose in the evening. It is recommended to increase the dose gradually until an effective dose is reached. The usual effective dose is 100 mg per day and should be adjusted on individual patient response. Doses of up to 300 mg per day have been given. Dosages above 150 mg should be given in divided doses.

In agreement with the consensus statement of the WHO, antidepressant medication should be continued for at least 6 months after recovery from a depressive episode. Luvox® at a fixed single daily dose of 100 mg is the recommended dose for the prevention of recurrence of depression.

Obsessive Compulsive Disorder (OCD)
Adults
The recommended starting dose is 50 mg per day for 3 - 4 days. The effective dosage usually lies between 100 mg and 300 mg per day. The dosage should be increased gradually until the effective dosage is achieved, with a maximum of 300 mg per day.
Doses up to 150 mg can be given as a single dose, preferably in the evening. It is advisable that a total daily dose of more than 150 mg is given in 2 or 3 divided doses.
If a good therapeutic response has been obtained, treatment can be continued at a dosage adjusted on an individual basis. If no improvement is observed within 10 weeks, treatment with fluvoxamine should be reconsidered. While there are no systematic studies to answer the question of how long to continue fluvoxamine treatment, OCD is a chronic condition and it is reasonable to consider continuation beyond 10 weeks in responding patients. Dosage adjustments should be made carefully on an individual patient basis, to maintain the patient at the lowest effective dose. The need for treatment should be reassessed periodically. Some clinicians advocate concomitant behavioural psychotherapy for patients who have done well on pharmacotherapy.

Long-term efficacy (more than 24 weeks) has not been demonstrated in OCD.

Children and adolescents
The starting dose for children from 8 years on and adolescents is 25 mg per day, preferably at bedtime. Increase every 4-7 days in 25 mg increments as tolerated until an effective dose is achieved. The effective dosage usually lies between 50 mg and 200 mg per day, the maximum dose in children should not exceed 200 mg per day. It is advisable that a total daily dose of more than 50 mg should be given in two divided doses. If the two divided doses are not equal, the larger dose should be given at bedtime.

Withdrawal symptoms seen on discontinuation of fluvoxamine
Abrupt discontinuation should be avoided. When stopping treatment with fluvoxamine, the dose should be gradually reduced over a period of at least one or two weeks in order to reduce the risk of withdrawal reactions (see section Special Warnings and Precautions for Use and Undesirable Effects). If intolerable symptoms occur following a decrease in the dose or upon discontinuation of treatment, then resuming the previously prescribed dose may be considered. Subsequently, the physician may continue decreasing the dose, but at a more gradual rate.

Hepatic or renal insufficiency
Patients suffering from hepatic or renal insufficiency should start on a low dose and be carefully monitored.

Method of administration
Fluvoxamine tablets should be swallowed with water and without chewing.

Contraindications
Luvox® tablets are contraindicated in combination with tizanidine and monoamine oxidase inhibitors (MAOIs) (see section Interaction with Other Medicinal Products and Other Forms of Interaction).

Treatment with fluvoxamine can be initiated:
- two weeks after discontinuation of an irreversible MAOI, or
- the following day after discontinuation of a reversible MAOI (e.g. moclobemide, linezolid).

At least one week should elapse between discontinuation of fluvoxamine and initiation of therapy with any MAOI.

Fluvoxamine immediate-release tablets should not be used in combination with pimozide and ramelteon (see Interaction with other medicinal products and other forms of interactions

Hypersensitivity to the active substance or to any of the excipients.

Special Warnings and Precautions for Use
Suicide/suicidal thoughts 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 fluvoxamine are 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. Therefore when treating patients with other psychiatric disorders, they should be closely monitored.

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 a greater risk of suicidal thoughts or suicide attempts, and should receive careful monitoring during treatment.

Paediatric population
Fluvoxamine should not be used in the treatment of children and adolescents under the age of 18 years. Due to lack of clinical experience the use of fluvoxamine in children for the treatment of depression cannot be recommended.

Young adults (ages 18 to 24 years)
A meta-analysis of placebo controlled clinical trials of antidepressant drugs in adult patients with psychiatric disorders showed an increased risk of suicidal behavior 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 behavior or thoughts and unusual changes in behavior and to seek medical advice immediately if these symptoms present.

Geriatric population
Data in elderly subjects give no indication of clinically significant differences in normal daily dosages compared to younger subjects. However, upward dose titration should be done slower in the elderly and dosing should always be done with caution.

Akathisia/psychomotor restlessness
The use of fluvoxamine has been associated with the development of akathisia, characterized 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.

Renal and hepatic impairment
Patients suffering from hepatic or renal insufficiency should start on a low dose and be carefully monitored.

Treatment with fluvoxamine has rarely been associated with an increase in hepatic enzymes, generally accompanied by clinical symptoms. In such cases treatment should be discontinued.

Nervous system disorders
Although in animal studies fluvoxamine has no pro-convulsive properties, caution is recommended when the drug is administered to patients with a history of convulsive disorders. Fluvoxamine should be avoided in patients with unstable epilepsy and patients with controlled epilepsy should be carefully monitored. Treatment with fluvoxamine should be discontinued if seizures occur or if seizure frequency increases.

On rare occasions, development of a serotonin syndrome or neuroleptic malignant syndrome-like events have been reported in association with treatment of fluvoxamine, particularly when given in combination with other serotonergic and/or neuroleptic drugs. As these syndromes may result in potentially life-threatening conditions, treatment with fluvoxamine should be discontinued if such events (characterized by clusters of symptoms such as hyperthermia, rigidity, myoclonus, autonomic instability with possible rapid fluctuations of vital signs, mental status changes including confusion, irritability, extreme agitation progressing to delirium and coma) occur and supportive symptomatic treatment should be initiated.

In exeptional circumtances, linezolid (an antibiotic which is a reversible relatively weak non-selective MAOI) can be given in combination with fluvoxamine provided that there are facilities for close observation and management of symptoms of serotonin syndrome and monitoring of blood pressure. if symptoms occur, physicians should consider discontinuing one or both agents.

Metabolism and nutrition disorders
As with other SSRIs, hyponatraemia has been rarely reported, and appears to be reversible when fluvoxamine is discontinued. Some cases were possibly due to the syndrome of inappropriate antidiuretic hormone secretion. The majority of reports were associated with older patients.
Glycaemic control may be disturbed (i.e., hyperglycaemia, hypoglycaemia, decreased glucose tolerance), especially in the early stages of treatment. When fluvoxamine is given to patients with a known history of diabetes mellitus, the dosage of anti-diabetic drugs may need to be adjusted.

Nausea, sometimes accompanied by vomiting, is the most frequently observed symptom associated with fluvoxamine treatment. This side effect usually diminishes within the first two weeks of treatment.

Eye Disorders
Mydriasis has been reported in association with SSRIs such as fluvoxamine. Therefore caution should be used when prescribing fluvoxamine in patients with raised intraocular pressure or those at risk of acute narrow-angle glaucoma.

Haematological disorders
There have been reports of cutaneous bleeding abnormalities such as ecchymoses and purpura as well as other haemorrhagic manifestations, such as gastrointestinal bleeding or gynaecological/postpartum haemorrhage, with SSRIs. Caution is advised in patients taking SSRIs, particularly in elderly patients and in patients who concomitantly use drugs known to affect platelet function (e.g. atypical antipsychotics and phenothiazines, most TCAs, acetylsalicylic acid, NSAIDs) or drugs that increase risk of bleeding as well as in patients with a history of bleeding disorders and in those with predisposing conditions (e.g. thrombocytopenia, or coagulation disorders).

SSRIs/may increase the risk of postpartum haemorrhage (see sections *Fertility, pregnancy and lactation* and *Undesirable effects*)

Cardiac disorders
When fluvoxamine combined with terfenadine, astemizole or cisapride, plasma concentration may be increased resulting in an increased risk for QT-prolongation/Torsade de Pointes. Therefore, fluvoxamine should not be co-administered with these drugs.

Fluvoxamine may cause an insignificant decrease in heartbeat (2-6 beats per minute).

Electroconvulsive therapy (ECT)
There is limited clinical experience of concomitant administration of fluvoxamine and ECT; therefore caution is advisable.

Withdrawal reactions
It is possible that withdrawal reactions may occur on stopping therapy with fluvoxamine although the available preclinical and clinical evidence does not suggest that this treatment causes dependence. The most commonly reported symptoms in association with withdrawal of the product include: dizziness, sensory disturbances (including paraesthesia, visual disturbances and electric shock sensations), sleep disturbances

(including insomnia and intense dreams), agitation, irritability, confusion, emotional instability, headache, nausea and/or vomiting, diarrhoea, sweating, palpitations, tremor and anxiety (see section Undesirable Effects). Generally these events are mild to moderate and are self-limiting; however in some patients they may be severe and/or prolonged. 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 fluvoxamine should be gradually tapered when discontinuing treatment over a period of several weeks or months, according to the patient's needs.

Mania/Hypomania
Fluvoxamine should be used with caution in patients with a history of mania/hypomania. Fluvoxamine should be discontinued in any patient entering a manic phase.

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

CYP2C19 in inhibiton
Since clopidgrel is metabolised to its active metabolite partly by CYP2C19, use of fluvoxamine that inhibit the activity of this enzyme would be expected to result in reduced drug levels of the active metabolite of clopidogrel. The clinical relevance of this interaction is uncertain. As a precaution concominant use of fluvoxamine should be discouraged.

Interaction with Other Medicinal Products and Other Forms of Interaction
Monoamine oxidase inhibitors
Fluvoxamine should not be used in combination with MAOIs, including linezolid, due to risk of serotonin syndrome (see section Contraindications).

Effect of fluvoxamine on the oxidative metabolism of other drugs
Fluvoxamine can inhibit the metabolism of drugs metabolized by certain cytochrome P450 isoenzymes (CYPs). A strong inhibition of CYP1A2 and CYP2C19 is demonstrated in *in vitro* and *in vivo* studies. CYP2C9, CYP2D6 and CYP3A4 are inhibited to a lesser extent. Drugs which are largely metabolised via these isoenzymes may have a higher/ lower (e.g. in case of prodrugs like Clopidogrel) plasma concentrations of the active substance/metabolite when coadministered with Fluvoxamine. Concomitant therapy of fluvoxamine and these drugs should be initiated at or adjusted to the low vs high end of their dose range. Plasma concentrations, effects or adverse effects of coadministered drugs should be monitored and their dosage should be reduced/increased if necessary. This is particularly relevant for drugs with a narrow therapeutic index.

Compounds with narrow therapeutic index
Co-administration of fluvoxamine and drugs with a narrow therapeutic index (such as tacrine, theophylline, methadone, mexiletine, phenytoin, carbamazepine and cyclosporine) should be carefully monitored when these drugs are metabolized exclusively or by a combination of CYPs inhibited by fluvoxamine.

If necessary, dose adjustment of these drugs is recommended.

Due to the narrow therapeutic index of pimozide and its known ability to prolong QT interval, concomitant use of pimozide and fluvoxamine is contraindicated- see section *Contraindications.*

Tricyclic antidepressants and neuroleptics
An increase in previously stable plasma levels of those tricyclic antidepressants (e.g., clomipramine, imipramine, amitriptyline) and neuroleptics (e.g., clozapine, olanzapine, quetiapine) which are largely metabolised through cytochrome P450 1A2 when given together with fluvoxamine, has been reported. A decrease in the dose of these products should be considered if treatment with fluvoxamine is initiated.

Benzodiazepines
The plasma levels of oxidatively metabolised benzodiazepines (e.g. triazolam, midazolam, alprazolam, and diazepam) are likely to be increased when co-administered with fluvoxamine. The dosage of these benzodiazepines should be reduced during co-administration with fluvoxamine.

Cases of increased plasma concentration
As plasma concentrations of propranolol are increased in combination with fluvoxamine, the propranolol dose may need to be lowered.

When given with fluvoxamine, warfarin plasma concentrations were significantly increased and prothrombin times prolonged.

Cases of increased side effects
Isolated cases of cardiac toxicity have been reported when fluvoxamine was combined with thioridazine.

Caffeine plasma levels are likely to be increased during co-administration with fluvoxamine. Thus, patients who consume high quantities of caffeine-containing beverages should lower their intake when fluvoxamine is administered and adverse caffeine effects (like tremor, palpitations, nausea, restlessness, insomnia) are observed.

Terfenadine, astemizole, cisapride, sildenafil: see section Special Warnings and Precautions for Use.

Glucuronidation
Fluvoxamine does not influence plasma concentrations of digoxin.

Renal excretion
Fluvoxamine does not influence plasma concentrations of atenolol.

Pharmacodynamic interactions
The serotonergic effects of fluvoxamine may be enhanced when used in combination with other serotonergic agents (including triptans, tramadol, SSRIs and St. John's Wort preparations). (see section Special Warnings and Precautions for Use)

Fluvoxamine has been used in combination with lithium in the treatment of severely ill, drug-resistant patients. However, lithium (and possibly also tryptophan) enhances the serotonergic effects of fluvoxamine. The combination should be used with caution in patients with severe, drug-resistant depression.

In patients on oral anticoagulants and fluvoxamine, the risk for haemorrhage may increase and these patients should therefore be closely monitored.

As with other psychotropic drugs patients should be advised to avoid alcohol use while taking fluvoxamine.

Fertility, Pregnancy and Lactation
Pregnancy

Epidemiological data have suggested that the use of Selective Serotonin Reuptake Inhibitors (SSRIs) in pregnancy, particularly in late pregnancy, may increase the risk of persistent pulmonary hypertension in the newborn (PPHN). The observed risk was approximately 5 cases per 1000 pregnancies. In the general population 1 to 2 cases of PPHN per 1000 pregnancies occur.

Fluvoxamine should not be used during pregnancy unless the clinical condition of the woman requires treatment with fluvoxamine.

Observational data indicate an increased risk (less than 2-fold) of postpartum haemorrhage following SSRI/exposure within the month prior to birth (see section Special Warnings and Precautions for Use and Undesirable Effects)

Isolated cases of withdrawal symptoms in the newborn child have been described after the use of fluvoxamine at the end of pregnancy.

Some newborns experience feeding and/ or respiratory difficulties, seizures, temperature instability, hypoglycaemia, tremor, abnormal muscle tone, jitteriness, cyanosis, irritability, lethargy, somnolence, vomiting, difficulty in sleeping and constant crying after third trimester exposure to SSRIs and may require prolonged hospitalization.

Reproduction toxicity studies in animals revealed treatment related increases in embryotoxicity (embryofetal death, fetal eye abnormalities). The relevance to humans is unknown. The safety margin for reproductive toxicity is unknown

Breastfeeding
Fluvoxamine is excreted via human milk in small quantities. Therefore, the drug should not be used by women who breast feed.

Fertility
Reproductive toxicity studies in animals have shown that fluvoxamine impairs male and female fertility. The relevance of these findings to humans is unknown (see section Preclinical Safety Data).

Fluvoxamine should not be used in patients attempting to conceive unless the clinical condition of the patient requires treatment with fluvoxamine.

Animal data have shown that fluvoxamine may effect sperm quality. Human case reports with some SSRIs have shown that an effect on sperm quality is reversible. Impact on human fertility has not been observed so far.

Effects on Ability to Drive and Use Machines
Fluvoxamine up to 150 mg has no or negligible influence on the ability to drive and use machines. It showed no effect on psychomotor skills associated with driving and operating machinery in healthy volunteers. However, somnolence has been reported during treatment with fluvoxamine. Therefore, caution is recommended until the individual response to the drug has been determined.

Undesirable Effects
Adverse events, observed in clinical studies at frequencies listed below, are often associated with the illness and are not necessarily related to treatment. Frequency estimate: Very common (>1/10), common (>1/100 to <1/10), uncommon (>1/1,000 to <1/100), rare (>1/10,000 to <1/1,000), very rare (<1/10,000), not known (cannot be estimated from the available data).

MedDra system organ class	Common	Uncommon	Rare	Very rare	Frequency not known
Endocrine disorders					Hyperprolactinaemia, Inappropriate antidiuretic hormone secretion
Metabolism and nutrition disorders	Anorexia				Hyponatraemia, weight increased, weight decreased.
Psychiatric disorders		Hallucination, confusional stage, aggression	Mania		suicidal ideation, suicidal behaviours
Nervous system disorders	Agitation, nervousness, anxiety, insomnia, somnolence, tremor, headache, dizziness	Extrapyramidal disorder, ataxia	Convulsion		Serotonin syndrome, neuroleptic malignant syndrome like events, akathisia/ psychomotor restlessness, paraesthesia, dysgeusia,
Eye disorders					Glaucoma, mydriasis
Cardiac disorders	Palpitations/ tachycardia				
Vascular disorders		(Orthostatic) hypotension			Haemorrhage (e.g. gastrointestinal haemorrhage, gynaecological haemorrhage, ecchymosis, purpura)
Gastrointestinal disorders	Abdominal pain, constipation, diarrhoea, dry mouth, dyspepsia, nausea*, vomiting				
Hepatobiliary disorders			Hepatic function abnormal		
Skin and subcutaneous tissue disorders	Hyperhydrosis, sweating	Cutaneous Hypersensitivity reactions (incl. angioneurotic oedema, rash, pruritis)	Photosensitivity reaction		
Musculoskeletal, connective tissue		Arthralgia, myalgia			**Bone fractures

and bone disorders					
Renal and Urinary disorders					micturition disorder (including urinary retention, urinary incontinence, pollakiuria, nocturia and enuresis)
Reproductive system and breast disorders		Abnormal (delayed) ejaculation	Galactorrhoea		Anorgasmia. menstrual disorders (such as amenorrhea, hypomenorrhea, metrorrhagia, menorrhagia) Postpartum haemorrhage***
General disorders and administration site reactions	Asthenia, malaise				drug withdrawal syndrome including drug withdrawal syndrome neonatal

*Nausea, sometimes accompanied by vomitting is the most frequently observed symptom associated with fluvoxamine treatment. This side effect usually diminishes within the first two weeks of treatment.

**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.

***This event has been reported for the therapeutic class of SRRIs (see section *Special Warnings & Precautions for Use and Fertility, Pregnancy and Lactation*)

Cases of suicidal ideation and sucidal behaviors have been reported during fluvoxamine therapy or early after treatment discontinuation.

Pediatric population
In one 10-week placebo-controlled trial in children and adolescents with OCD, frequently reported adverse events with a higher incidence than placebo, were: insomnia, asthenia, agitation, hyperkinesia, somnolance and dyspepsia. Serious adverse events in this study included: agitation and hypomania.

Convulsion in children and adolescents have been reported during use outside clinical trials.

Withdrawal symptoms seen on discontinuation of fluvoxamine treatment
Discontinuation of fluvoxamine (particularly when abrupt) commonly leads to withdrawal symptoms. It is therefore advised that when fluvoxamine treatment is no longer required, gradual discontinuation by dose tapering should be carried out (see section Posology and Method of Administration and section Special Warnings and Precautions for Use).

Overdose
Symptoms

Symptoms include gastro-intestinal complaints (nausea, vomiting and diarrhoea), somnolence and dizziness. Cardiac events (tachycardia, bradycardia, hypotension), liver function disturbances, convulsions and coma have also been reported.

Fluvoxamine has a wide margin of safety in overdose. Since market introduction, reports of death attributed to overdose of fluvoxamine alone have been extremely rare. The highest documented dose of fluvoxamine ingested by a patient is 12 gram. This patient recovered completely. Occasionally, more serious complications were observed in cases of deliberate overdose of fluvoxamine in combination with other drugs.

Treatment
There is no specific antidote to fluvoxamine. In case of overdose the stomach should be emptied as soon as possible after tablet ingestion and symptomatic treatment should be given. The repeated use of medicinal charcoal, if necessary accompanied by an osmotic laxative, is also recommended. Forced diuresis or dialysis is unlikely to be of benefit.

PHARMACOLOGICAL PROPERTIES

Pharmacodynamic Properties

Pharmacotherapeutic group: Antidepressants, Selective serotonin reuptake inhibitors.
ATC code: N06AB08

Receptor binding studies have demonstrated that fluvoxamine is a potent serotonin reuptake inhibitor in vitro as well as in vivo and has a minimal affinity for serotonin receptors subtypes. Its capacity of binding to alpha adrenergic, beta adrenergic, histaminergic, muscarinic, cholinergic or dopaminergic receptors is negligible.

Fluvoxamine has a high affinity for sigma-1 receptors, where it acts as an agonist, at therapeutic doses.

Pharmacokinetic Properties

Absorption
Fluvoxamine is completely absorbed following oral administration. Maximum plasma concentrations occur within 3-8 hours of dosing. The mean absolute bioavailability is 53%, due to first-pass metabolism.

The pharmacokinetics of Luvox® is not influenced by concomitant food intake.

Distribution
In vitro plasma protein binding of fluvoxamine is 80%. Volume of distribution in humans is 25 l/kg.

Metabolism
Fluvoxamine undergoes extensive metabolism in the liver. Although CYP2D6 is in vitro the main isoenzyme involved in fluvoxamine's metabolism, plasma concentrations in poor metabolisers for CYP2D6 are not much higher than those in extensive metabolisers.

The mean plasma half-life is approximately 13-15 hours after a single dose, and slightly longer (17-22 hours) during repeated dosing, when steady-state plasma levels are usually achieved within 10-14 days.

Fluvoxamine undergoes extensive hepatic transformation, mainly via oxidative demethylation, into at least nine metabolites, which are excreted by the kidneys. The two major metabolites showed negligible pharmacological activity. The other metabolites are not expected to be pharmacologically active.
Fluvoxamine is a potent inhibitor of CYP1A2 and CYP2C19. A moderate inhibition was found for CYP2C9, CYP2D6 and CYP3A4.

Fluvoxamine displays linear single-dose pharmacokinetics. Steady-state concentrations are higher than calculated from single-dose data, and this disproportional increase is more pronounced with higher daily doses.

Special Patients groups
The pharmacokinetics of fluvoxamine is similar in healthy adults, elderly patients, and patients with renal insufficiency. The metabolism of fluvoxamine is impaired in patients with liver disease.

Steady-state plasma concentrations of fluvoxamine were twice as high in children (aged 6-11)

Preclinical Safety Data
Carcinogenesis and mutagenesis
There is no evidence of carcinogenicity or mutagenicity with fluvoxamine.

Fertility and reproductive toxicity
Animal studies on male and female fertility revealed reduction of mating performance, decreased sperm count and fertility index and increased ovary weights at levels higher than human exposure. The effects were observed at exposured >two-fold higher than exposures at the maximum therapeutic dose.
As there is no safety margin between exposure at the NOAEL in the reproductive studies and the exposure at the maximum therapeutic dose a risk to patients cannot be ruled out.

Reproductive toxicity studies in rats have shown that fluvoxamine is embryotoxic (increased embryofetal death [resorptions], increased fetal eye abnormalities [folded retina], reduced fetal weights and delayed ossification). The effects on fetal weights and ossification are likely to be secondary to maternal toxicity (reduced maternal bodyweight and bodyweight gain).

In addition an increased incidence of perinatal pup mortality in pre-and postnatal studies was seen.

The safety margin for reproductive toxicity is unknown.

Physical and psychological dependence
The potential for abuse, tolerance and physical dependence has been studied in a nonhuman primate model. No evidence of dependency phenomena was found.

PHARMACEUTICAL PARTICULARS

List of Excipients
Luvox® film-coated tablets contain the following excipients:

Tablet core:
mannitol,
maize starch,
pregelatinised starch,
sodium stearyl fumarate,
colloidal anhydrous silica,

Film-coating:
hypromellose,
polyethylene glycol 6000,
talc,
titaniumdioxyde (E171).

Incompatibilities
Not applicable.

Shelf Life
The expiry date is indicated on the packaging

Special Precautions for Storage
Store below 30°C. Store in the original package and in dry place, protected from direct sunlight. Keep the medicine out of the reach and sight of children.

Nature and Contents of Container
- Luvox® film-coated tablet 50 mg: Box of 3 blisters @ 20 tablets. Reg. No.: DKI1127000417A1
- Luvox® film-coated tablets 100 mg: Box of 2 blisters @ 15 tablets. Reg. No.: DKI1127000417B1

Special Precautions for Disposal
No Special recommendation

HARUS DENGAN RESEP DOKTER

Manufactured by:
Mylan laboratories SAS., Chatillon Sur Chalaronne, France

Imported by:
PT. Abbott Indonesia, Depok, Indonesia

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INFORMASI UNTUK PASIEN

Luvox® Tablet salut selaput
Fluvoxamine maleate 50 mg & 100 mg

- Luvox® mengobati depresi dan gejalanya serta mengobati gangguan obsesif kompulsif (OCD). Seperti semua obat-obatan, Luvox® dapat memiliki efek yang tidak diinginkan. Karena itu penting bagi Anda dan dokter Anda untuk mempertimbangkan manfaat pengobatan terhadap kemungkinan efek yang tidak diinginkan, sebelum memulai pengobatan.
- Luvox® tidak boleh digunakan untuk mengobati depresi pada anak-anak dan remaja di bawah 18 tahun, kecuali untuk pengobatan gangguan obsesif kompulsif (OCD). Lihat bagian 2, Penggunaan pada anak-anak dan remaja di bawah 18 tahun.
- Luvox® tidak akan langsung bekerja. Beberapa orang akan merasa lebih buruk sebelum merasa lebih baik. Dokter Anda sebaiknya mengontrol Anda secara teratur selama menjalani pengobatan. Beri tahu dokter Anda jika Anda belum mulai merasa lebih baik.
- Pada orang yang mengalami depresi atau kecemasan dan berpikir untuk melukai atau bunuh diri. Jika Anda mulai merasa lebih buruk, atau berpikir untuk melukai atau bunuh diri, temui dokter Anda atau langsung pergi ke rumah sakit.
- Jangan berhenti minum Luvox® tanpa berkonsultasi dengan dokter Anda. Jika Anda berhenti minum Luvox® secara tiba-tiba atau lupa minum Luvox® sebanyak satu dosis, Anda mungkin mengalami efek putus obat. Lihat Bagian 3, Cara mengonsumsi Luvox®.
- Jika Anda merasa gelisah, seperti tidak bisa duduk atau diam, beri tahu dokter Anda. Peningkatan dosis Luvox® dapat membuat perasaan ini lebih buruk.
- Menggunakan obat lain bersamaan dengan Luvox® dapat menyebabkan permasalahan. Anda mungkin perlu berkonsultasi dengan dokter Anda. Lihat bagian 2, Apakah Anda minum obat lain.
- Jika Anda sedang hamil atau berencana hamil, konsultasikan dengan dokter Anda. Lihat bagian 2, Kehamilan dan menyusui.

Bacalah seluruh brosur ini dengan seksama sebelum Anda memulai meminum obat ini karena brosur ini mengandung informasi penting untuk Anda.

- Simpanlah brosur ini, mungkin suatu saat Anda perlu membacanya lagi. Jika Anda mempunyai pertanyaan lebih lanjut, tanyakan kepada dokter atau apoteker Anda.
- Obat ini hanya diresepkan untuk Anda saja. Jangan memberikannya kepada orang lain, karena mungkin dapat membahayakan mereka, meskipun tanda-tanda penyakit mereka sama dengan penyakit Anda.
- Jika Anda mengalami efek samping, bicarakan dengan dokter atau apoteker Anda. Ini meliputi efek samping yang tidak tercantum dalam brosur ini. Lihat bagian 4.

Apa saja yang ada di brosur ini:

1. Obat apa Luvox® itu dan digunakan untuk apa?

Refer to RDCCDS00052v9.0-v13.0

DISETUJUI OLEH BPOM: 14/12/2021

ID: EREG10034612100173
EREG10034612100174

Luvox® termasuk dalam kelompok obat-obatan Inhibitor reuptake serotonin selektif (SSRI). Luvox® mengandung Fluvoxamine, yang merupakan antidepresan. Luvox® digunakan untuk mengobati depresi dan gejalanya. Luvox® juga digunakan untuk mengobati gangguan obsesif kompulsif (OCD).

2. Apa yang perlu Anda ketahui sebelum meminum Luvox®?

Jangan minum Luvox® jika Anda mengalami salah satu hal di bawah ini:

- Alergi terhadap Fluvoxamine atau bahan lainnya yang terkandung dalam obat ini (lihat bagian 6, Berapa isi kemasan dan apa informasi lainnya?)
- Anda sedang mengonsumsi obat-obatan golongan Monoamin Oksidase Inhibitor (MAOI), yang terkadang diresepkan untuk mengobati depresi atau kecemasan, termasuk Linezolid. Pengobatan dengan Fluvoxamine hanya boleh dimulai minimal 2 minggu setelah penghentian ireversible MAOI. Namun, pengobatan dengan Fluvoxamine setelah penghentian reversible MAOI dapat dimulai pada hari berikutnya. Dalam kasus khusus, linezolid dapat digunakan dengan Fluvoxamine asalkan dokter dapat memantau Anda dengan seksama. Dokter Anda akan memberi tahu Anda bagaimana memulai menggunakan Luvox® setelah Anda berhenti minum MAOI.
- Anda sedang mengonsumsi tizanidine
- Anda sedang mengonsumsi ramelteon
- Anda menggunakan Pimozide, obat neuroleptik yang digunakan untuk pengobatan skizofrenia dan penyakit psikiatri lainnya
- Anda sedang menyusui

Perhatian

Bicaralah dengan dokter atau apoteker Anda sebelum minum obat, jika:

- Anda baru-baru ini mengalami serangan jantung
- Anda sedang hamil, atau mungkin hamil
- Anda menderita epilepsi
- Anda memiliki riwayat perdarahan atau jika Anda secara teratur menggunakan obat-obatan yang meningkatkan risiko pendarahan, seperti penghilang nyeri.
- Anda menderita diabetes
- Anda menjalani perawatan dengan terapi electroconvulsive (ECT)
- Anda pernah mengalami mania (perasaan sangat gembira atau terlalu bersemangat)
- Anda memiliki masalah hati atau ginjal
- Anda mengalami glaukoma
- Anda berusia di bawah 18 tahun (Lihat juga bagian 3 ' Bagaimana cara meminum Luvox®?)

Obat-obatan seperti Luvox (SSRIs) dapat menyebabkan gejala disfungsi seksual. Dalam beberapa kasus, gejala-gejala tersebut dapat berlanjut setelah penggunaan obat dihentikan.

Jika Anda mengalami salah satu hal di atas, dokter Anda akan memberi tahu apakah aman bagi Anda untuk mulai mengonsumsi Luvox®.

Kadang-kadang, perasaan gelisah, misalnya Anda tidak bisa duduk atau diam (akathisia) dapat terjadi atau dapat meningkat selama beberapa minggu pertama pengobatan dengan Luvox®, sampai efek antidepresan mulai bekerja.

Beri tahu dokter Anda segera jika Anda mengalami gejala-gejala ini. Mungkin penyesuaian dosis dapat membantu mengatasi hal tersebut.

Pikiran untuk bunuh diri dan memburuknya depresi atau gangguan kecemasan

Jika Anda mengalami depresi dan / atau memiliki gangguan kecemasan, Anda terkadang memiliki pikiran untuk melukai atau bunuh diri. Hal ini dapat meningkat ketika pertama kali memulai mengonsumsi antidepresan, karena obat-obatan ini membutuhkan waktu untuk bekerja, biasanya sekitar dua minggu tetapi kadang-kadang lebih lama.

Anda mungkin akan berpikir seperti ini:
- Jika sebelumnya Anda berpikir untuk bunuh diri atau melukai diri sendiri.
- Jika Anda seorang dewasa muda. Informasi uji klinis menunjukkan bahwa peningkatan risiko bunuh diri pada orang dewasa berusia kurang dari 25 tahun yang diberikan antidepresan.

Jika Anda berpikir untuk melukai atau bunuh diri, hubungi dokter Anda atau langsung pergi ke rumah sakit.

Anda mungkin perlu memberi tahu kerabat atau teman dekat bahwa Anda mengalami depresi atau memiliki gangguan kecemasan, dan minta mereka membaca brosur ini. Anda dapat meminta mereka untuk memberi tahu Anda apakah menurut mereka depresi atau kecemasan Anda semakin buruk, atau jika mereka khawatir tentang perubahan perilaku Anda.

Beri tahu dokter Anda segera jika Anda memiliki pikiran atau pengalaman yang membahayakan.

Penggunaan pada anak-anak dan remaja di bawah 18 tahun
Anak-anak dan remaja di bawah 18 tahun tidak boleh minum obat ini, kecuali mereka sedang dirawat karena gangguan obsesif kompulsif (OCD).
Luvox® tidak dapat digunakan untuk mengobati depresi pada anak berusia di bawah 18 tahun.
Ketika menggunakan obat jenis ini, anak di bawah 18 tahun memiliki risiko peningkatan efek samping seperti percobaan bunuh diri, berpikir tentang bunuh diri dan permusuhan, seperti agresi, perilaku menyerang, kemarahan.

Jika dokter Anda meresepkan Luvox® untuk anak di bawah 18 tahun dan Anda ingin mendiskusikan ini, silakan kembali ke dokter Anda. Anda harus memberi tahu dokter Anda jika salah satu gejala yang tercantum di atas berkembang atau memburuk ketika pasien di bawah 18 tahun menggunakan Luvox®.
Tidak diketahui apakah menggunakan Luvox® di bawah usia 18 tahun dapat mempengaruhi pertumbuhan, kematangan, perkembangan kecerdasan atau, perilaku dalam jangka panjang.
Jika dokter Anda menyarankan Anda untuk mengonsumsi lebih dari 150 mg per hari, jangan meminumnya sekaligus; tanyakan kepada dokter Anda kapan Anda harus meminumnya.

Apakah Anda minum obat lain?
- Anda tidak boleh mengonsumsi obat herbal St John's Wort ketika Anda sedang menonsumsi Luvox® karena ini dapat mengakibatkan peningkatan efek yang tidak diinginkan. Jika Anda sudah mengonsumsi St John's Wort ketika Anda mulai menggunakan Luvox®, berhentilah mengonsumsi St John's Wort dan beri tahu dokter Anda pada kunjungan Anda berikutnya.
- Jika Anda telah minum obat untuk mengobati depresi atau kecemasan dalam dua minggu terakhir, atau Anda menderita skizofrenia, tanyakan kepada dokter atau apoteker Anda.

Dokter atau apoteker Anda akan memeriksa apakah Anda sedang menggunakan obat-obatan lain untuk mengobati depresi atau kondisi terkait, ini termasuk:
- Benzodiazepin
- Antidepresan trisiklik dan neuroleptik
- Lithium
- Triptofan

- Inhibitor monoamin oksidase (MAOI) seperti moclobemide
- Pimozide
- Inhibitor reuptake serotonin selektif (SSRI) seperti citalopram

Dokter Anda akan memberi tahu Anda apakah aman untuk mulai mengonsumsi Luvox®.
Anda juga harus memberi tahu dokter atau apoteker jika Anda mengonsumsi obat-obatan yang tercantum di bawah ini:

- Aspirin (asam asetilsalisilat) atau obat-obatan seperti aspirin, digunakan untuk mengobati rasa sakit dan peradangan (radang sendi)
- Siklosporin, digunakan untuk mengurangi aktivitas sistem kekebalan tubuh
- Metadon, digunakan untuk mengobati nyeri dan gejala putus obat
- Mexiletine, digunakan untuk mengobati irama jantung abnormal
- Fenitoin atau carbamazepine, digunakan untuk mengobati epilepsi
- Propranolol, digunakan untuk mengobati tekanan darah tinggi dan kondisi jantung
- Ropinirole, untuk penyakit Parkinson.
- 'Triptan', digunakan untuk mengobati migrain, misalnya sumatriptan
- Terfenadine, digunakan untuk mengobati alergi. Luvox® tidak boleh diminum bersamaan dengan terfenadine.
- Sildenafil, digunakan untuk mengobati disfungsi ereksi
- Teofilin, digunakan untuk mengobati asma dan bronkitis
- Tramadol, penghilang nyeri
- Warfarin, nicoumalone, clopidogrel atau obat lain yang digunakan untuk mencegah pembekuan darah

Jika Anda menggunakan atau baru saja menggunakan salah satu obat dalam daftar di atas dan Anda belum berkonsultasi dengan dokter Anda, kembalilah ke dokter Anda dan tanyakan apa yang harus Anda lakukan. Dosis Anda mungkin perlu diubah atau Anda mungkin perlu diberi obat lain.

Harap beri tahu dokter atau apoteker Anda jika Anda sedang mengonsumsi atau telah minum obat lain, termasuk obat-obatan yang diperoleh tanpa resep dokter, termasuk obat-obatan herbal.

Penggunaan Luvox® dengan makanan dan minuman
Jangan minum alkohol jika Anda minum obat ini. Alkohol berinteraksi dengan Luvox® dan menyebabkan Anda mengantuk dan tidak stabil.
Jika Anda biasanya minum banyak teh, kopi, dan minuman ringan yang mengandung dengan kafein, Anda mungkin memiliki gejala seperti tangan gemetar, merasa sakit, detak jantung yang cepat (jantung berdebar), gelisah dan sulit tidur (insomnia). Jika Anda menurunkan jumlah kafein yang Anda minum, gejala-gejala ini mungkin hilang.

Kehamilan dan menyusui
Mintalah nasihat dokter atau apoteker Anda sebelum minum obat apa pun.

Kehamilan
Hanya ada pengalaman terbatas mengenai penggunaan Fluvoxamine selama kehamilan. Jangan minum Fluvoxamine jika Anda hamil kecuali dokter Anda menganggapnya perlu. Jika saat ini Anda sedang mengonsumsi Fluvoxamine dan berencana untuk hamil atau menjadi ayah dari seorang anak, silakan berkonsultasi dengan dokter Anda untuk memutuskan apakah pengobatan alternatif diperlukan.
Jika Anda menggunakan Luvox® menjelang akhir kehamilan Anda, mungkin ada peningkatan risiko perdarahan vagina berat sesaat setelah lahir, terutama jika Anda memiliki riwayat gangguan

perdarahan. Dokter atau bidan Anda harus mengetahui bahwa Anda menggunakan Luvox® sehingga mereka dapat menginformasikan mengenai kemungkinan ini kepada Anda.

Fluvoxamine telah terbukti mengurangi kualitas sperma dalam penelitian pada hewan. Secara teoritis, Luvox® dapat mempengaruhi kesuburan, tetapi dampak pada kesuburan manusia belum diamati. Pastikan bidan dan / atau dokter tahu Anda menggunakan Fluvoxamine. Ketika dikonsumsi selama kehamilan, terutama dalam 3 bulan terakhir kehamilan, obat-obatan seperti Fluvoxamine dapat meningkatkan risiko kondisi serius pada bayi, yang disebut hipertensi paru persisten pada bayi baru lahir (PPHN), membuat bayi bernapas lebih cepat dan tampak kebiru-biruan. Gejala-gejala ini biasanya berlangsung selama 24 jam pertama setelah bayi lahir. Jika ini terjadi pada bayi Anda, Anda harus segera menghubungi bidan dan / atau dokter Anda.

Anda tidak harus menghentikan pengobatan dengan Fluvoxamine secara tiba-tiba. Jika Anda menggunakan Fluvoxamine dalam 3 bulan terakhir kehamilan, bayi Anda mungkin memiliki beberapa gejala lain ketika ia lahir selain mengalami kesulitan bernapas atau kulit kebiruan, seperti tidak bisa tidur atau makan dengan benar, terlalu panas atau dingin, sakit, tantrum, otot kaku atau terkulai, lesu, mengantuk, gemetaran, gelisah atau gugup. Jika bayi Anda memiliki gejala-gejala ini ketika dilahirkan, segera hubungi dokter Anda.

Menyusui
Fluvoxamine dapat masuk ke dalam ASI. Ada risiko efek pada bayi. Karena itu, Anda harus mendiskusikan masalah ini dengan dokter Anda, dan ia akan memutuskan apakah Anda harus berhenti menyusui atau menghentikan terapi dengan Fluvoxamine.

Mengemudi dan menggunakan mesin
Anda dapat mengemudi dan menggunakan mesin saat Anda menjalani perawatan ini, selama obat ini tidak membuat Anda mengantuk.

3. Bagaimana cara meminum Luvox®?
Berapa banyak Luvox® yang diminum:
Selalu minum Luvox® sesuai yang diperintahkan dokter kepada Anda. Anda harus memeriksa dengan dokter atau apoteker Anda jika Anda tidak yakin.

Dosis awal untuk orang dewasa (18 tahun ke atas):
Pengobatan depresi dan gejalanya
Mulai dengan 50 atau 100 mg setiap hari, diminum di malam hari.

Perawatan untuk gangguan kompulsif obsesif (OCD)
Mulailah dengan 50 mg setiap hari, lebih disukai di malam hari.
Jika Anda belum mulai merasa lebih baik setelah beberapa minggu, konsultasikan dengan dokter Anda. Dokter Anda mungkin akan meningkatkan dosis secara bertahap.
Dosis harian tertinggi yang direkomendasikan adalah 300 mg.
Jika dokter Anda menyarankan Anda untuk mengonsumsi lebih dari 150 mg per hari, jangan meminumnya sekaligus; tanyakan kepada dokter Anda kapan Anda harus meminumnya.

Dosis untuk anak-anak dan remaja dengan gangguan obsesif kompulsif - OCD (8 tahun ke atas):
Mulailah dengan 25 mg (setengah tablet) per hari, lebih disukai sebelum tidur. Dokter Anda dapat meningkatkan dosis setiap 4 - 7 hari dengan peningkatan 25 mg sampai dosis efektif tercapai.
Dosis harian tertinggi adalah 200 mg.

Jika dokter Anda menyarankan Anda untuk mengonsumsi lebih dari 50 mg per hari, jangan meminumnya sekaligus; tanyakan kepada dokter Anda kapan Anda harus meminumnya. Jika dosisnya tidak dibagi secara merata, dosis yang lebih besar harus diminum pada malam hari.
Anak-anak dan remaja di bawah usia 18 tidak boleh meminum obat ini untuk mengobati depresi. Obat ini diresepkan untuk anak-anak atau remaja untuk gangguan kompulsif obsesif (OCD) saja.

Cara minum Luvox®
Telan tablet dengan air. Jangan mengunyahnya.
Tablet ini dapat dibagi menjadi dua bagian yang sama. Anda dapat memecah tablet menjadi dua jika dokter menyarankan Anda.

Berapa lama Luvox® mulai bekerja
Luvox® mungkin memerlukan sedikit waktu untuk mulai bekerja. Beberapa pasien tidak merasa lebih baik dalam 2 atau 3 minggu pertama perawatan.

Teruslah meminum Luvox® sampai dokter memberitahu Anda untuk berhenti. Bahkan ketika Anda mulai merasa lebih baik, dokter Anda mungkin ingin Anda terus meminum Luvox® selama beberapa waktu, setidaknya selama enam bulan untuk memastikan bahwa obat telah bekerja sepenuhnya.
Jangan berhenti minum Luvox® terlalu cepat.

Anda mungkin mengalami gejala putus obat, seperti:
- Agitasi dan kecemasan
- Kebingungan
- Diare
- Sulit tidur
- Pusing
- Ketidakstabilan emosional
- Sakit kepala
- Lekas marah
- Mual dan / atau muntah
- Palpitasi (detak jantung lebih cepat)
- Gangguan sensorik (seperti sensasi sengatan listrik atau gangguan visual)
- Berkeringat
- Gemetaran

Ketika berhenti meminum Luvox®, dokter Anda akan mengurangi dosis secara perlahan selama beberapa minggu atau bulan. Hal ini akan membantu mengurangi kemungkinan terjadinya efek putus obat. Pada kebanyakan orang, gejala ringan yang dialami pada penghentian Luvox® akan hilang dengan sendirinya dalam waktu dua minggu. Bagi sebagian orang, gejala-gejala ini mungkin lebih parah, atau berlangsung lebih lama.

Jika Anda mengalami efek putus obat saat Anda mengentikan penggunaan Luvox®, dokter Anda mungkin menyarankan Anda untuk melakukannya secara perlahan. Jika Anda mengalami efek putus obat yang parah ketika Anda berhenti minum Luvox®, silakan kunjungi dokter Anda. Ia mungkin akan meminta Anda untuk mulai meminum kembali Luvox® dan menghentikannya secara perlahan (lihat bagian 4 'Apakah kemungkinan efek sampingnya?'). Jika Anda mengalami gejala apa pun saat menghentikan pengobatan, hubungi dokter Anda.

Jika Anda mengonsumsi lebih banyak Luvox® dari yang seharusnya
Jika Anda atau orang lain mengonsumsi terlalu banyak Luvox® (overdosis), bicarakan dengan dokter atau langsung pergi ke rumah sakit dengan membawa Luvox®.
Gejala overdosis termasuk, tetapi tidak terbatas pada, mual, muntah, diare dan merasa mengantuk atau pusing. Detak jantung lambat atau cepat, tekanan darah rendah, kelainan hati, kejang-kejang dan koma telah dilaporkan.

Jika Anda lupa meminum Luvox®
Jika Anda lupa meminum satu tablet, tunggu hingga dosis berikutnya tiba.
Jangan meminum dosis yang Anda lewatkan di antara dosis yang terlewat dengan dosis berikutnya.
Jika Anda memiliki pertanyaan lebih lanjut tentang penggunaan produk ini, tanyakan kepada dokter atau apoteker Anda.

4. Apakah kemungkinan efek sampingnya?
Seperti semua obat, Luvox® dapat menyebabkan efek samping (efek atau reaksi yang tidak diinginkan), tetapi tidak semua orang mengalaminya.

Frekuensi efek samping dikelompokkan menjadi:
- Sangat umum: lebih dari 1 dari 10 orang
- Umum: 1 hingga 10 dari 100 orang
- Tidak umum: 1 hingga 10 dari 1.000 orang
- Jarang: 1 hingga 10 dari 10.000 orang
- Sangat jarang: kurang dari 1 dari 10.000 orang
- Tidak diketahui: tidak dapat diperkirakan berdasarkan data yang tersedia

Efek samping yang berkaitan dengan obat jenis ini
Kadang-kadang, pikiran bunuh diri atau melukai diri sendiri dapat terjadi atau dapat meningkat dalam beberapa minggu pertama pengobatan dengan Luvox®, sampai efek antidepresannya bekerja.
Beri tahu dokter Anda segera jika Anda memiliki pikiran atau pengalaman yang membahayakan.
Jika Anda mengalami beberapa gejala sekaligus, Anda mungkin mengalami salah satu kondisi langka berikut:
- Sindrom serotonin: jika Anda berkeringat, kekakuan atau kejang otot, ketidakstabilan, kebingungan, lekas marah, atau agitasi ekstrem.
- Sindrom maligna neuroleptik: jika Anda mengalami otot kaku, suhu tinggi, kebingungan, dan gejala terkait lainnya.
- SIADH: jika Anda merasa lelah, lemah atau bingung dan otot terasa pegal, kaku atau tidak terkontrol, berhenti minum Luvox® dan hubungi dokter Anda segera.

Jika memar yang tidak biasa atau bercak ungu muncul di kulit Anda atau Anda muntah darah atau mengeluarkan darah di tinja Anda, hubungi dokter Anda untuk berkonsultasi.
Menghentikan Fluvoxamine (terutama ketika tiba-tiba) biasanya mengakibatkan gejala putus obat (lihat bagian 3 ‘Gejala putus obat’).

Kadang-kadang pasien merasa sedikit sakit ketika Luvox® mulai bekerja. Meskipun sakit, itu akan segera berlalu jika Anda tetap meminum Luvox® sesuai yang diresepkan. Ini mungkin membutuhkan waktu beberapa minggu.

Efek samping yang secara spesifik terkait dengan Fluvoxamine
<u>Efek samping umum:</u>

- Agitasi
- Kecemasan
- Sembelit
- Diare
- Sulit tidur
- Pusing
- Mulut kering
- Detak jantung lebih cepat
- Merasa mengantuk (lesu)
- Merasa tidak enak badan (malaise)
- Sakit kepala
- Gangguan pencernaan
- Kehilangan selera makan
- Gugup
- Sakit perut
- Berkeringat
- Tremor
- Kelemahan otot (asthenia)
- Muntah

Efek samping tidak umum:
- Reaksi alergi pada kulit (termasuk pembengkakan pada wajah, bibir atau lidah, ruam atau gatal)
- Kebingungan
- Ejakulasi tertunda
- Pusing ketika berdiri terlalu cepat
- Halusinasi
- Kurang koordinasi
- Nyeri otot atau sendi
- Agresi

Efek samping jarang:
- Kejang
- Gangguan hati
- Mania (perasaan sangat gembira atau terlalu bersemangat)
- Sensitivitas terhadap sinar matahari
- Aliran ASI yang tidak terduga

Efek samping lain-lain yang dilaporkan:
- Akathisia (kegelisahan)
- Rasa tidak normal
- Anorgasmy (kegagalan mencapai orgasme)
- Untuk pasien wanita: gangguan menstruasi
- Perdarahan vagina berat sesaat setelah lahir (perdarahan pasca persalinan)
- Gangguan berkemih (sering buang air kecil di siang hari dan / atau malam hari buang air kecil di siang hari dan / atau malam hari kurang terkontrol, atau sulit buang air kecil)
- Parestesia (kesemutan atau mati rasa)
- Glaukoma

- Pupil terdilatasikan
- Peningkatan hormon prolaktin (hormon yang meningkatkan produksi ASI pada ibu menyusui)
- Perubahan berat badan

Peningkatan risiko patah tulang telah diamati pada pasien yang menggunakan obat jenis ini.

Efek samping terkait dengan pengobatan OCD, pada anak-anak dan remaja dengan frekuensi tidak diketahui:

- Hipomania (perasaan gembira yang berlebihan)
- Agitasi
- Kejang-kejang
- Kesulitan tidur (insomnia)
- Kurang energi (asthenia)
- Hiperaktif (hiperkinesia)
- Mengantuk
- Gangguan pencernaan

Pelaporan efek samping
Jika Anda mmengalami efek samping, bicarakan dengan dokter, apoteker, atau perawat Anda, termasuk kemungkinan efek samping yang tidak tercantum dalam leaflet ini. Dengan melaporkan efek samping, Anda dapat membantu memberikan informasi lebih lanjut tentang keamanan obat ini.
Tidak diketahui apakah menggunakan Fluvoxamine di bawah usia 18 tahun dapat mempengaruhi pertumbuhan, kematangan atau perkembangan kecerdasan atau perilaku dalam jangka panjang.

5. Bagaimana cara menyimpan Luvox®?

Jauhkan dari pandangan dan jangkauan anak-anak.
Jangan menggunakan tablet setelah tanggal kedaluwarsa (EXP) yang dicetak pada karton dan kemasan blister.
Jangan menyimpan di atas 30°C.
Jika dokter Anda menghentikan pengobatan Anda, kembalikan tablet yang tidak digunakan kepada apoteker.
Obat-obatan tidak boleh dibuang melalui air limbah atau limbah rumah tangga. Tanyakan apoteker Anda cara membuang obat-obatan yang tidak lagi diperlukan. Langkah-langkah ini akan membantu melindungi lingkungan.

6. Berapa isi kemasan dan apa informasi lainnya?

Luvox® mengandung fluvoxamine maleate.
Setiap tablet 50 mg mengandung 50 mg fluvoxamine maleate.
Setiap 100 mg tablet mengandung 100 mg fluvoxamine maleate.
Bahan-bahan lain adalah: mannitol, pati jagung, pati pregelatinisasi, natrium stearil fumarate, silika anhidrat koloid, hypromellose, macrogol 6000, talk, dan titanium dioksida (E171).

Seperti apa fluvoxamine dan isi kemasannya
Luvox® 50 mg merupakan tablet salut selaput berbentuk bulat, memiliki garis bagi, berwarna putih hingga hamper putih, terdapat emboss “291” pada kedua sisi yang dipisahkan garis bagi, sedangkan sisi lainnya tidak memiliki emboss.

Luvox® 100 mg merupakan tablet salut selaput berbentuk oval, bikonveks, memiliki garis bagi, berwarna putih hingga hamper putih, terdapat emboss “313” pada kedua sisi yang dipisahkan garis bagi, sedangkan sisi lainnya tidak memiliki emboss.

Besar kemasan:
Luvox® 50 mg: Dus, berisi 3 blister yang masing-masingnya berisi 20 tablet salut selaput
Luvox® 100 mg: Dus, berisi 2 blister yang masing-masingnya berisi 15 tablet salut selaput

Diproduksi oleh:

Mylan laboratories SAS., Chatillon Sur Chalaronne, France

Diimpor oleh:

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