Master Summary of Product Characteristics

Fluvoxamine Maleate

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NAME OF THE MEDICINAL PRODUCT

Fevarin ®, film-coated tablets, 25mg
Fevarin ®, film-coated tablets, 50 mg
Fevarin ®, film-coated tablets 75 mg
Fevarin ®, film-coated tablets, 100 mg

Fluvoxamine maleate is authorized as
Dumirox, Dumyrox, Faverin, Favoxil, Fevarin, Fevalat, Floxyfral, Luvox, Maveral and Uvox

1. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active ingredient: fluvoxamine maleate
Each tablet contains 25mg, 50 mg, 75mg or 100 mg of fluvoxamine maleate.
For a full list of excipients see section 6.1

3. 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.

Film-coated tablets 25mg, 50 mg, 75mg (Japan, only)
Round, biconvex, yellow film-coated tablets for oral administration

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

- Major depressive episode.
- Obsessive Compulsive Disorder (OCD).

- Social Anxiety Disorder (SAD)
(Social Anxiety Disorder for Japan only)

4.2 Posology and method of administration

Depression

The recommended starting dose is 50 or 100 mg, given as a 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.
Fluvoxamine at a fixed single daily dose of 100 mg is the recommended dose for the prevention of recurrence of depression.

Obsessive compulsive disorder

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 for adults and 200 mg per day for children from 8 years on/adolescents.

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.

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 4.4 and section 4.8). 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.

4.3 Contraindications

Trademark tablets are contraindicated in combination with tizanidine and monoamine oxidase inhibitors (MAOIs) (see section 4.5).

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 ramelteon (see section 4.5)

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

4.4 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. 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.

Paediatric population
Fluvoxamine should not be used in the treatment of children and adolescents under the age of 18 years except for patients with OCD. Due to lack of clinical experience the use of fluvoxamine in children for the treatment of depression cannot be recommended. 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 antidepressant compared to those treated with placebo. If based on clinical need, a decision to treat is taken; the patient should be carefully monitored for the appearance of suicidal symptoms.

In addition, long-term safety data in children and adolescents concerning growth, maturation and cognitive and behavioural development are lacking.

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 behaviour with antidepressants compared to placebo in patients less than 25 years old.

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 syndromelike
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 (characterised 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.

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 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).

Cardiac disorders
When combined with fluvoxamine plasma concentrations of terfenadine, astemizole or

cisapride 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 4.8). 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. It is therefore advised that fluvoxamine should be gradually tapered when discontinuing treatment according to the patient's needs (see section 4.2).

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.

4.5 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 4.3).

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 are eliminated slower and may have higher plasma concentrations when co-administered with Fluvoxamine. Concomitant therapy of fluvoxamine and these drugs should be initiated at or adjusted to the low end of their dose range. Plasma concentrations, effects or adverse effects of co-administered drugs should be monitored and their dosage should be reduced if necessary. This is particularly relevant for drugs with a narrow therapeutic index.

Ramelteon

When immediate-release fluvoxamine maleate tablets 100 mg twice daily was administered for 3 days prior to single-dose co-administration of ramelteon 16 mg and immediate-release fluvoxamine maleate tablets, the AUC for ramelteon increased approximately 190-fold and the Cmax increased approximately 70-fold compared to ramelteon administered alone.

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.

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 ropinirol may be increased in combination with fluvoxamine thus increasing the risk of overdose, surveillance and reduction in the posology of ropinirol during fluvoxamine treatment and after its withdrawal may be required.

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 4.4.

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 4.4)

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.

4.6 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.

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.

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 5.3).

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

4.7 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.

4.8 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**
Blood and lymphatic system disorders					Haemorrhage (e.g. gastrointestinal haemorrhage, gynaecological haemorrhage, ecchymosis, purpura)
Endocrine disorders					Hyperprolactinaemia, Inappropriate

MedDra system organ class	Common	Uncommon	Rare	Very rare	Frequency not known
					antidiuretic hormone secretion
Metabolism and nutrition disorders	Anorexia				Hyponatraemia, weight increased, weight decreased.
Psychiatric disorders		Hallucination, confusional stage	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			
Gastrointestinal disorders	Abdominal pain, constipation, diarrhoea, dry mouth, dyspepsia, nausea, vomiting				
Hepatobiliary disorders			Hepatic function abnormal		

MedDra system organ class	**Common**	**Uncommon**	**Rare**	**Very rare**	**Frequency not known**
Skin and subcutaneous tissue disorders	Hyperhydrosis	Cutaneous hypersensitivity reactions (incl. angioneurotic oedema, rash, pruritis)	Photosensitivity reaction		
Musculoskeletal, connective tissue and bone disorders		Arthralgia, myalgia			*Bone fractures
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)
General disorders and administration site reactions	Asthenia, malaise				drug withdrawal syndrome including drug withdrawal syndrome neonatal

*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.

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 4.2 and section 4.4).

4.9 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.

5. PHARMACOLOGICAL PROPERTIES

5.1 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.

5.2 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 Trademark® 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) as in adolescents (aged 12-17). Plasma concentrations in adolescents are similar to those in adults.

5.3 Preclinical safety data

Carcinogenesis and mutagenesis

There is no evidence of carcinogenicity or mutagenicity with fluvoxamine.

Fertility and reproductive toxicity
Reproduction studies in animals revealed impaired fertility, increased embryofoetal death and decreased foetal body weight in fluvoxamine exposures exceeding human exposures at maximum recommended human doses at about 4 times. In addition an increased incidence of perinatal pup mortality in pre-and postnatal studies were seen.

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.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Trademark 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).

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years

6.4 Special precautions for storage

Do not store above 25°C. Keep in original package.

6.5 Nature and contents of container

Fluvoxamine maleate film-coated tablets are supplied in packages containing xx tablets (50 mg) or xx tablets (100 mg), packaged in PVC/PVDC-aluminium press-through blister strips of xx tablets per strip.

(xx meaning different from country to country)

6.6 Special precautions for disposal
No special recommendation.

MARKETING AITHORIZATION HOLDER:
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