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The International Journal of Neuropsychiatric Medicine

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AUTHOR GUIDELINES 2000

Introduction

CNS Spectrums is a peer-reviewed journal that publishes original scientific literature and reviews on a wide variety of neuroscientific topics of interest to the clinician. CNS Spectrums publishes 12 issues in 2000. As the immense prevalence of comorbid diseases among patients seen by psychiatrists and neurologists increases, these physicians will jointly diagnose and treat the neuropsychiatrically ill. Our mission is to provide these physicians with an editorial package that will enhance and increase their understanding of neuropsychiatry; therefore, manuscripts that address crossover issues germane to neurology and psychiatry will be given immediate priority.

Scope of Manuscripts

CNS Spectrums will consider the following types of articles for publication:

Original Reports: Original reports present methodologically sound original data.

Reviews: Reviews are overview articles that summarize and synthesize the literature on various topics in a scholarly and clinically relevant fashion. Suitable topics include mood disorders, schizophrenia and related disorders, personality disorders, substance-use disorders, anxiety disorders, neuroscience, psychosocial aspects of psychiatry, child psychiatry, geriatric psychiatry, and other topics of interest to clinicians. nb: Original flowcharts designed to aid the clinician in diagnosis and treatment will be considered for publication in reviews and are encouraged.

Case Reports: Single or multiple case reports will be considered for publication.

Letters to the Editor: Letters will be considered for publication.

Manuscript Submissions

General information: Four copies of the manuscript should be submitted to Eric Hollander, editor (or in Europe to Joseph Zohar, international editor), c/o MBL Communications, Inc., 665 Broadway, Suite 805, New York, NY 10012; T: 212.328.0800, F: 212.328.0600. Authors are required to submit their manuscripts on computer disks. If possible, please provide them in MSWord, WordPerfect, or Word for Windows in either a Macintosh or IBM format. (Saving the file in a lower version, eg, MSWord 3.0, is also encouraged.) Disks should be labeled with the word-processing program, title of paper, and first author's name.

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Peer review: Authors should provide five names of particularly qualified potential reviewers with no conflict of interest in reviewing the work. Contact information, including complete

address, phone, fax numbers, E-mail address, and affiliations, should be included. The corresponding author will be notified by the editors when a decision regarding acceptance has been made. Accepted manuscripts and letters will be edited for clarity and style.

Manuscript Preparation

Length: Reviews should not exceed 20 manuscript pages (10,000 words). Original reports should not exceed 15–25 manuscript pages (6,250 words, maximum). Letters should not exceed 2–6 manuscript pages (1,500 words, maximum). Single case reports should not exceed 10–15 manuscript pages (3,750 words, maximum) and may be submitted with a photograph, if applicable. Diagnostic/treatment algorithms (see Reviews) should contain an extensive introduction, a flowchart or series of graphs that fill eight to 12 journal pages, and a concise summary.

Spacing: One space should be left after commas and periods. Manuscripts should also be double-spaced.

Abstract: Authors should provide a brief abstract.

References: American Medical Association style. See the following examples:

1. Jones J. Necrotizing Candida esophagitis. JAMA. 1980;244:2190-2191.

2. Stryer L. Biochemistry. 2nd ed. San Francisco, Calif: WH Freeman Co; 1980:559-596.

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- Copies of permission letters to reproduce previously published and unpublished material
- 3. A brief abstract of article.
- 4. Two multiple-choice questions with answers
- 5. Disk labeled with the word-processing program, title of paper, and first author's name
- 6. Names and addresses of five potential reviewers.

GUIDE TO DSM-IV AND ICD-10 CODES

imentia of the Alzheimer Type, With Farly Opent With Decreased Mood	DSM-IV	ICD-10
mentia of the Alzheimer Type, With Early Onset With Depressed Mood ecify if: With Behavioral Disturbance	290.13	F00.03
ementia of the Alzheimer's Type, With Late Onset With Depressed Mood becify if: With Behavioral Disturbance	290.21	F00.13
lirium Due to: Indicate General Medical Condition	293.0	F05.0
ychotic Disorder Due to: Indicate General Medical Condition With Delusions	293.81	F06.2
th Hallucinations	293.82	F06.0
ood Disorder Due to: Indicate General Medical Condition xiety Disorder Due to: Indicate General Medical Condition	293.83 293.89	F06 F06.4
nestic Disorder Due to: Indicate General Medical Condition	293.89	F02.8
mentia NOS	294.8	F03
nnestic Disorder NOS	294.8	R41.3
hizophrenia	295	F20
hizophrenia—Disorganized Type hizophrenia—Catatonic Type	295.10 295.20	F20.1 F20.2
nizophrenia—Catatonic Type nizophrenia—Paranoid Type	295.20	F20.2 F20.0
nizophrenia—Residual Type	295.60	F20.5
nizoaffective Disorder	295.70	F25
hizophrenia—Undifferentiated Type	295.90	F20.3
jor Depressive Disorder	296	F32
olar Disorder olar Disorder NOS	296 296.80	F30 F39
polar II Disorder	296.89	F31.8
od Disorder NOS	296.90	F39
chotic Disorder NOS	298.9	F29
istic Disorder	299.00	F84
perger's Disorder	299.80	F84.5
vasive Developmental Disorder NOS iety Disorder NOS	299.80 300.00	F84.9 F41.9
nic Disorder Without Agoraphobia	300.00	F41.9
neralized Anxiety Disorder	300.02	F41.1
sociative Identity Disorder	300.14	F44.81
sociative Disorder NOS	300.15	F44.9
titious Disorder NOS	300.19	F68.1
nic Disorder With Agoraphobia Braphobia Without History of Panic Disorder	300.21 300.22	F40.01 F40
sial Phobia	300.22	300.23 F40.1
ecific Phobia	300.29	F40.2
sessive-Compulsive Disorder	300.3	F42.8
sthymic Disorder	300.4	F34.1
personalization Disorder	300.6	F48.1
dy Dysmorphic Disorder matization Disorder	300.7 300.81	F45.2 F45.
matoform Disorder NOS	300.81	F45.9
lothymic Disorder	301.13	F34
phol Dependence	303.90	F10.2
aine Dependence	304.20	F14.2
nnabis Dependence	304.30 304.40	F12.2 F15.2
phetamine Dependence phol Abuse	305.00	F10.1
nnabis Abuse	305.20	F12.1
caine Abuse	305.60	F14.1
phetamine Abuse	305.70	F15.1
ttering	307.0	F98.5
rexia Nervosa	307.1	F50
Disorder NOS rette Disorder	307.20 307.23	F95.9 F95.2
nary Insomnia	307.42	F51.0
nary Hypersomnia	307.44	F51.1
epwalking Disorder	307.46	F51.3
somnia NOS	307.47	F51.9
ntmare Disorder asomnia NOS	<u>307.47</u> 307.47	F51.5 F51.8
ng Disorder NOS	307.50	F50.9
mia Nervosa	307.51	F50.2
ding Disorders of Infancy or Early Childhood	307.59	F98.2
nmunication Disorder NOS	307.9	F80.9
ttraumatic Stress Disorder	309.81	F43.1
ressive Disorder NOS ulse-Control Disorder NOS	311 312.30	F32.9 F63.9
nological Gambling	312.30	F63.0
mania	312.33	F63.1
otomania	312.34	F63.2
hotillomania	312.39	F63.3
ruptive Behavior Disorder NOS	312.9	F91.9
ention-Deficit/Hyperactivity Disorder, Combined Type	314.01	F90 F90.9
ention-Deficit/Hyperactivity Disorder NOS Irning Disorder NOS	314.9 315.9	F81.9
velopmental Coordination Disorder	315.4	F82
colepsy	347	G47.4
ep Disorder Due to: Indicate General Medical Condition	780	G47

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 ☐ Current Uses of Dopamine Agonists ☐ Monotherapeutic Uses for Dopamine Agonists ☐ Management of Social Anxiety Disorder (Social Phobia) ☐ Diagnosis and Treatment of Premenstrual Dysphoric Disord ☐ Current Treatment for Restless Legs Syndrome 	☐ The Use of Anticonvulsants in the Treatment of Neuropathic Pain ☐ Overview of Social Anxiety Disorder (Social Phobia): der Recognition and Treatment
REFERENCE MATERIALS The Black Book of Psychotropic Dosing and Monitoring 1999 Guide to Psychotropic Drug Interactions	g 2000

LUVOX® [fluvoxamine maleate) 25 mg TABLETS, 50 mg and 100 mg SCORED TABLETS Brief Summary (For full Prescribing Information and Patient Information, refer to package insert.)

INDICATIONS AND USAGE

LUVOX** Tablets are indicated for the treatment of alssessions and compulsions in adults and children and adolescents (ages 8-17) with Obsessive Compulsive Disorder (OCD), as defined in the DSM-III-R.

CONTRAINDICATIONS

Coordininstration of terfenodine, asternizale, asopride, or pimozide with LUVOX® Tablets is contraindicated (see WARNINGS and PRECAUTIONS). LUVOX® Tablets are contraindicated in patients with a history of hypersensitivity to fluvoxamine maleate.

WARNINGS

In patients receiving another serotonin reuptake inhibitor drug in combination with monoamine oxidase inhibitors (MAOI), there have been reports of serious, sometimes fatal, reactions. Some cases presented with features resembling neuroleptic medignant syndromen. Therefore, it is recommended that LUVOX* Tablets not be used in combination with of MAOI, or within 14 days of discontinuing treatment with a MAOI. After stopping LUVOX* Tablets, at least 2 weeks should be allowed before starting a MAOI. Terfenadine, actor

starting a MAUI. Terfanadine, astemizole, cisapride, and pimozide are all metabolized by the cytochrome P450IIIA4 isozyme. Increased plasma concentrations of terfanadine, astemizole, cisapride, and pimozide cause QT prolongation and have been associated with torsodes de pointes-type ventriculor tachycardia, sometimes fatal. Although it has not been definitively demonstrated that fluvoxamine is a potent IIIA4 inhibitor, it is likely to be. Consequently, it is recommended that fluvoxamine not be used in combination with either terfanadine, astemizole, cisapride, and pimozide.

combination with either terfenadine, astemizale, disapride, and pimozide.

Other Potentially Important Drug Interactions. (Also see PECAUTIONS - Dug Interactions). Benzadiazepines: Benzadiazepines: Benzadiazepines: Benzadiazepines metabolized by hyborato makine (e.g. olprazopin, midzozlam, inscionn, etc.) should be used with custom because the cleanons of these drugs is likely to be reduced by hovoxamine. The cleanons of bress drugs is likely to be reduced by hovoxamine. The cleanons of bress drugs is likely to be reduced by thousamine, and prazolam: When fluvoxamine molecte (100 mg qd) and alprazolam (1 mg qid) were crodimistered to steady state, plasmo concentrations and other pharmacokinetic parameters (AUC, C.,..., 1.) of otparzolam were approximately hivis: those observed when observe superst. (in-a), the devotice of anazopam was seauced by 0.5% and mat or Adestinentylaazapam to a level that was the law to the measure over the code of the 2 week long study. It is likely that this experience significantly understanders the degree of accumulation that might occur with repeated diazepam administration. Moreover, as noted with alprazolam, the effect of fluvoxamine may even be more pronounced when it is administered at higher doses. Accordingly, diazepam and fluvoxamine should not ordinarily be continuistered. The phylitille: The effect of steady-state fluvoxamine (SD mg jub) her phomosphalines of a single dose of theophylline is 25% ang s4 42 mg anainpolythille via so-calabled in 12 beathy non-making, male valunteers. The clearance of theophylline was decreased approximately three-fold, Therefore, if theophylline is co-administered with fluvoxamine maleate, its dose should Ceautic of inequipment with secretary operations, interesting in inequipment of containment interestine interestin

PRECAUTIONS

General

Activation of Mania/Hypomania: During premarketing studies involving primarily depressed patients, hypomania or mania occurred in approximately

1% of potients treated with fluvocomine. Activation of mania/hypomania has dos been reported in a small proportion of patients with mojor affective
disorder who were treated with other marketed antidepressons. As with all antidepressons, LIVOX** flotlest should be used cuntiously in patients with depressive promote sharp studies, serious were exported in 0.2% of theoremine-treated patients. LIVOX** flotlest should be used cuntiously in patients with a dispersion of seriously in patients with a dispersion of seriously in patients with depressive symptoms, whether these occur in primary depression or in association with another primary disorder such particular to lices supervision on high risk patients should accompany rindled dury therapy. Prescriptions for LIVOX** flotlests on the written for the reduction of high risk patients should accompany rindled dury therapy. Prescriptions for LIVOX** flotlests with Concomitant Illness; Closely another of clinical experience with LIVOX*** flotlest in patients with a recent history of myocardial inferction or unstable heard disease. Potients with these diagnoses were systemated or used to any appreciable extent in potients with a recent history of myocardial inferction or unstable heard disease. Potients with these diagnoses were systemated or used to any appreciable extent in potients with a recent history of myocardial inferction or unstable heard disease. Potients with these diagnoses were systemated or used to any appreciable extent in potients with a concomitant experience with these diagnoses were systemated or used to any appreciable extent in potients with a concomitant experience with these diagnoses were systemated or used to any appreciable and present and applications. LIVOX** flotlests have not been revoluted or used to any appreciable extent in potients with these diagnoses were systemated to used to any ap dysfunction during the initiation of treatment.

dysturction during the infiliation of heatment. Information during the infiliation of realizations are advised to discuss the following issues with patients for whom they prescribe LUVOX* Toblets: Interference with Cognitive or Mator Performance: Since any psychocotive day may impoir judgement, thinking, or mator skills, perients should be couloned about operating heardown mechanics; indicating nutromobiles, until they are certain that LUVOX* Toblets thereby does not ordered yillard their oblight you engage in such carbitises. Programacy: Potients should be achiesed to notify their physicians if they become pregnant or intend to become pregnant during therapy with LUVOX* Toblets. Norsing: Potients should be achiesed to be achiesed to notify their physicians if they are breast leading an infant. (See PECAUTIONS: Norsing Mothers). Concentitant Medications: Potients should be achiesed to notify their physicians if they are toking, up persiphon or over-the-counter drugs; since there is a potential for clinically important interactions with LUVOX Toblets. Machine Is with other psychotacyic medications, potients should be advised to avoid alcohol while taking LUVOX* Toblets. Allergic Reactions: Potients should be advised to notify their physicians if they develop a rosh, thirse, or a related allergic phenomenon during therapy with LUVOX* Toblets. See a programment of the programment

Laboratory Tests: There are no specific laboratory tests recommended.

Loboratory Tests: There have been rose postric loboratory tests ecommended.

Drug lateractions: There have been rore postmarketing reports describing patients with weckness, hypereflexia, and incoordination following the use of a selective seatonin reupoke inhibitor (SSR) and summtriptan. If concentitont freatment with summtriptan and SSRI (e.g., fluovetine, fluovoamine, paroxxetine, sertoline) is dirically warranted, appropriate observation of the patient is advised. Potential interactions with drugs that inhibit or are Metabolized by Cytochrome P450 Isozymes: Based on a finding of substantial interactions of fluovoamine with certain days and limited in with data for the Illus fazzyme, in appears that fluovoamine inhibits possines that are known to be invoked in the metabolism of large such as wordorn, theophylline, certain bearcadiazepines and phenytoni. II UPOX* labels are to be administrated together day for the fluored part is eliminated via outdome metabolism and have a narrow therapteric window, possional evels and/or phenometabolism of the or anorow therapteric window, possional levels and/or phenometabolisms or recommendations regarding CNS drugs such as monoromine evidates inhibitors, adprazalam, diazegeam, lorazegeam, inhibitors, vardaini, adjoin, diazeze. Effects of Smoking on Havoxamine Metabolisms: Snokers had a 25% increase in the metabolism of fluovoamine compared to nonsmokers. Electroconvulsive Theory (ECT): There or no clinical studies establishing the benefits or risks of combined use of ECT and fluovoamine molecte.

Carcinogenesis, Mutagenesis, Impairment of Fertility

Carcinogenesis. Metagenesis, Impairment of Fertility Carcinogenesis: Interior to evidence of carcinogenesis: There is no evidence of carcinogenicity, multogenicity or impairment of fertility with fluvoxomine molecte. There was no evidence of carcinogenicity in the treated coally with fluvoxomine molecte for 30 months or humsters hereted coally with fluvoxomine molecte for 20 (females) or 26 (males) months. The daily does in the high does groups in these studies were increased over the course of the study from a minimum of 16 flur mg/kg in common of 16 flur mg/kg in phases. The maximum does of 1240 mg/kg is approximately 5 times the maximum humen daily dose on a mg/m² basis. Matagenesis: No evidence of mutagenic potential was observed in a mouse microarcides test, an in wind chromosome observation test, or the Amers microbal mutagen lest with or without metabolic activation. Impairment of Fertility: in fertility studies of male and female rate, up to 80 mg/kg/ day or orally orally of fluvoxomine maletate (approximately 2 times the maximum humon daily dose on a mg/m² basis) had no effect on moting performance, divarian of gestation, or preparancy rate.

Pregnancy

Terratogenic Effects: Pregnancy Category C: In tentology studies in rats and rabbits, daily and doses of fluvoxomine moleate of up to 80 and 40 mg/kg, respectively (approximately 2 times the maximum human daily dose on a mg/m² basis') caused no fetal mathematical. However, in memory reproduction, suchies in which pregnant risk were dosed through wearing the west (1) an increase in purp matrially to this fiscent at 10 mg/kg and above but not at 20 mg/kg), and (2) decreases in postnatial pure weights (seen at 160 but not at 80 mg/kg) and survival (seen at all doses; lowest dose lested = 5 mg/kg). (Doses of 5, 20, 80, and 160 mg/kg are approximately 0.1, 0.5, 2, and 4 times the maximum human daily dose on a mg/m² basis.)

While the results of a cross-fostering study implied that at least some of these results likely occurred secondarily to maternal toxicity, the role of a direct dring effect on the fethese on puts could not be risked out. There are no adequate and well-controlled studies in pregnant women. Fluvoxomine maleate should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Labor and Delivery: The effect of fluvoxomine on labor and delivery in humans is unknown.

Nursing Mothers: As for many other drugs, flavoxamine is secreted in human breast milk. The decision of whether to discontinue nursing or to discontinue the drug should take into account the potential for serious adverse effects from exposure to fluvoxamine in the nursing infant as well as the potential benefits of LUVÖX" (fluvoxamine maleate) Tablets therapy to the mother.

Pediatric Use: The efficacy of fluvoxaminie maleate for the treatment of Obsessive Compulsive Disorder was demonstrated in a 10-week multicenter placebo controlled study with 120 outpatients ages 8-17. The odverse event profile observed in that study was generally similar to that observed in odulf studies with fluvoxamine (see ADVERSE REACTIONS).

Decreased appetits and weight loss have been observed in association with the use of fluvoxomine as well as other SSRIs. Consequently, regular monitoring of weight and growth is recommended if treatment of a child with an SSRI is to be cantinued long term.

Geriatric Use: Approximately 230 patients participating in controlled premarketing studies with LUVOX® Tablets were 65 years of age or over. No overall

differences in safety were observed between these potients and younger patients. Other reported clinical experience has not identified differences in response between the elderly and younger potients. However, fluxoumnine has been associated with several cases of clinically significant hypocontermio in elderly potients (see PRECAUTIONS, General). Furthermore, the clearance of fluvouronine is decreased by about 50% in elderly compared to younger potients, and greater sensitivity of some older individuals also commot be ruled out. Consequently, LUVOS⁴⁴ Tablets should be slowly throtted during inhibition of therapy.

ADVERSE REACTIONS

Associated with Discontinuation of Treatment: Of the 1087 OCD and depressed patients treated with fluvoxamine maleate in controlled clinical

miols conducted in North America, 22% discontinued treatment due to an adverse event.

Incidence in Controlled Trials - Commonly Observed Adverse Events in Controlled Clinical Trials: LIVOX* Toblets have been studied.

Incidence in Controlled Trials - Commonly Observed Adverse Events in Controlled Clinical Trials: LIVOX® Toblets have been studied in controlled that of OCD (H=270) and depression (H=1850). In general, otherse event rates were similar in the two data sets as well as in the podular COD study. The most commonly observed nelverse events associated with the use of LIVOX® Toblets and likely to be diregulated (incidence of 5% or greater and at least twice that for placebo) derived from Toble I were: sommolence, insomnia, nervousness, termor, nausen, chyspessia, connexia, venitaria and procuration, extension and severage. In a pool of two studies involving only potients with OCD, the following additional events were identified using the above rule: approximate the control of the studies involving and proteints with OCD, the following additional events were identified using the above rule: approximate the studies of the population and the studies. For the studies of the population and studies of the studi

Table 1: TREATMENT-EMERGENT ADVERSE EVENT INCIDENCE RATES BY BODY SYSTEM IN ADULT OCD AND DEPRESSION POPULATIONS COMBINED' (fliwoxomine (N=92) vs. placebo (N=78) by preheits—percentique): BODY AS WHOLE: Headache (22 vs. 20); Asthenia (14 vs. 6); Flo Syndrome (3 vs. 2); Chills (2 vs. 1). CARDIOVASCULAR: Polynthian (3 vs. 2); DiffeSTIVE SYSTEM: Nussed (4 vs. 10); Bornade (14 vs. 6); Florent (3 vs. 1); DiffeStive (14 vs. 10); Bornade (14 vs. 10); Month (14 vs. 10); Menousness (12 vs. 5); Bozzines (11 vs. 6); Florent (5 vs. 1); Anabley (5 vs. 3); Vscalabitation (2 vs. 1); DiffeStive (4 vs. 10); Menousness (12 vs. 5); Bozzines (11 vs. 6); Florent (5 vs. 1); Anabley (5 vs. 3); Vscalabitation (3 vs. 1); Purposition (2 vs. 1); DiffeStive (4 vs. 10); Menousness (12 vs. 5); Bozzines (11 vs. 6); Florent (5 vs. 1); Anabley (6 vs. 3); Vscalabitation (3 vs. 1); Purposition (2 vs. 1); Purposition (Table 1: TREATMENT-EMERGENT ADVERSE EVENT INCIDENCE RATES BY BODY SYSTEM IN ADULT OCD AND DEPRESSION

were: astheria, abnormal ejaculation (mostly delayed ejaculation), anxiety, infection, thiratis, anagysmia (in males), depression, libido decreased, phanyagitis, opliation, impotence, myecious/which, thirst, weight loss, leg cramps, myelgia and univary retention. These events are listed in order of decreasing rates in the CO thirds.

Other Adverse Events in OCD Pediatric Population: In Pediatric patients (N=57) treated with LUVOX® Tables, the averall profile of adverse events is similar to that seen in adult studies. Other reactions which have been reported in two or more pediatric patients, and were more frequent than in the placebo group group were: admortad thinking, cough increase, dysmenorthea, ecolymosis, emotional dability, epistosoi, hyperkinesia, infection, manic reaction, rash, sinusitis, and

weight decrease.

Vital Sign. Changes: Comparisons of fluvoxamine mulecte and placeba groups in separate pools of shart-term OCD and depression trials on (1) median change from baseline on various wital signs variables and on (2) incidence of patients meeting criteria for potentially important changes from baseline on various wital signs variables revealed no important differences between fluvoxamine molecute and placebo.

Laboratory Changes: Comparisons of fluvoxamine medicale and placebo groups in separate pools of short-term OCD and depression trials on (1) median between the membrate placebours and introduces variables and on (2) incidence of onlinets meeting criteria from placebours and introduces variables and on (2) incidence of onlinets meeting criteria from placebours and introduces variables and on (2) incidence of onlinets meeting criteria from placebours and introduces variables and on (2) incidence of onlinets meeting criteria from the placebours and placebours are considered and on (2) incidence of onlinets meeting criteria.

change from baseline on various serum chemistry, hematology, and urinadysis variables and an (2) incidence of potients meeting critiena for potentially important changes from baseline on various serum chemistry, hematology, and uninalysis variables revealed no important differences between fluvoxamine maleate and placeho

change from baseline on various seum chemistry, hermotology, and urinalysis variobles and an (2) incidence of patients meeting criteria for potentially important changes from baseline on various seum chemistry, hermotology, and urinalysis variobles variobles and of the wavamine maleate and placebo groups in separate pools of short-term OCD and depression trids on (1) mean change from baseline on various ECG variables and an (2) incidence of patients meeting criteria for potentially important honges from baseline on various ECG variables revealed no important differences between flavocarrine meloate and placebo.

Other Events Observed During the Premarketing Evolutation of LIVOX** Tablets: During premarketing clinical thick conducted in North America and Europe, multiple doses of flavocarrine maleate were administrated for a combined total of 2737 potient exposures in patients suffering OCD and Major Depressive Disorder. Unlowand events associated with this exposure were recorded by clinical investigators using descriptive terminology of the own changing similar types of unlowand events associated with the exposure were recorded by clinical investigators using descriptive terminology of the own changing similar types of unlowand events associated with the exposure were recorded by clinical investigators using descriptive terminology of the COSIAR broad Chicaronary terminology has been used to desafy reported of devets the COSIAR broad Chicaronary terminology that on the cost of the properties of the common terminology of the cost of the cost

Non-US Postmarketing Reports: Voluntary reports of adverse events in patients taking LUVOX** Tablets that have been received since market introduction and are of unknown coasel relationship to LUVOX*** Tablets are include: toxic epidermal nearohysis, Stevens-Johnson syndrome, Henoch-Scheenlein purum, Julious exuption, priopism, organizan/posts, neuropism, pubsictio enterial, anaphylocist, reaction, hyponothemia, ocute renal failure, hepatitis, and severe akinesia with fever when fluvoxamine was co-administered with antipsychotic medication.

OVERDOSAGE

Refer to package insert (15E Rev S/99) for overdosage information.

DOSAGE AND ADMINISTRATION

Refer to package insert (15E Rev 5/99) for desage and administration information

Solvay Pharmaceuticals Marietta, GA 30062

Rev 6/99 (1280/1285 15E Rev 5/99)

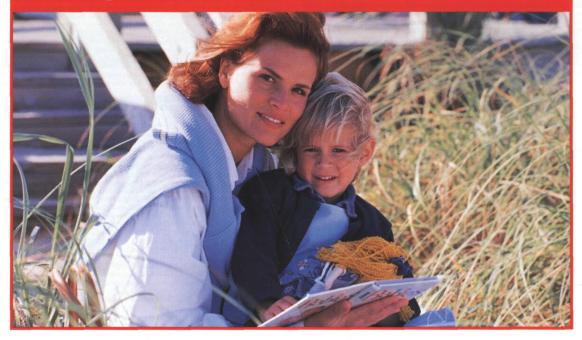
Solvay **Pharmaceuticals**

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TVX00025

January 2000

"My doctor diagnosed obsessions and compulsions and prescribed LUVOX® Tablets."



- ▼ IMPROVES OBSESSIVE-COMPULSIVE SYMPTOMS IN ADULTS, CHILDREN, AND ADOLESCENTS^{2,3}
- ▼ LOW INCIDENCE OF SEXUAL DYSFUNCTION IN ADULTS⁴
 LUVOX® Tablets vs placebo: decreased libido 2% vs 1%; delayed ejaculation 8% vs 1%; impotence 2% vs 1%
- ▼ LOW INCIDENCE OF AGITATION IN ADULTS⁴ 2% vs 1% for placebo

In adults, the most commonly observed adverse events compared to placebo were somnolence 22% vs 8%; insomnia 21% vs 10%; nervousness 12% vs 5%; nausea 40% vs 14%; asthenia 14% vs 6%⁴

In children and adolescents, the most commonly observed adverse events compared to placebo were: agitation 12% vs 3%; hyperkinesia 12% vs 3%; depression 5% vs 0%; dysmenorrhea 7% vs 3%; flatulence 5% vs 0%; rash 7% vs 3%⁴

Concomitant use of LUVOX® Tablets and monoamine oxidase inhibitors is not recommended.4

Fluvoxamine should not be used in combination with terfenadine, astemizole, cisapride, or pimozide.4

As any psychoactive drug may impair judgment, thinking, or motor skills, patients on LUVOX® Tablets should be advised to exercise caution until they have adapted to therapy.4

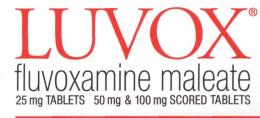
References: 1. Physician Drug & Diagnosis Audit (PDDA) and Source™ Prescription Audit (SPA) August 1999-September 1999. Scott-Levin, a division of Scott-Levin PMSI Inc. 2. Goodman WK, Kozak MJ, Liebowitz M, et al. Treatment of obsessive-compulsive disorder with fluvoxamine: a multi-centre, double-blind, placebo-controlled trial. *Int Clin Psychopharmacol*. 1996;11:21-29. 3. Data on file, Study in Children and Adolescents (Report No. CR200.0116), Solvay Pharmaceuticals. 4. LUVOX® Tablets Full Prescribing Information.

VISIT OUR OCD WEB SITE AT www.ocdresource.com

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Please see brief summary of prescribing information on adjacent page.

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First-line SSRI therapy for obsessions and compulsions