PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S5

LUVOX 100 mg film-coated tablets

Fluvoxamine maleate

Contains sugar (303 mg mannitol per tablet).

Read all of this leaflet carefully before you start taking LUVOX

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- LUVOX has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What LUVOX is and what it is used for
2. What you need to know before you take LUVOX
3. How to take LUVOX
4. Possible side effects
5. How to store LUVOX
6. Contents of the pack and other information.

1. What LUVOX is and what it is used for

LUVOX belongs to a group of medicines called selective serotonin re-uptake inhibitors (SSRI).

LUVOX contains a substance called fluvoxamine. This is an antidepressant. It is used to treat depression (major depressive episode).

LUVOX can also treat people who have obsessive-compulsive disorder (OCD).

2. What you need to know before you take LUVOX

Do not take LUVOX:

- If you are allergic (hypersensitive) to fluvoxamine maleate or any of the other ingredients of LUVOX (listed in section 6).
- If you are taking medicines called monoamine oxidase inhibitors (MAOI) used to treat depression or anxiety.

  Treatment with LUVOX should only be started at least 2 weeks after stopping treatment of an MAOI. At least one week should elapse between stopping LUVOX and starting treatment with an MOAI. Your doctor will advise you how you should begin taking LUVOX once you have stopped taking the MAOI.
- If you are taking tizanidine, a medicine often used as a muscle relaxant.
- If you are pregnant or breastfeeding.
- If you are under the age of 18 years.
- If you have liver or kidney function problems.
- If you suffer from epilepsy.
- If you are taking pimozide, a medicine used for the treatment of schizophrenia and other psychiatric diseases.

Warnings and precautions

Thoughts of suicide and worsening of your depression or anxiety disorder

If you are depressed and/or have anxiety disorders, you can sometimes have thoughts of harming or killing yourself. These may be increased when first starting antidepressants, since these medicines all take time to work, usually about two weeks but sometimes longer.

You may be more likely to think like this:

- If you have previously had thoughts about killing or harming yourself.
- If you are a young adult. Information from clinical trials has shown an increased risk of suicidal behaviour in adults aged less than 25 years with psychiatric conditions who were

treated with an antidepressant.

If you have thoughts of harming or killing yourself at any time, **contact your doctor or go to a hospital straight away**.

You may find it helpful to tell a relative or close friend that you are depressed or have an anxiety disorder and ask them to read this leaflet.

You might ask them to tell you if they think your depression or anxiety is getting worse, or if they are worried about changes in your behaviour.

Tell your doctor immediately if you have any distressing thoughts or experiences.

Take special care with LUVOX:

- If you recently had a heart attack.
- If you have epilepsy.
- If you have a history of bleeding problems or if you regularly use medicines which increase the risk of bleeding, such as common pain killers, or if you are pregnant.
- If you have diabetes (high blood sugar levels).
- If you are having treatment with electroconvulsive therapy (ECT).
- If you ever had mania (a feeling of elation or over-excitement).
- If you have liver or kidney problems.
- If you have high pressure in your eyes (glaucoma).

If any of the above applies to you, your doctor will tell you whether it is safe for you to start taking LUVOX.

Occasionally, thoughts of restlessness for example, you cannot sit or stand still (akathisia) may occur or may increase during the first few weeks of treatment with LUVOX, until the antidepressant effect has started working. Tell your doctor immediately if you experience these symptoms.

Medicines like LUVOX (so called SSRIs) may cause symptoms of sexual dysfunction (see section 4). In some cases, these symptoms have continued after stopping treatment.

On rare occasions development of a serotonin syndrome or neuroleptic malignant syndrome-like events have been reported in association with treatment of LUVOX, particularly when given in combination with other serotonergic and/or neuroleptic medicines. Inform your doctor immediately if you experience symptoms such as high fever, stiffness, feeling unstable with possible rapid fluctuations of vital signs, mental status changes including confusion, irritability, extreme agitation progressing to delirium and coma.

Children and adolescents

Children and adolescents under 18 years of age should not take LUVOX.

Other medicines and LUVOX

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

Your doctor or pharmacist will check if you are taking other medicines to treat your depression or other related mental disorders, these may include:

- benzodiazepines (e.g. triazolam, midazolam, alprazolam and diazepam)
- tricyclic antidepressants (such as amitriptyline)
- neuroleptics (such as chlorpromazine) or antipsychotics (such as clozapine)
- lithium
- selective serotonin reuptake inhibitors
- tryptophan
- monoamine oxidase inhibitors (MAOIs) such as moclobemide
- pimozide.

Tell your doctor or pharmacist if you are already taking any of the following medicines:

- terfenadine or astemizole (used to treat allergies)
- cisapride (used to treat stomach disorders such as heartburn)
- tacrine (used to treat Alzheimer's disease)
- theophylline (used to treat asthma and bronchitis)
- methadone (used to treat pain or medicine withdrawal symptoms)
- mexiletine (used to treat abnormal heart rhythms)
- warfarin or other oral anticoagulants (used to prevent blood clots)
- thioridazine (used to treat mental disorders)
- propranolol or atenolol (used to treat high blood pressure and heart disorders)
- ropinirole (used to treat Parkinson's disease)
- phenytoin or carbamazepine (used to treat epilepsy)
- ciclosporin (used to reduce the activity of the immune system)
- caffeine-containing beverages (see section **LUVOX with food, drink and alcohol** below)
- digoxin (used to treat heart disorders)
- other serotonergic agents (including sumatriptan used to treat migraines, tramadol used to treat pain, St John's Wort, an herbal remedy used to treat mood disorders)
- aspirin or aspirin-like medicines, used to treat pain and inflammation (arthritis)
- sildenafil (used to treat erectile dysfunction)
- alcohol (see section **LUVOX with food, drink and alcohol** below).

LUVOX with food, drink and alcohol

LUVOX tablets should be swallowed with water and without chewing the tablets.

Do not take LUVOX with alcohol as it may make you sleepy and unsteady.

If you normally drink a lot of tea, coffee and soft drinks with caffeine in them, you may have symptoms such as your hands shaking, feeling sick (nausea), faster heartbeat (palpitations), restlessness and difficulty sleeping (insomnia). If you lower how much caffeine you drink, these

symptoms might disappear.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

Do not take LUVOX if you are pregnant or breastfeeding.

Driving and using machines

You may feel sleepy after taking LUVOX. Do not drive or operate machines until you know how LUVOX affects you.

3. How to take LUVOX

Do not share medicines prescribed for you with any other person.
Always take LUVOX exactly as your doctor or pharmacist has instructed you. You should check with your doctor or pharmacist if you are unsure.
If you have the impression that the effect of LUVOX is too strong or too weak, tell your doctor or pharmacist.

Major depressive episodes

The usual daily dose usually varies between 100 mg and 200 mg and should be adjusted to the individual response of the patient up to a maximum of 300 mg. The minimum recommended starting dose is 100 mg per day and 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.

Obsessive-compulsive disorder

The usual daily dosage usually varies between 100 mg and 200 mg, with some patients requiring

up to 300 mg per day. The recommended starting dose is 50 mg per day for 3 to 4 days. The dosage should be increased gradually until the effective dosage is achieved, with a maximum of 300 mg per day. If no improvement is observed within 10 weeks, treatment with LUVOX should be reconsidered.

LUVOX tablets should be swallowed with water and without chewing the tablets.

If you take more LUVOX than you should

In the event of an overdosage, consult your doctor or pharmacist.
If neither is available, contact the nearest hospital or poison centre. Take this leaflet and the remaining tablets with you so the doctor knows what you have taken.

If you forget to take LUVOX

If you forget to take a tablet, do not take a double dose to make up for a forgotten tablet but continue as prescribed.

If you stop taking LUVOX

You should not discontinue treatment with LUVOX abruptly.
Withdrawal symptoms, including headache, paraesthesia, nausea, dizziness and anxiety, have been reported after abrupt discontinuation of LUVOX. Consult your doctor for advice.

4. Possible side effects

LUVOX can have side effects.
Not all side effects reported for this medicine are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking this medicine, please consult your health care provider for advice.

If any of the following happens, stop taking LUVOX and tell your doctor immediately or go to the

casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching,
- fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to LUVOX. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Frequent side effects:

- agitation
- anxiety
- constipation
- diarrhoea
- difficulty sleeping (insomnia)
- dizziness
- dry mouth
- very fast heartbeat
- feeling drowsy (somnolence)
- feeling unwell (malaise)
- headache
- indigestion
- loss of appetite (anorexia)
- nervousness
- stomach pain
- sweating
- tremor
- muscle weakness (asthenia)

- feeling sick (nausea)
- being sick (vomiting)

Less frequent side effects:

- allergic skin reactions (including swelling of face, lip or tongue, rash or itching)
- confusion
- delayed ejaculation
- dizziness when standing up too quickly
- hallucinations
- lack of coordination
- muscle or joint pain
- convulsions
- liver problems
- mania (a feeling of elation or over-excitement)
- sensitivity to sunlight
- unexpected milk flow

Other side effects reported (frequency not known):

- akathisia (restlessness)
- abnormal taste
- anorgasmia (failure to achieve orgasm)
- disorders with menstruation (monthly bleeding) in female patients
- heavy vaginal bleeding shortly after birth (postpartum haemorrhage)
- micturition disorders (such as the need to urinate frequently during the day and/or the night, the sudden lack of control over urination during the day and/or the night, or the lack of ability to urinate)
- paraesthesia (tingling or numbness)
- glaucoma (increased pressure in eye)

- dilated pupils
- increase in the hormone prolactin (a hormone that supports milk production in a nursing mother)
- weight changes

An increased risk of bone fractures has been observed when taking this type of medicine.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reaction Reporting Form**", found online under SAHPRA's publications: http://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of LUVOX.

5. How to store LUVOX

- Store at or below 30 °C in original packs, protected from direct sunlight.
- Do not take the tablets after the expiry date printed on the packet.
- If you don't need to take this medicine anymore, take it to your doctor or nearest pharmacy who will dispose of it.
- **Store all medicines out of reach of children.**

6. Contents of the pack and other information

What LUVOX contains

The active substance is 100 mg fluvoxamine maleate.

The other ingredients are colloidal anhydrous silica, maize starch, mannitol (E421), pregelatinised starch, sodium stearyl fumarate, hypromellose, polyethylene glycol 6000, talc, titanium dioxide (E171) (colourant).

What LUVOX looks like and contents of the pack

Oval, biconvex, white, film-coated, breakable tablets, inscribed with “S” on the one side and “313” on the other.

Clear PVC/PVdC/aluminium blisters strips in an outer carton.

Available in packs of 30 tablets.

Holder of certificate of registration

Abbott Laboratories S.A. (Pty) Ltd

Abbott Place, 219 Golf Club Terrace

Constantia Kloof 1709

South Africa

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NAMIBIA:

NS3 LUVOX 100

Reg. No.: 04/1.2/1369