LUVOX®

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using LUVOX?

LUVOX contains the active ingredient fluvoxamine. LUVOX is used to treat depression and Obsessive Compulsive Disorder (OCD). For more information, see Section 1. Why am I using LUVOX? in the full CMI.

2. What should I know before I use LUVOX?

Do not use if you have ever had an allergic reaction to fluvoxamine or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding. For more information, see Section 2. What should I know before I use LUVOX? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with LUVOX and affect how it works. A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How do I use LUVOX?

- Your doctor will decide what dose you should receive.
- The usual starting dose for adults is 50 mg each day, but your doctor may adjust the number of tablets or the strength of the tablets you are taking until the desired response is achieved up to a maximum of 300 mg per day.

More instructions can be found in Section 4. How do I use LUVOX? in the full CMI.

5. What should I know while using LUVOX?

Things you should do	• Remind any doctor, dentist or pharmacist you visit that you are using LUVOX. • Tell your doctor immediately if you become pregnant or are breast-feeding while taking LUVOX. • Tell your doctor immediately if you have any suicidal thoughts or other mental/mood changes.
Things you should not do	• Do not stop using this medicine suddenly, increase or lower the dose, without first checking with your doctor. • Do not give this medicine to anyone else, even if their symptoms seem similar to yours. • Do not use LUVOX to treat any other complaints unless your doctor tells you to.
Driving or using machines	• Be careful driving or operating machinery until you know how LUVOX affects you. • LUVOX may cause drowsiness, dizziness or sleepiness in some people and affect alertness. If you have any of these symptoms, do not drive or operate machinery.
Drinking alcohol	• You should avoid drinking alcohol while taking LUVOX.
Looking after your medicine	• Keep the pack in a cool, dry place (below 25°C) in its original packaging. • Do not store LUVOX in the bathroom, near a sink or leave it in the car on hot days. • Keep your tablets where young children cannot reach it.

For more information, see Section 5. What should I know while using LUVOX? in the full CMI.

6. Are there any side effects?

Tell your doctor if you notice any of the following and they worry you: nausea, vomiting, stomach pain, constipation, diarrhoea, heart burn, loss of appetite, dry mouth, drowsiness, difficulty sleeping, dizziness, nervousness, headache, muscle weakness, muscular pains, pins and needles, abnormal taste, faster heartbeat, sweating, weight gain, weight loss, restlessness, pacing.

Tell your doctor immediately, or go to Accident and Emergency at your nearest hospital, if you notice any of the following: Muscle spasms or twitches, significant bleeding or bruising, allergic reaction including swelling of limbs, face, lips, mouth or throat which may cause difficulty swallowing or breathing, sudden onset of prolonged muscular spasm, affecting the eyes, head, neck and body, sudden increase in body temperature, severe convulsions.

For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

LUVOX®

Active ingredient(s): *fluvoxamine maleate*

Consumer Medicine Information (CMI)

This leaflet provides important information about using LUVOX. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using LUVOX.**

Where to find information in this leaflet:

1. Why am I using LUVOX?
2. What should I know before I use LUVOX?
3. What if I am taking other medicines?
4. How do I use LUVOX?
5. What should I know while using LUVOX?
6. Are there any side effects?
7. Product details

1. Why am I using LUVOX?

LUVOX contains the active ingredient fluvoxamine.

LUVOX belongs to a family of medicines known as selective serotonin reuptake inhibitors (SSRIs) and is used for treatment of the conditions listed below, or your doctor may prescribe LUVOX for another reason.

LUVOX is used to treat depression.

LUVOX is used to treat depression in adults only. It is not recommended for treatment of this condition in children and adolescents as the safety and effectiveness of this medicine, when used for depression in this age group, have not been established.

Depression is longer lasting and/or more severe than the "low moods" everyone has from time to time due to the stress of everyday life. It can affect your whole body and can cause emotional and physical symptoms such as feeling low in spirit, loss of interest in activities, being unable to enjoy life, poor appetite or overeating, disturbed sleep, often waking up early, loss of sex drive, lack of energy and feeling guilty for no reason.

LUVOX is used to treat Obsessive compulsive disorder (OCD)

LUVOX is also used to treat a condition known as obsessive compulsive disorder (OCD) in adults and children eight years of age or older.

People with OCD can have two types of symptoms - obsessions and compulsions. Obsessions are unwanted repeated thoughts or feelings, which are ongoing. Compulsions are the need to repeat actions over and over. The symptoms of OCD can vary from patient to patient.

Both of these conditions are thought to be caused by a chemical imbalance in parts of the brain. LUVOX corrects this chemical imbalance and may help relieve the symptoms of depression and OCD.

Ask your doctor if you have any questions about why LUVOX has been prescribed for you.

Your doctor may have prescribed it for another purpose.

There is no evidence that this medicine is addictive.

LUVOX is only available with a doctor's prescription.

2. What should I know before I use LUVOX?

Warnings

Do not use LUVOX if:

- you are allergic to fluvoxamine maleate, or any of the ingredients listed at the end of this leaflet. Some of the symptoms of an allergic reaction may include:
  - shortness of breath
  - wheezing or difficulty breathing
  - swelling of the face, lips, tongue or other parts of the body
  - rash, itching or hives on the skin

  Always check the ingredients to make sure you can use this medicine.
- you are taking another antidepressant medicine called a monoamine oxidase inhibitor (MAOI) (e.g. moclobemide and selegiline) or have been taking it within the last 14 days. Taking LUVOX with these types of medicines may cause a serious reaction with a sudden increase in body temperature, extremely high blood pressure and severe convulsions.
- you are taking any of the following medicines:
  - pimozide
  - cisapride
  - tizanidine
  - ramelteon

  Ask your doctor or pharmacist if you are not sure if you have been taking one of these medicines.
- **the expiry date (EXP) printed on the pack has passed or the packaging is torn or shows signs of tampering.**

  If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Check with your doctor if you:

- are allergic to any other medicines, foods, dyes or preservatives
- had, or have any other medical conditions including:
  - bipolar disorder or mania
  - any other mental illness
  - liver problems
  - kidney problems
  - epilepsy or convulsive disorders
  - a history of bleeding disorders
  - diabetes
  - glaucoma, an eye condition
- take any medicines for any other condition

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Do not breast-feed if you are taking this medicine.

The active ingredient in LUVOX passes into breast milk and there is a possibility that your baby may be affected.

Your doctor can discuss with you the risks and benefits involved.

If you have not told your doctor about any of the above, tell him/her before you start taking LUVOX.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and LUVOX may interfere with each other. Some of these include:

- other medicines for the treatment of depression called monoamine oxidase inhibitors (MAOIs), such as moclobemide and selegiline. Taking LUVOX with or within 14 days of stopping a MAOI may cause a serious reaction with sudden increase in body temperature, extremely high blood pressure, and convulsions
- medicines used to treat depression, obsessive compulsive disorder, anxiety disorders, mood disorders, or other psychoses such as sertraline, amitriptyline, clomipramine, imipramine, clozapine, olanzapine, quetiapine, lithium, pimozide and haloperidol
- medicines used for strong pain management such as tramadol
- some benzodiazepine medicines such as alprazolam, triazolam, midazolam and diazepam
- medicines called NSAIDs used to relieve pain, swelling and inflammation including arthritis such as ibuprofen and diclofenac
- medicines used to help control epilepsy such as carbamazepine or phenytoin
- medicines used to treat migraine such as sumatriptan, zolmitriptan or eletriptan
- medicines used to help stop the blood from clotting such as warfarin, aspirin or clopidogrel
- cisapride, a medicine used to treat gastroesophageal reflux disease
- tizanidine, a medicine used as a muscle relaxant
- ramelteon, a medicine used to treat insomnia
- terfenadine and astemizole, medicines used to treat symptoms of allergic reaction
- phentermine, a medicine used to assist weight loss
- theophylline, a medicine used to treat breathing conditions such as asthma
- ciclosporin, a medicine used for immunosuppression
- methadone, a medicine used for opioid detoxification
- any herbal remedies that include St John's Wort or tryptophan
- opioid medicines such as buprenorphine or buprenorphine combined with naloxone for strong pain

There are many other medicines not listed here which could interfere with LUVOX and vice versa. Always tell your doctor or pharmacist that you are taking LUVOX before taking a new medication or complementary health product. These medicines may be affected by LUVOX or may affect how well it works. You may need to take different amounts of your medicine or you may need to take different medicines.

Some combinations of medicines (including herbal and other remedies) can interact with LUVOX and increase the risk of side effects, some of which can be potentially life-threatening.

Your doctor or pharmacist may have more information on medicines to avoid while taking LUVOX.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect LUVOX.

4. How do I use LUVOX?

Follow all directions given to you by your doctor or pharmacist carefully.

These directions may differ from the information contained in this leaflet.

If you do not understand the instructions on the box, ask your doctor or pharmacist for help.

How much to take

- Your doctor or pharmacist will tell you how many LUVOX tablets to take each day. These will be printed on the pharmacy label on the container.

To treat depression:

- Adults: The usual starting dose is 50 mg each day, but your doctor may adjust the number of tablets or the strength of the tablets you are taking until the desired response is achieved up to a maximum of 300 mg per day. If a daily dose of more than 150 mg is needed, the dose should be divided and taken 2 or 3 times per day.

To treat OCD:

- Adults: The usual starting dose is 50 mg each day, but your doctor may adjust the number of tablets or the strength of the tablets you are taking until the desired response is achieved up to a maximum of 300 mg per day. If a daily dose of more than 150 mg is needed, the dose should be divided and taken 2 or 3 times per day.
- Children & Adolescents: The usual starting dose is 25 mg each day. The doctor will probably adjust the dose until the desired response is achieved.

Follow the instructions provided and use LUVOX until your doctor tells you to stop.

When to take LUVOX

- LUVOX should be taken at the same time each day.

How to take it

- **Swallow the tablet with a full glass of water. Do not chew the tablets.**
- **Take LUVOX with or without food.**
- **If you have any concerns about how to take this medicine, ask your doctor or pharmacist.**

How long to take it

Even if you feel better, continue taking your medicine until your doctor tells you to stop.

- The length of treatment will depend on how quickly your symptoms improve. Most antidepressants take time to work, so don't be discouraged if you don't feel better right away. Some of your symptoms may improve in 1 or 2 weeks but it can take up to 4 or 6 weeks to feel any real improvement. Even when you feel well, you will usually have to take LUVOX for several months or even longer to make sure the benefits are maintained.
- In general, antidepressant medication should be continued for at least 6 months following recovery of a depressive episode.

This medicine should not be stopped abruptly (unless you develop a severe side effect to LUVOX (see Section 6. Are there any side effects**?)**

- If your LUVOX treatment needs to be stopped, your doctor or pharmacist will provide you with instructions to reduce the dose gradually over a period of at least one or two weeks.

If you forget to use LUVOX

LUVOX should be used regularly at the same time each day.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to. Otherwise, take it as soon as you remember, then go back to taking it as you would normally.

Do not take a double dose to make up for the dose you missed.

- If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

If you use too much LUVOX

If you think that you have used too much LUVOX, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (Australia telephone 13 11 26) for advice, or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention. The most common symptoms are nausea (feeling sick), vomiting and diarrhoea. You could also experience drowsiness and dizziness, rapid or irregular heartbeats, tremors or feel faint.

If possible, show the doctor the pack of tablets.

5. What should I know while using LUVOX?

Things you should do

- **If you are about to start or stop any medicine, including any that you buy without a prescription from your pharmacy, supermarket or health food shop, tell your doctor and pharmacist that you are taking LUVOX.**
- **Tell all doctors, dentists and pharmacists who are treating you that you are taking LUVOX.**
- **Tell your doctor if, for any reason, you have not taken your medicine exactly as prescribed.**

  Otherwise, your doctor may think that it was not effective and change your treatment unnecessarily.
- **Tell your doctor if you feel the tablets are not helping your condition.**
- **If you are being treated for depression, be sure to discuss with your doctor any problems you may have and how you feel, especially any feelings of severe sadness or bursts of unusual energy or anger.**

  This will help your doctor to determine the best treatment for you.
- **Tell your doctor immediately if you become pregnant while taking LUVOX.**
- **Be sure to keep all of your appointments with your doctor so that your progress can be checked.**

  Your doctor may want to take some blood tests and check your heart and blood pressure from time to time. This helps prevent unwanted side effects.
- Remind any doctor, dentist or pharmacist you visit that you are using LUVOX.

Things you should not do

- **Do not stop taking LUVOX, increase or lower the dose, without first checking with your doctor. Do not let yourself run out of medicine over the weekend or on holidays.**

  Suddenly stopping it may cause headache, nausea, dizziness and anxious feelings.
- **Do not give this medicine to anyone else, even if their symptoms seem similar to yours or if they have the same condition as you.**
- **Do not use LUVOX to treat any other complaints unless your doctor tells you to.**

Things to be careful of

Tell your doctor immediately if you have any suicidal thoughts or other mental/mood changes.

Care givers should consider all mentions of suicide or violence, which must be taken seriously.

Immediately contact your doctor or go to the nearest hospital for help if you or someone you know who are being treated for depression (or for any other condition) are demonstrating any of the warning signs of suicide.

Families and caregivers of children and adolescents who are taking LUVOX should be especially watchful of the warning signs associated with suicide listed below.

- The warning signs include:
  - Thoughts or talk of death or suicide
  - Thoughts or talk of self-harm or harm to others
  - Any recent attempts of self-harm
  - Mood changes such as an increase in aggressive or unusual behaviour, anxiety, irritability, agitation, panic attacks, insomnia, impulsivity, restlessness, or worsening of depressive symptoms.

Be especially careful of any suicidal thoughts or other mental/mood changes in the first few months of taking LUVOX or when the dose is changed.

There is a greater risk of suicide in people with history of suicidal thoughts prior to starting LUVOX, and in those aged less than 24 years, including those not being treated for depression.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how LUVOX affects you.

LUVOX may cause drowsiness, dizziness or sleepiness in some people and affect alertness.

Drinking alcohol

Tell your doctor if you drink alcohol.

You should avoid drinking alcohol while taking LUVOX.

Drinking caffeine

You should minimise your intake of caffeine-containing beverages (e.g. coffee or tea) while taking LUVOX.

LUVOX can increase the effects of caffeine. People having large amounts of caffeine whilst on LUVOX can experience tremor (shaking), palpitations (fast or irregular heart beat), nausea, restlessness and trouble or inability to sleep.

Older people may become confused when taking LUVOX. Families and carers should be aware of this. Special care may be needed.

You should be careful for 1 or 2 weeks after stopping this medicine, because it will still be in your blood stream.

Looking after your medicine

Follow the instructions in the carton on how to take care of your medicine properly.

Keep your tablets in their original pack until it is time to take them.

Keep the pack in a cool, dry place (below 25°C). Do not store LUVOX in the bathroom, near a sink or leave it in the car on hot days.

Heat and dampness can destroy some medicines.

Keep LUVOX where young children cannot reach it.

A locked cupboard at least one-and-a half metres above the ground is a good place to store medicines.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

Check with your doctor as soon as possible if you do not feel well while you are taking LUVOX, even if you do not think the problems are connected with the medicine or are not listed in this leaflet.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
• nausea, vomiting, stomach pain, constipation, diarrhoea, heart burn, loss of appetite, dry mouth • drowsiness, difficulty sleeping, dizziness, nervousness, feeling anxious, headache • muscle weakness, muscular pains, pins and needles • abnormal taste • faster heartbeat, sweating • weight gain, weight loss • restlessness, pacing, swinging of the legs while seated, rocking from foot to foot Side effects observed more frequently in children • abnormal thoughts or behaviour • cough • increased period pain • nose bleeds • increased restlessness • infection • sinusitis	**Speak to your doctor if you have any of these less serious side effects and they worry you.**

Serious side effects

Serious side effects	What to do
• Muscle spasms or twitches • Significant bleeding or bruising • Allergic reaction including swelling of limbs, face, lips, mouth or throat which may cause difficulty swallowing or breathing • Sudden onset of prolonged muscular spasm, affecting the eyes, head, neck and body • Sudden increase in body temperature, severe convulsions • Fast heartbeat, sweating, racing thoughts and restlessness • Severe blisters and bleeding in the lips, eyes, mouth, nose and genitals • Severe skin reaction with painful red areas, large blisters and peeling skin. This may be accompanied by fever and chills, aching muscles and generally feeling unwell.	**Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.**

Serious side effects	What to do
These are very serious, though rare, side effects.	

Tell your doctor if you notice anything else that is making you feel unwell including any suicidal thoughts or other mental/mood changes.

Other side effects not listed above may occur in some patients.

Ask your doctor or pharmacist to answer any questions you may have.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems . By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What LUVOX contains

Active ingredient (main ingredient)	LUVOX 50 mg tablets fluvoxamine maleate 50 mg LUVOX 100 mg tablets fluvoxamine maleate 100 mg
Other ingredients (inactive ingredients)	• mannitol • maize starch • pregelatinised potato starch • sodium stearyl fumarate • colloidal anhydrous silica • hypromellose • macrogol 6000 • purified talc • titanium dioxide
Potential allergens	N/A

Do not take this medicine if you are allergic to any of these ingredients.

What LUVOX looks like

LUVOX 50 mg tablets are round, biconvex, scored, white to off-white film coated tablets inscribed on one face with 291 on either side of the score line and other face plain. Packs of 30 tablets. (AUST R 57632).

LUVOX 100 mg tablets are oval, biconvex, scored, white to off-white film coated tablets inscribed on one face with 313 on either side of the score line and other face plain. Packs of 30 tablets. (AUST R 57633).

Who distributes LUVOX

Viatris Pty Ltd

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

www.viatris.com.au

Phone: 1800 274 276

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