

WHAT IS IN THIS LEAFLET

This leaflet answers some common questions about FluvoHEXAL. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist. Please read this entire leaflet carefully before you start to take your medicine. This medicine is for you. Never give it to other people even if their condition appears to be the same as yours. If you have any questions about this medicine ask your pharmacist. Keep this leaflet, you may need to read it again.

1. WHAT IS FluvoHEXAL USED FOR

Fluvohexal is used to treat:

- depression
- obsessive compulsive disorder (OCD).

Ask your doctor if you have any questions about why this medicine was prescribed for you. Your doctor may have prescribed it for another reason.

2. HOW FluvoHEXAL WORKS

Fluvoxamine belongs to a family of medicines known as selective serotonin reuptake inhibitors (SSRIs) which are thought to work by increasing the activity of a chemical called serotonin in the brain.

3. BEFORE YOU TAKE FluvoHEXAL

Fluvohexal should not be given to children and adolescent under 18 years of age unless under specific circumstances upon the advice from your doctor.

Do not take this medicine if

- You are hypersensitive to the active ingredient or any ingredients (e.g: lactose) in the formulation or any other similar medicines.
- You are taking monoamine oxidase inhibitors (MAOIs) such as selegiline.

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

Before you start taking this medicine

Tell your doctor if you:

- Have allergies to any other medicines, food, preservatives or dyes.
- Have or have had any medical conditions especially:
 - liver or kidney problems,
 - diabetes,
 - any psychological conditions
 - bleeding or coagulations (blood clotting) disorders
 - seizure.
- Are pregnant or breastfeeding or intend to become pregnant.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines you obtained without a prescription.

These medicines may be affected by Fluvohexal, or may affect how well it works. You may need different amount of your medicines, or you may need to take different medicines. Your doctor and pharmacist will have more information on medicines to be careful with or avoid.

Tell your doctor if you are taking the following:

- Tricyclic antidepressants, eg: clomipramine, imipramine and amitriptyline
- Antipsychotics or mood stabilizer, eg: clozapine, olanzapine, thioridazine, carbamazepine
- Benzodiazepines (tranquilizers), eg: triazolam, midazolam, alprazolam, diazepam
- Tacrine, ropinirol for Parkinson's disease
- Theophylline for asthma
- Methadone, used in drug addiction treatment
- Mexiletine, for irregular heart beat
- Propranolol, for high blood pressure
- Phenytoin, for epilepsy
- Astemizole, for allergic reactions

- Ciclosporin, an immunosuppressant commonly used during organ transplant
- Preparation that affects serotonin release like triptans (eg. sumatriptan) for migraine, tramadol for chronic pain, other SSRIs (drug of the same group).
- St. John's Wort preparations.
- Lithium, for bipolar disorder
- Oral anticoagulants such as warfarin
- alcohol
- Coffee or caffeine-containing preparation
- Digoxin, for heart failure

Pregnancy and lactation

Safety of fluvoxamine use during pregnancy is not established and is not recommended for women of childbearing age. If you are pregnant while taking this medicine, consult your doctor immediately. Fluvoxamine is excreted into breast milk and may affect your baby. Nursing is not recommended while you are using fluvoxamine.

4. HOW TO TAKE FluvoHEXAL

Take your medication exactly as directed by your doctor.

How much to take:

The usual dosage is 50mg to 100mg daily, taken once in the evening. Depending on your condition and response, your doctor may gradually increase the dose.

How to take:

Swallow the tablet with a glass of water. Do not chew.

When to take:

Single dose should be taken in the evening. Divided dose can be taken in the morning, afternoon and evening. If doses are not equal, the larger dose can be administered in the evening.

How long to take it

Continue taking your medicine for as long as your doctor tells you. Most

antidepressant takes time to work and is normally continued for a certain period of time after recovery from a depressive state. It is very important that you do not stop taking *Fluvohexal* suddenly.

If you forget to take it

Take your dose as soon as you remember, and continue to take it as you would normally. If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to. Do not take a double dose to make up for the dose that you missed.

If you are not sure what to do, ask your doctor or pharmacist.

If you take too much

If you or anyone else takes too many tablets, you tell your doctor and go to your nearest hospital emergency department immediately. Do this even if there are no signs of discomfort or poisoning. Take the carton or any remaining tablets you have with you.

Symptoms of an overdose may include nausea, vomiting, diarrhea, sleepiness, dizziness, rapid heart beat, slow heart beat, low blood pressure, liver function disturbances and convulsions.

5. WHILE YOU ARE USING *FluvoHEXAL*

Things you must do

- If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking *Fluvohexal*
- Tell any other doctors, dentists, and pharmacists who treat you that you are taking *Fluvohexal*.
- If you are going to have surgery, tell the surgeon or anaesthetist that you are taking *Fluvohexal*. It may affect other medicines used during surgery.
- Keep all of your doctor's appointments so that your progress can be checked.
- Tell your doctor if you become pregnant while taking *Fluvohexal*.

Things you must not do

- Do not give your medicine to anyone else, even if they have the same condition as you.
- Do not stop taking your medicine or lower the dosage without checking with your doctor.
- Do not take alcohol while using *Fluvohexal*.

Things to be careful of

- Be careful driving or operating machinery until you know how *Fluvohexal* affects you. This medicine may cause drowsiness in some people especially in higher doses. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

6. POSSIBLE SIDE EFFECTS

Like all medicines, *Fluvohexal* can cause side effects, although not everybody gets them. The following side effects may happen with this medicine:

Common:

- nausea
- loss of strength
- feeling sick
- abnormal heart beat
- rapid heart beat
- abdominal pain
- loss of appetite
- constipation
- diarrhea
- dry mouth
- indigestion
- agitation
- dizziness
- headache
- insomnia
- nervousness
- drowsiness
- tremor
- anxiety
- sweating

Others (uncommon and rare):

- sudden drop in blood pressure when changing position causing dizziness or fainting.
- joint pain
- muscle pain
- inability to control muscle movement

- confusion
- hallucinations
- sexual problems
- rash
- itchy
- swelling especially on the face, mouth, tongue
- liver functions abnormality
- convulsions
- mania (intense enthusiasm)
- inappropriate milk production not associated with childbirth
- sensitive to light
- restlessness
- weight gain or loss
- serotonin syndromes (e.g: palpitation, diarrhea, fast heart beat, loss of coordination, overactive reflexes)
- neuroleptic malignant syndrome (e.g: muscle rigidity, fever, delirium)
- electrolyte and hormonal disturbance
- prickling and burning sensation on the skin

Tell your doctor or pharmacist if you notice anything else that is making you feel unwell. Other side effects not listed above may also occur in some people.

7. HOW TO STORE *FluvoHEXAL*

Storage

Keep medicines in original packaging. Store in a cool (below 25°C), dry place, away from direct heat and light and excessive moisture. Do not leave your medicine in the car.

Keep all medicines out of the reach of children.

Disposal

Medicines should not be disposed of via household waste. Ask your doctor and pharmacist how to dispose of medicines.

8. PRODUCT DESCRIPTION

What *Fluvohexal* looks like and contents of the pack.

FluvoHEXAL 50 mg film-coated Tablet: White, biconvex, round tablet and scored.

FluvoHEXAL 100 mg film-coated

Tablet: White, biconvex, round tablet and scored.

Active ingredient:

FluvoHEXAL 50 mg film-coated Tablet:

Each tablet contains 50mg of fluvoxamine maleate.

FluvoHEXAL 100 mg film-coated

Tablet: Each tablet contains 100mg of fluvoxamine maleate.

Other ingredients: mannitol, maize starch, pregelatinised starch, sodium stearyl fumarate, colloidal silica, titanium dioxide, lactose, hypromellose, polyethyleneglycol

Packing: blisters of 10 tablets packed in 2 x 10's, 5 x 10's, 10 x 10's tablets per pack

Registration No:

FluvoHEXAL 50mg film-coated Tablet:
MAL09122033A

FluvoHEXAL 100mg film-coated Tablet:
MAL09122032A

**9. MARKETING AUTHORIZATION
HOLDER AND MANUFACTURER**

Manufactured by

Salutas Pharma GmbH
Otto-von-Guericke-Allee 1,
39179 Barleben, Germany

For

Hexal AG
Industriestraße 25,
83607 Holzkirchen,
Germany.

Marketing Authorization Holder

IMEKS Pharma Sdn. Bhd.

No. 1 & 2, Jalan 6/33B,
MWE Commercial Park,
52000 Kuala Lumpur, Malaysia

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