

SALIPAX™ CAPSULE

Fluoxetine (20 mg)

Consumer Medication Information Leaflet (RiMUP)

What is in this leaflet

1. What SALIPAX is used for
2. How SALIPAX works
3. Before you use SALIPAX
4. How to use SALIPAX
5. While you are using it
6. Side effects
7. Storage and Disposal of SALIPAX
8. Product description
9. Manufacturer and Product Registration Holder
10. Date of Revision

What SALIPAX is used for

SALIPAX is used to treat:

- Depression
- Obsessive Compulsive Disorder (OCD) (persistent, obsessive thoughts that make you carry out repetitive behaviour)
- Premenstrual Dysphoric Disorder (PMDD) (a severe form of premenstrual syndrome that affects the woman's daily activities and relationship with others before menstruation.)

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.

How SALIPAX works

Fluoxetine hydrochloride belongs to a group of medicine called Selective Serotonin Reuptake Inhibitors (SSRIs). SSRIs are thought to work by their action on brain chemicals, called amines, which are involved in controlling mood.

Before you use SALIPAX

- When you must not use it

Hypersensitive to active ingredient

Do not take SALIPAX if you are hypersensitive to the active ingredient or any ingredients in the

formulation (see section Product Description) or any other similar medicines.

Do not take SALIPAX if you are taking Monoamine Oxidase Inhibitor (MAOI), including the selective MAOI selegiline and the reversible MAOI (RIMA) moclobemide or have just stopped using it for less than 2 weeks. Similarly, do not start a new MAOI or RIMA if you have just stopped using SALIPAX for less than 5 weeks.

Taking SALIPAX with MAOIs may cause a serious reaction with features resembling "serotonin syndrome". (See section Side effect).

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

- Before you start use it

Ask your doctor or pharmacist for advice before taking any medicine.

Tell your doctor if you:

- are pregnant, trying to get pregnant or think you may be pregnant. Do not take SALIPAX whilst pregnant until you and your doctor have discussed the risks and benefits involved.
- are currently breast-feeding or you plan to breast-feed. SALIPAX passes into breast milk and may affect your baby. SALIPAX is not recommended for breast-feeding women.
- have allergies to any other medicines, food, preservatives or dyes.
- have any medical conditions, especially: liver or kidney problems, seizures (fits), any other psychiatry conditions, heart problems, diabetes, bleeding disorder.

- undergoing Electroconvulsive Therapy (ECT) (usually used for severe depression).
- a history of mania (uncontrollable excitement that causes unusual behaviour) or hypomania (a condition similar to mania but less severe).
- a history of suicide-related events.

- Taking other medicines

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

These medicines may be affected by SALIPAX, 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 have more information on medicines to be careful with or avoid while taking SALIPAX.

Tell your doctor if you are taking the following:

- monoamine oxidase inhibitors (MAOIs), e.g. selegiline (see also When you must not use it)
- other antidepressants such as imipramine and desipramine
- anticonvulsant or antiepileptic, e.g. carbamazepine and phenytoin
- antipsychotics, e.g. clozapine, haloperidol and zotepine
- benzodiazepines, e.g. diazepam and alprazolam
- tramadol for pain relief
- sumatriptan for migraine
- lithium, for bipolar disorder
- tryptophan, a type of amino acid
- flecainide, for irregular heart beat
- warfarin, to prevent blood clot formation
- alcohol
- St. John's Wort (a herbal medicine usually used for depression)

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How to use SALIPAX

- How much to use

Take your medication exactly as directed by your doctor. The usual dosage is one capsule daily. Depending on your condition, a higher dosage might be given by your doctor.

Depression:

The usual recommended dose is one capsule a day.

Obsessive compulsive disorder (OCD):

A dose range of one to three capsule/s a day.

Premenstrual dysphoric disorder (PMDD):

The recommended dose is one capsule a day.

Your doctor may increase or decrease your dose depending on your condition. For any condition, the daily dose should not exceed 80mg (four capsules).

- When to use it

Swallow the capsule with a glass of water. SALIPAX may be administered with or without food.

- How long to use it

Continue taking your medicine for as long as your doctor tells you. Most antidepressants take time to work. The duration of treatment depends on how quickly your symptoms improve.

It is very important that you do not stop taking SALIPAX suddenly.

- If you forget to use it

Take your doses as soon as you remember and continue to take it as 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 use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of SALIPAX. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention. Take the carton or any remaining capsules you have with you.

Symptoms of an overdose may include nausea, vomiting, seizures, restlessness and excitation.

While you are using it

- Things you must do

Take your medicine exactly as your doctor has told you.

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking SALIPAX.

Tell any other doctors, dentists and pharmacists who treat you that you are taking SALIPAX.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking SALIPAX. 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 immediately if you become pregnant while taking SALIPAX.

- Things you must not do

Do not stop taking the medicine unless advised by your doctor. Your doctor may want you to gradually reduce the amount of

SALIPAX you are taking before stopping completely. This should help reduce the chance of withdrawal symptoms such as dizziness, anxiety, headache, feeling sick or tingling or numbness of hand or feet.

Do not take any new medicines without consulting your doctor.

Do not give SALIPAX to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

Be careful driving or operating machinery until you know how SALIPAX affects you. SALIPAX may impair judgement or skills. Do not drive or operate machinery until you are certain that it is safe to do so.

Consuming alcohol while taking SALIPAX may worsen the symptoms of dizziness and drowsiness.

Side effects

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

- chills or fever
- diarrhea
- nausea, vomiting
- indigestion
- loss of appetite, change in taste
- dry mouth
- agitation
- short term memory loss
- sleep disorders
- change in personality
- euphoria (intense excitement)
- dizziness, drowsiness
- headache
- fatigue, weakness
- abnormal movement
- restlessness
- frequent or difficulty in urination
- sexual problems
- hair loss
- vision disturbances

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- joint or muscular pain
- sudden drop in blood pressure when changing position causing dizziness or fainting.

Inform your doctor immediately if you notice the following while taking this medication:

- features resembling serotonin syndrom such as hyperthermia (increase in body temperature), muscular hypertonia (increase in muscle tone leading to rigidity or stiffness), myoclonus (involuntary twitching of muscles), autonomous dysfunction (unstable blood circulation system with possible rapid fluctuations of vital signs such as body temperature, blood pressure, heart rate and breathing rate), disturbance of consciousness (confusion, delirium and coma).
- severe allergic reactions such as rashes and itchiness, swelling of the face, lips, tongue or limbs, or difficulties in breathing.
- seizure or increase frequency of seizures attack.
- psychological effects such as mania, suicidal thought, hallucination (hearing voices or seeing things which are not there), anxiety and confusion.
- weight loss.
- bleeding problems (easily bruise, blue-purple patch under 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.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website portal.bpfk.gov.my (Consumers→Reporting).

Storage and Disposal of SALIPAX

- Storage

Keep medicines in original packaging. Store dry below 30°C. Avoid from direct heat and light and excessive moisture. Do not leave your medicine in the car.

Keep all medicines out of the reach and sight of children.

- Disposal

Medicines should not be disposed of via household waste. Ask your doctor and pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- What it looks like

SALIPAX capsule: Hard gelatin capsule containing a white odourless powder.

Cap: Light-green opaque
Body: Ivory opaque

- Ingredients

- Active ingredient

Each capsule contains 20mg of Fluoxetine.

- Inactive ingredients

Lactose Monohydrate,
Microcrystalline Cellulose,
Magnesium Stearate, Colloidal Anhydrous Silica

Colouring agents of capsule:

Titanium dioxide (E171)
Yellow Iron Oxide (E172)
Quinoline Yellow (E104)
Indigo Carmine (E132)

- Packing

Blisters of 10 capsules packed in 3x10's capsules per box

- MAL number

MAL20061563A

Manufacturer

ACINO PHARMA AG
Dornacherstrasse 114
4147 Aesch Basel
Switzerland

Product Registration Holder

MEPHARM (MALAYSIA) SDN BHD
No.15, Jalan USJ 1/19
Taman Subang Permai
47600 Subang Jaya
Selangor.

Date of revision

15/07/2015

Serial Number

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