

# ASENTRA FC TABLETS

Sertraline (50 mg, 100 mg)

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## What *Aseotra* is used for

*Aseotra* is used to treat:

- Various forms and stages of depressive disorders, including those accompanied by anxiety.
- Obsessive-compulsive disorders (OCD) (Persistent, obsessive thoughts that make you carry out repetitive behavior)
- Panic disorders with or without agoraphobia (fear of public or open spaces)

## How *Aseotra* works

*Aseotra* contains the active ingredient sertraline. *Aseotra* belongs to a group of medicines called selective serotonin reuptake inhibitors (SSRIs) antidepressants. *Aseotra* blocks the reabsorption of serotonin by the nerve cells, thereby increasing the amount of serotonin in your brain. Serotonin is one of the chemicals in your brain which helps control your mood.

## Before you use *Aseotra*

### - When you must not use it

Do not take *Aseotra* if you have:

- Hypersensitivity to sertraline or any of the other ingredients of the *Aseotra* (see section Product description)
- Concurrent therapy with monoamine oxidase inhibitors (MAOIs)

Cases of serious reactions, sometimes fatal, have been reported in patients receiving sertraline in combination with a MAOI, including selegiline (used for Parkinson's disease and moclobemide (used for depression). Some cases presented with features resembling serotonin syndrome (see section Side effects).

Do not take sertraline until 14 days after stopping any MAOI, and do not take MAOIs until 14 days after stopping sertraline. Your doctor will know when it is safe to start sertraline after the MAOI has been stopped.

### - Before you start use it

### Pregnancy and lactation

Safety of use of sertraline during pregnancy and lactation has not been established. The drug is administered only in individual urgent cases when the anticipated benefit for the mother justifies the potential risk to the child.

Tell your doctor if you are currently pregnant, breast-feeding, or trying to get pregnant. Do not take *Aseotra* until you and your doctor have discussed the risks and benefits involved.

### - Taking other medicines

Before you start taking this medicine, tell your doctor if you have or have had any of the followings:

- Bipolar disorder (extreme mood swings ranging from episodes of depression to mania); episodes of mania (feeling elated or over-excited, which causes unusual behaviour) or hypomania (a condition similar to mania but less severe) may suddenly be activated during *Aseotra* therapy.
- Epilepsy or fits (you should avoid taking sertraline if your epilepsy is not properly controlled; if it is properly controlled your doctor will wish to watch you carefully if you take *Aseotra*).
- Heart problems.
- Liver problems.
- Kidney problems.
- Thoughts or actions relating to self-harm or suicide.
- Electroconvulsive therapy (ECT) (usually used for severe depression or other mental illness).

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

Tell your doctor if you are taking:

- MAOIs (see When you must not use it)
- CNS depressants and alcohol

- Medicines used to treat mental illness, such as lithium
- Medicines used to relieve anxiety, such as diazepam
- Medicines used to treat seizures (fits), such as phenytoin
- Medicines used to relieve migraine, such as sumatriptan
- Medicines used to treat diabetes, such as tolbutamide
- Blood-thinning medicines, such as warfarin

## How to use *Aseotra*

### - How much to use

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

### Depression

The usual dose of sertraline is 50 mg once daily. If the therapy is not effective, the daily dose may be gradually increased by 50 mg at intervals not shorter than 1 week, to maximum 200 mg daily.

### Obsessive-compulsive disorders

The initial dose is 50 mg sertraline once daily. The daily dose may be gradually increased by 50 mg at intervals not shorter than 1 week, to maximum 200 mg daily.

### Panic disorders

The initial dose is 25 mg sertraline once daily. After one week, the daily dose is increased to 50 mg sertraline once daily, and then it can be gradually increased by 50 mg at intervals not shorter than 1 week, to maximum 200 mg daily.

If you are using *Aseotra* for prevention of relapse or occurrence of new depressive episodes, your doctor may maintain you at the lowest still effective dose, which is occasionally adjusted with regard to the therapeutic response.

If you are having troubles with your liver, your doctor may prescribe a lower or less frequently administered dose.

No dosage adjustment is required in kidney insufficiency.

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No dosage adjustment is required in elderly.

- When to use it

Use as directed by your doctor or pharmacist.

*Aseotra* may be taken in the morning or in the evening, with food or an empty stomach.

- How long to use it

Continue taking *Aseotra* for as long as your doctor recommends.

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 week but it can take up to 2 to 4 weeks to feel any real improvement.

- If you forget to use it

Consult your doctor or pharmacist on what you should do if you forget to use it.

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

- 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 this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Taking too many tablets may cause nausea, vomiting, drowsiness, tachycardia (fast heartbeat), agitation, dizziness, excitement, diarrhea, excessive sweating, myoclonus (involuntary muscle twitch) and hyperreflexia (over responsive reflexes).

**While you are using it**

- Things you must do

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists that are treating you that you are taking *Aseotra*.

Tell your doctor immediately if you become pregnant while taking this medication.

Tell your doctor immediately if you have thoughts about harming or killing yourself.

- 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 *Aseotra* you are taking before stopping completely.

Do not take any new medicines without consulting your doctor.

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

- Things to be careful of

Driving and using machines

*Aseotra* may cause dizziness, drowsiness or impaired concentration in some people, especially those with concurrent intake of alcohol or medicines that affect brain activity.

Your ability to drive motor vehicles and operate machines should be evaluated by your doctor, by taking into account the severity of the underlying disease, response to the treatment and possible undesirable effects.

**Side effects**

Like all medicines, *Aseotra* can cause side effects, although not everybody gets them.

Visit your doctor or pharmacist immediately if you experience any side effects after taking this medicine.

Autonomic nervous system:

- dry mouth and increased sweating
- mydriasis (dilation of the pupil)
- priapism (persistent and often painful erection)

Central and peripheral nervous system:

- dizziness and tremor, coma, fits, headache, migraine
- movement disorders (including extrapyramidal symptoms such as hyperkinesia [an increase in muscular activity that can result in excessive abnormal movements, excessive normal movements, or a

combination of both], hypertonia [a condition marked by an abnormal increase in muscle tension and a reduced ability of a muscle to stretch], teeth grinding or gait abnormalities)

- involuntary muscle contractions, paresthesia (numbness) and hypoesthesia (a reduced sense of touch or sensation)

Also reported were signs and symptoms associated with a rare but potentially life threatening condition called serotonin syndrome: extremely high body temperature, rigid muscle, muscle twitching, autonomic instability with possible rapid fluctuations of vital signs, mental status changes that include confusion, irritability and extreme agitation progressing to delirium (sudden severe confusion) and coma.

Gastrointestinal:

- diarrhoea or loose stools, constipation
- dyspepsia (indigestion or heartburn), abdominal pain, appetite increased, nausea, vomiting
- pancreatitis (inflammation of the pancreas)

Reproductive:

- sexual dysfunction (principally ejaculatory delay in males)
- irregular menstruations

Body as whole:

- allergic reaction, allergy, anaphylactoid reaction (an acute fatal or potentially fatal hypersensitivity reaction)
- asthenia (weakness), fatigue, fever, hot flushes, malaise (a feeling of general discomfort or uneasiness)
- weight decrease and weight increase

Cardiovascular:

- swelling of tissue, swelling around the eyes
- chest pain, fast and/or hard heartbeat, hypertension, syncope

Endocrinological:

- galactorrhea (milky nipple discharge unrelated to the normal milk production of breast-feeding), enlargement of breast in men

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- hyperprolactinemia (a high level of prolactin, a hormone related to production of breastmilk)
- hypothyroidism (underactive of thyroid gland)
- syndrome of inappropriate ADH secretion (SIADH) (a condition which can result in lowered levels of electrolytes like sodium)
- itching and rash (including rare reports of serious scaling, peeling skin disorder: e.g. Stevens-Johnson syndrome and epidermal necrolysis) and urticaria (rash that might be triggered by an allergen)

## Hearing/vestibular/vision:

- tinnitus (hearing of sound when no external sound is present)
- abnormal vision

## Blood/haematopoietic:

- altered platelet function, low platelet count, abnormal bleeding (such as nosebleed, gastrointestinal bleeding or blood in the urine), purpura (bleeding underneath the skin which indicated by reddish-purple spot, which like a bruise)
- decrease in the number of white blood cells

Laboratory changes: abnormal clinical laboratory results

## Liver/gall bladder:

- serious liver events (including inflammation of the liver, jaundice [yellowing of skin and eyes] and liver failure)
- elevations in blood liver enzymes without symptoms

Metabolic/nutritional: low blood sodium level and increased blood cholesterol

Musculoskeletal: joint pain

## Psychiatric:

- restlessness, aggressive reactions, anxiety, depressive symptoms, euphoria (a feeling or state of intense excitement and happiness)
- hallucinations (sensations that appear real but are created by your mind)
- nightmare, mental disorder and yawning
- decreased sexual desire in male and female

Respiratory: Wheezing

## Skin:

- hair loss, rapid swelling, photosensitivity skin reaction

## Product Description

### - What it looks like

*Asentra 50 mg:* White, round, filmcoated tablets, bevel-edged, one side scored; diameter of cores is app. 8 mm, thickness: 3.3 – 3.9 mm.

*Asentra 100 mg:* white, round, filmcoated tablets, bevel-edged, one side scored; diameter of cores is app. 11 mm, thickness: 3.5 – 4.1 mm.

### - Ingredients

#### - Active ingredient

*Asentra 50 mg:* Each film-coated tablet contains 50 mg sertraline as sertraline hydrochloride.

*Asentra 100 mg:* Each film-coated tablet contains 100 mg sertraline as sertraline hydrochloride.

#### - Inactive ingredients

Tablet core:

- Hydrogen phosphate dihydrate
- microcrystalline cellulose
- sodium starch glycolate (type A)
- hydroxypropylcellulose
- talc
- magnesium stearate

Film coating:

- hypromellose
- titanium dioxide
- talc
- propylene glycol

### - MAL numbers:

Tablets 50 mg: MAL06061682AZ  
Tablets 100 mg: MAL06061683AZ

## Manufacturer

KRKA, d.d., Novo mesto, Šmarješka cesta 6, 8501 Novo mesto, Slovenia

## Product Registration Holder

Pahang Pharmacy Sdn. Bhd.  
Lot 5979, Jalan Teratai, 5 ½ Miles off Jalan Meru, Klang, Selangor, MALAYSIA.

## Date of revision

04/06/2015

## Serial Number

BPFK(R4/1)030615/00138

## Urinary:

- swelling in the face
- loss of bladder control and inability to empty the bladder completely

Other: symptoms following the discontinuation of sertraline (withdrawal symptoms) have been reported and including agitation, anxiety, dizziness, headache, nausea and numbness.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist. Other side effects not listed above may also occur in some people.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

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](http://portal.bpfk.gov.my) (Consumers →Reporting).

## Storage and Disposal of *Asentra*

### - Storage

Keep out of the reach and sight of children.

Do not store above 25 °C.

Do not use your medicine after the expiry date which is stated on the pack after 'EXP'. The expiry date refers to the last day of that month.

### - Disposal

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