

AKTIPROL TABLETS

Amisulpride 400mg

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What Aktiprol is used for

Aktiprol contains a medicine called amisulpride. This belongs to a group of medicines called 'antipsychotics'. This medicine is used to treat people with schizophrenia. Schizophrenia is a mental illness characterized by various mental and behavioral disorders, such as hallucinations or agitation.

How Aktiprol works

Aktiprol works by improving disturbed thoughts, feelings and behavior. It is used to treat schizophrenia when it starts and also over the long term.

Before you use Aktiprol

- When you must not use it

Do not take Aktiprol:

- if you are allergic to amisulpride or any of the other ingredients of this medicine (listed in *Product Description*);
- if you have breast cancer;
- if you have a growth in the pituitary gland;
- if you have a pheochromocytoma (excessive growth on the adrenal gland around the kidneys);
- in children below 18 years old;
- if you have a rare inherited heart disease manifested by slow heart rate and irregular heartbeats (QT prolongation syndrome)
- if you are taking other medicines. If this is the case, make sure that combined use with Aktiprol is not contraindicated.

- Before you start to use it

Talk to your doctor or pharmacist before taking Aktiprol, especially if:

- you have heart disease or family history of heart problems;
- you have kidney problems;

- you have epilepsy or Parkinson's disease;
- you have or are at a risk of having diabetes (e.g. being overweight or a family history of diabetes). Your doctor should check your blood sugar before you start taking Aktiprol and regularly during treatment.
- you or someone else in your family has a history of blood clots, as medicines like these have been associated with formation of blood clots;
- you or someone else in your family has a history of breast cancer;
- you are an elderly, particularly if you have dementia, because if the risk of a drop in blood pressure and of drowsiness; if you have kidney failure your doctor may reduce the dose;
- you have risk factors for stroke, which occurs when the blood flow is abruptly interrupted in part of the brain

Tell your doctor immediately:

- if you develop infection or fever as this medicine may have an effect on your blood cells, i.e. reduce the number of white blood cells;
- if you develop a high fever, muscle stiffness, impaired awareness and strong sweating; these can be fatal and require immediate medical attention.

Severe liver problems have been reported with amisulpride. Talk to your doctor immediately if you experience fatigue, loss of appetite, nausea, vomiting, abdominal pain or yellow discoloration of the eyes or skin.

Treatment with this medicine should not be suddenly stopped because this can cause a withdrawal syndrome. This is characterized by signs such as insomnia, nausea and vomiting. Abnormal movements may also be observed and psychotic disorders recur.

Pregnancy and lactation

Please consult your doctor or pharmacist if you are pregnant, planning for pregnancy or breast-feeding before using this medicine.

Pregnancy

Aktiprol is not recommended during pregnancy and in women of childbearing

potential not using effective contraception. If you use Aktiprol during the last three months of pregnancy, your baby may suffer from agitation, increased muscle tension, involuntary trembling of the body, sleepiness, breathing problems, or difficulty in feeding. Talk to your doctor, if your baby develops any of these symptoms.

Breast-feeding

You should not breast-feed during therapy with Aktiprol. Talk to your doctor about the best way to feed your baby if you are taking Aktiprol.

- Taking other medicines

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

In particular, do not take this medicine if you are on a treatment with:

- levodopa, a medicine to treat Parkinson's disease;
- medicines called dopamine agonists (e.g. bromocriptine, ropinirole);
- medicines for heart rhythm disturbances (for example amiodarone, sotalol, quinidine, disopyramide);
- other medicines such as bepridil, cisapride, sultopride, thioridazine, methadone, erythromycin IV, vincamin IV, halofantrine, pentamidine, sparfloxacin.

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

- medicines for high blood pressure (diltiazem, verapamil, beta blockers such as metoprolol);
- medicines for heart rhythm disturbances (digoxin);
- medicines used for migraines and hot flashes (clonidine);
- antidepressants (imipramine);
- medicines for arthritis or connective tissue diseases (for example corticosteroids, prednisolone);
- medicines used for constipation (sodium picosulfate, bisacodyl);
- pain-killers such as morphine, oxycodone, tramadol;
- medicines for epilepsy (phenobarbital);

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- antihistamines which make you sleepy;
- medicines used to treat fear and anxiety (benzodiazepines) and
- medicines to treat mental disorders (for example pimozide, haloperidol, lithium);
- certain types of diuretics;
- medicines which help you sleep during operation (anaesthetics);
- medicines to treat fungus infections given in your veins (amphotericin B);
- medicines for malaria (for example mefloquine);
- antipsychotic medication (clozapine);
- cough medication.

How to use Aktiprol

- 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.

The recommended dose is:

Adults

50-300 mg daily or 400-800 mg daily, depending on your symptoms. In individual cases, the daily dose may be increased up to 1200 mg/day.

Your doctor will adjust the dose according to your individual reaction.

Use in children and adolescents

Aktiprol should not be given to children before puberty.

The use of amisulpride from puberty to the age of 18 years is not recommended because of limited data.

Use in elderly

Your doctor may reduce the dose. You should follow the doctor's instructions.

Use in patients with hepatic insufficiency

A dosage reduction is not necessary.

Use in patients with kidney problems

Your doctor may reduce the dose. You should follow the doctor's instructions.

- When to use it

Use as directed by your doctor or pharmacist.

The amount of Aktiprol you take will depend on your illness. Follow your doctor's instructions carefully.

Swallow Aktiprol with plenty of water.

- How long to use it

Keep taking Aktiprol until your doctor tells you to stop.

If you suddenly stop the treatment, after high doses of amisulpride, nausea, vomiting and insomnia may occur. Reappearance of the symptoms that you are treated for and involuntary movement disorders may also occur.

- 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)

If you take more tablets than you should, contact your doctor or go to the Emergency Department of your nearest hospital straight away. Take the medicine pack with you. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Symptoms of overdose may include drowsiness, sleepiness, involuntary writhing movements, dizziness, fainting (due to low blood pressure) and coma.

While you are using it

- Things you must do

Tell all the doctors, dentists and pharmacists treating you that you are using Aktiprol.

If you are about to start on any new medicine, tell your doctor and pharmacist that you are taking Aktiprol

Taking Aktiprol may affect the results of some blood and urine tests. These include tests to measure the hormone called 'prolactin' and liver tests. If you are going to have a blood test, it is important to tell your doctor you are taking Aktiprol. Take Aktiprol only with a doctor's prescription.

- Things you must not do

Do not stop using the medicine unless advised by your doctor.

Do not use any new medicines without consulting your doctor or pharmacist.

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

Do not drink alcohol while you are taking Aktiprol. This is because it can affect the way the medicine works.

- Things to be careful of

Aktiprol contains lactose

Aktiprol contains lactose, a type of sugar. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

Driving and using machines

During treatment with this medicine, you may feel less alert, drowsy or sleepy and have blurred vision. If this happens, do not drive or use any tools or machines.

Side effects

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

Stop taking Aktiprol and visit your doctor or pharmacist immediately if you experience any side effects after using this medicine.

The following side effects are very common (may affect more than 1 in 10 people):

- Slow, involuntary movements, shaking of hands and head, rigid movements, stiffened facial expressions, muscle tension and producing more saliva than usual

The following side effects are common (may affect up to 1 in 10 people):

- Hyperprolactinaemia (too much prolactin, the hormone that induces milk production, in the blood), which may cause:
 - In women: abnormal production of breast milk, absence of menstrual period, breast pain
 - In men: erectile dysfunction, swelling of breast
- Insomnia, anxiety, restlessness, lack of sexual pleasure
- Stiff neck, oculogyric crises (cramps in eye muscles staring upwards), intense contraction of jaws
- Drowsiness
- Blurred vision
- Low blood pressure
- Weight gain
- Constipation, nausea, vomiting, dry mouth

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The following side effects are uncommon (may affect up to 1 in 100 people):

- Tendency to inflammation (infections), especially sore throat and fever due to changes in the blood (decrease in the number of white blood cells, agranulocytosis)
- Allergic reactions
- Frequent urination, thirst, fatigue due to high blood sugar (blood glucose).
- Increased risk of atherosclerosis due to high cholesterol and/or fat (triglycerides) levels in the blood.
- Confusion
- Seizure
- Slow pulse
- High blood pressure
- Stuffy nose (nasal congestion), pneumonia
- Increased risk of fractures due to osteopenia and osteoporosis. May develop into a serious side effect. Contact your doctor if you experience sudden pain in the back

The following side effects are rare (may affect up to 1 in 1000 people)

- Tumor in the pituitary gland (with symptoms like milk secretion and cessation of menstruation) due to elevated hormone (prolactin) levels in the blood. In men, breast enlargement and impotence
- Nausea, discomfort, muscle weakness and confusion due to low sodium in the blood (hyponatraemia), Syndrome of inappropriate secretion of antidiuretic hormone (SIADH).
- High temperature, muscle stiffness, severe sweating, confusion, drowsiness or agitation (neuroleptic malignant syndrome).
- Blood clots in the veins especially in the legs (symptoms include swelling, pain and redness in the legs), which may travel through blood vessels to the lungs causing chest pain and difficulty in breathing.
- Rash (hives) and swelling of face, lips and tongue

The following side effects may occur but their frequency is unknown:

- Withdrawal syndrome in newborns (see section "Pregnancy and breast-feeding").
- Restless legs syndrome (unpleasant feelings in the legs temporarily relieved by movement and the symptoms worsen at night)

- Increased skin sensitivity to sun and ultraviolet light.

Talk to your doctor or pharmacist if you experience:

- Increases in blood sugar level and/or symptoms of high blood sugar (e.g. increased thirst, increase hunger, and frequent urination)
- Unpleasant leg sensations and an intense urge to move the legs (restless legs syndrome)
- Difficulty or inability to pass urine (urinary retention)

Aktiprol may also cause side effects that you usually do not notice. These are changes in certain laboratory tests due to the effects of the blood, the liver and the heartbeat. The laboratory tests will be normal again when treatment ceases.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring visiting the website nptra.gov.my [Consumers→ Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of Aktiprol

- Storage

Keep out of the reach and sight of children

Do not use this medicine after the expiry date which is stated on the carton. The expiry date refers to the last day of that month

Store below 30°C in the original package

- 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.

Product Description

- What it looks like

Aktiprol 400mg tablets: White, biconvex, capsule shaped tablets, scored on both sides, with dimensions 19 x 10 mm. The score line is only to facilitate breaking for ease of swallowing and not to divide into equal doses.

The tablets are supplied in PVC/PVDC-Alu blisters packs containing 30, 60 and 100 tablets.

Not all pack sizes may be marketed.

- Ingredients

- Active ingredient

Aktiprol tablets contain 400mg of the active ingredient, amisulpride

- Inactive ingredients

The inactive ingredients in Aktiprol 400mg tablets are lactose monohydrate, sodium starch glycolate type A, hypromellose E5, cellulose microcrystalline PH-101, magnesium stearate

- MAL number(s):

Aktiprol 400mg Tablet
MAL24056073AZ

Manufacturer

Medochemie Ltd (Central Factory), 1-10, Constantinoupoleos street, 3011 Limassol, Cyprus

Product Registration Holder

Komedic Sdn Bhd, 4, Jalan PJS 11/14, Bandar Sunway, 46150 Petaling Jaya, Selangor

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