

AKTIPROL TABLETS

Amisulpride (100mg, 400mg)

What is in this leaflet

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

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*); This is because this medicine may have an effect on your blood cells, i.e. reduce the number of white blood cells. This problem can be seen in a blood test
- if you have a pheochromocytoma (excessive growth on the adrenal gland around the kidneys)
- in children under 15 years old
- if you have a prolactin-dependent tumor (prolactin is a hormone that stimulates milk production), e.g. breast cancer or pituitary disorders
- if you are taking other medicines. If this is the case, make sure that combined use with Aktiprol is not contraindicated.

Do not take this medicine if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking Aktiprol.

• Before you start to use it

Talk to your doctor or pharmacist before taking Aktiprol. Your doctor may ask you to have an electrocardiogram (ECG) before starting treatment. This medicine can cause heart rhythm disorders. This medicine should be used with caution in the following situations:

- you are an elderly, particularly if you have dementia, because of the risk of a drop in blood pressure and of drowsiness; if you have kidney failure your doctor may reduce the dose;
- if you have risk factors for stroke, which occurs when the blood flow is abruptly interrupted in part of the brain
- if 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
- if you have kidney problems (kidney failure), in which case your doctor may reduce the dose
- if you have epilepsy or Parkinson's disease
- if 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.
- If you have a history of hyperprolactinemia (too much prolactin in the blood) or a prolactin-dependent tumor (prolactin is a hormone that stimulates milk production), e.g. breast cancer or pituitary disorders. If this is the case, your doctor will have to monitor you closely during treatment

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

Stop treatment and tell your doctor immediately if you experience muscle rigidity or muscle loss associated with muscle pain (rhabdomyolysis), and if you have an increase in the level of the muscle enzyme creatine phosphokinase (CPK) in the blood and disturbances in consciousness accompanied by unexplained fever as this can have a potentially fatal outcome.

If you have visual disturbances or headaches during treatment, quickly talk to your doctor.

If you develop an infection or unexplained fever, your doctor may have you undergo a blood test immediately. This is because this medicine may have an effect on your blood cells, i.e. reduce the number of white blood cells. This problem can be seen in a blood test.

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:

- Sedative agents that can have additive depressant effects on the central nervous system and contribute to a decrease in alertness: Morphine derivatives (analgesics, cough

AKTIPROL TABLETS

Amisulpride 400mg

- suppressants and replacement therapies), neuroleptics, barbiturates, benzodiazepines, anxiolytics other than benzodiazepines (such as meprobamate), hypnotics, sedative antidepressants (amitriptyline, doxepin, mianserine, mirtazapine, trimipramine), sedative H1-antihistamines, centrally acting antihypertensives agents, baclofen and thalidomide.
- Drugs likely to induce torsades de pointes
 - Administered intravenously of dolasteron, erythromycin, spiramycin, and vincamine can cause arrhythmia. Using two torsadogenic drugs concomitantly is contraindicated.
 - Citalopram, escitalopram, domperidone, hydroxyzine and piperazine
 - Contraindicated combinations
 - Non-antiparkinsonian dopamine agonists excluding antiparkinsonians (cabergoline, quinagolide)
 - Citalopram, escitalopram, domperidone, hydroxyzine, piperazine, increase risk of ventricular arrhythmias, especially torsades de pointes
 - Inadvisable combinations
 - Antiparasitics (chloroquine, halofantrine, lumefantrine, pentamidine)
 - Antiparkinsonian dopamine agonist (amantadine, apomorphine, bromocriptine, entacapone, lisuride, pergolide, priribedil, pramipexole, rasagiline, ropinirole, selegiline)
 - Class IA antiarrhythmics (quinidine, hydroquinidine, disopyramide) and class III antiarrhythmics (amiodarone, dronedarone, sotalol, dofetilide, ibutilide), and other drugs such as arsenic compounds, diphemanil, dolasetron IV, erythromycin IV, levofloxacin, mequitazine, mizolastine, prucalopride, vincamine IV, moxifloxacin, spiramycin IV, toremifene, vandetanib.
 - Other neuroleptics (chlorpromazine, cyamemazine, droperidol, flupenthixol, fluphenazine, haloperidol, levomepromazine, pimozide, pipamperone, pipotiazine, sertindole, sulpiride, sultopride, tiapride, zuclopenthixol).
 - Alcohol consumption, levodopa, methadone, sodium oxybate, hydrochloroquine
 - Combinations requiring precautions for use
 - Anagrelide, Azithromycin, ciprofloxacin, clarithromycin, levofloxacin, norfloxacin, roxithromycin
 - Beta-blockers in patients with heart failure (bisoprolol, carvedilol, metoprolol, nebivolol)
 - Bradycardia agents (particularly class IA antiarrhythmics, beta-blockers, certain class III antiarrhythmics, certain calcium channel blockers, digitalis glycosides, pilocarpine, anticholinesterase agents)
 - Potassium-depleting agents (potassium-lowering diuretics, alone or in combination, stimulant laxatives)
 - Lithium, ondansetron
 - Combinations to be taken into consideration
 - Other sedative drugs, orlistat

How to use Aktiprol

• How much to use

Always take Aktiprol exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Do not stop the treatment of your own accord.

This medicine should be taken by mouth. Swallow the tablet(s) with a small amount of water.

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

Adults

The usual dose is between 50mg and 800mg each day. Your doctor may start you on a lower dose if necessary. If necessary, your doctor can prescribe up to 1200mg each day. Doses up to 400mg each day can be taken as a single dose. Take the dose at the same time each day. Doses above 400mg should be taken as half in the morning and half in the evening

Use in elderly

Your doctor will need to keep a close check on you as you are more likely to have low blood pressure or sleepiness due to this medicine

Use in patients with kidney problems

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

Use in children and adolescents

Aktiprol should not be given to children under 15 years of age. Use of this medicine is not recommended in children between 15 and 18 years of age.

• When to use it

Use as directed by your doctor or pharmacist.

Swallow the tablet whole with a drink of water. Do not chew your tablet.

If you feel the effect of your medicine is too weak or too strong, do not change the dose yourself, but ask your doctor

• How long to use it

Keep taking Aktiprol until your doctor tells you to stop. Do not stop taking Aktiprol just because you feel better. If you stop, your illness may get worse or come back. Unless your doctor tells you otherwise, Aktiprol should not be stopped suddenly.

Stopping treatment suddenly may cause withdrawal effects such as difficulty in sleeping or feeling very restless, muscle stiffness or unusual body movements and your original condition may come back.

• 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.

AKTIPROL TABLETS

Amisulpride 400mg

Symptoms of overdose may include drowsiness, sedation (a relaxing effect), a drop in blood pressure, extrapyramidal symptoms (particular trembling and muscle stiffness) or you may fall into a 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

If you have any further questions on the use of this product, ask your doctor or pharmacist.

• Things you must not do

Do not take more than the recommended dose unless your doctor tells you to. This can increase the risk of side effects.

Do not give this medicine to anyone else, even if they have the same condition as yours.

Do not use this medicine to treat any other complaints unless your doctor tells you to.

Do not drink alcohol while you are taking Aktiprol. This can increase the risk of side effects.

• Things to be careful of

Aktiprol contains lactose

This medicine contains a type of sugar (lactose) that is broken down into galactose and glucose. You should not use this medicine if you have galactose intolerance, Lapp lactase deficiency or glucose/galactose malabsorption syndrome (rare hereditary diseases).

If your doctor has told you that you have an intolerance to certain sugars, contact him/her before taking this medicine.

Driving and using machines

During treatment with this medicine, you may feel drowsiness and blurred vision. In such a case, do not drive or use machinery.

Side effects

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

If, during treatment, you develop muscle stiffness and consciousness disorders, along with an unexplained fever, stop treatment immediately and seek urgent medical attention.

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

- Trembling, muscle stiffness, cramps, abnormal movements, producing more saliva than usual

The following side effects are common (may affect up to 1 to 10 patients in 100):

- Stiff neck, oculogyric crises (abnormal movement of certain eye muscles), intense contraction of jaws
- Somnolence
- Insomnia, anxiety, agitation
- Constipation, nausea, vomiting, dry mouth
- Frigidity (lack of sexual pleasure in women)
- Hyperprolactinemia (too much prolactin, the hormone that induces milk production, in the blood), which may cause:
 - In women: absence of menstrual periods, abnormal production of breast milk, breast pain
 - In men: swelling of breasts, impotence (erection difficulties)
- Weight gain
- Low blood pressure (hypotension)
- Blurred vision

The following side effects are uncommon (may affect 1 to 10 patients in 1000):

- Involuntary movements of the tongue and/or face
- Seizures (involuntary contractions of one or more muscles)
- Hyperglycaemia (too much sugar in the blood)
- Hypertriglycaemia (too much fat (triglycerides) in the blood)
- Hypercholesterolaemia (too much cholesterol in the blood)
- Slow heartbeat
- Increases levels of certain liver enzymes, mainly transaminases
- Liver tissue injury
- Reduced bone density or change in bone structure (osteopenia, osteoporosis), weakening the bones
- Allergic reactions
- Confusion
- Stuffy nose

- Lung disorders (aspiration pneumonia) that may appear as inflammation, difficulty breathing, an infection, cough (mainly in combination with other drugs with a central nervous depressant effect)
- Increase in blood pressure
- Difficulty urinating
- Leukopenia, neutropenia

The following side effects are rare (may affect 1 to 10 patients in 10000)

- Agranulocytosis (a low level of white blood cells)
- Benign pituitary tumour, which may cause signs such as visual disturbances or headaches
- Drop in the amount of sodium in the blood (hyponatremia), syndrome of inappropriate antidiuretic hormone secretion
- Unexplained fever, along with general and neurological disorders
- Serious fainting (loss of consciousness), heart rhythm disorders possibly causing death
- Swelling, pain and redness of the legs. This is because blood clots in the veins (particularly in the legs) can move through blood vessels to reach the lungs, causing chest pain and difficulty breathing
- Sudden swelling of the face and/or neck that can lead to difficulty breathing and may be life-threatening (angioedema), red, itchy patches on the skin (hives).

The following side effects may occur but their frequency is not known:

- Withdrawal syndrome in newborns
- Restless legs syndrome (unpleasant feelings in the legs that is temporarily relieved by movement and the symptoms worsen at night)
- Increased skin sensitivity to sun and ultraviolet light.
- Falls due to loss of balance, which may involve fractures.
- Destruction of muscle fibres and muscle pain (rhabdomyolysis)
- Increase levels of creatine phosphokinase in the blood (blood test indicating muscle injuries).

Talk to your doctor or pharmacist if you experience:

AKTIPROL TABLETS

Amisulpride 400mg

- 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)
- Trouble breathing during sleep (sleep apnoea)
- Difficulty or inability to pass urine (urinary retention)

Tell your doctor or pharmacist if any of the side effects get serious or lasts longer than a few days, or if you notice any side effects not listed in this leaflet.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring visiting the website npa.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 100mg tablets: White, round, flat, tablets, with diameter 9.5 mm, embossed MC on one side

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.

- Ingredients

- Active ingredient

The tablets contain 100mg or 400mg of the active ingredients, Amisulpride

- Inactive ingredients

Aktiprol 100mg: Sodium starch glycolate (Type A), Hypomellose 2910, Microcrystalline cellulose PH101, Lactose Monohydrate

Aktiprol 400mg: Lactose monohydrate 230 mesh, Sodium starch glycolate type A, Hypomellose 2910 E5, Microcrystalline cellulose 101, Magnesium stearate

- MAL number(s):

Aktiprol 100mg Tablet

MAL*****AZ

Aktiprol 400mg Tablet

MAL24056073AZ

Manufacturer

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

Product Registration Holder

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

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