
PATIENT INFORMATION LEAFLET**SCHEDULING STATUS:** S5**AMPERI 5 mg/mL solution for injection****Haloperidol**

Sugar free.

Read all of this leaflet carefully before you start using AMPERI 5 mg/mL.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.

What is in this leaflet

1. What AMPERI 5 mg/mL is and what it is used for
2. What you need to know before you use AMPERI 5 mg/mL
3. How to use AMPERI 5 mg/mL
4. Possible side effects
5. How to store AMPERI 5 mg/mL
6. Contents of the pack and other information

1. What AMPERI 5 mg/mL is and what it is used for

AMPERI 5 mg/mL contains the active substance haloperidol.

Haloperidol belongs to a group of medicines called 'antipsychotics'.

AMPERI 5 mg/mL is used in adults for illnesses affecting the way you think, feel or behave. These include mental health problems (such as schizophrenia and bipolar disorder) and behavioural problems.

These illnesses may make you:

- Feel confused (delirium).

- See, hear, feel or smell things that are not there (hallucinations).
- Believe things that are not true (delusions).
- Feel unusually suspicious (paranoia).
- Feel excited, agitated, enthusiastic, impulsive or hyperactive.

AMPERI 5 mg/mL is used in children to treat:

- Explosive hyperexcitability and extreme hyperactivity in children (feeling aggressive, exaggerated changes in your child's mood, difficulty sustaining attention, impulsive behaviour and hyperactivity).
- Tourette's syndrome (repetitive movements or unwanted sounds (tics), such as repeatedly blinking the eyes, shrugging shoulders or blurting out offensive words).

AMPERI 5 mg/mL may be used on its own or with other medicine and is sometimes used when other medicines or treatments have not worked, caused unacceptable side effects, or cannot be taken by mouth.

2. What you need to know before you use AMPERI 5 mg/mL

AMPERI 5 mg/mL should not be administered to you or your child:

- If you are hypersensitive (allergic) to haloperidol or any of the other ingredients of AMPERI 5 mg/mL (see section 6).
- If you have Parkinson's disease.
- If you are less aware of things around you or your reactions become unusually slow.
- If you have bone-marrow suppression.
- If you have phaeochromocytoma (a rare tumour of the adrenal gland).
- If you have a type of dementia called 'Lewy body dementia'.
- If you have progressive supranuclear palsy (PSP) (brain disorder that causes serious problems with walking, balance and eye movements, and later with swallowing).
- If you have a heart condition called 'prolonged QT interval', or any other problem with your heart rhythm that shows as an abnormal tracing on an ECG (electrocardiogram).

- If you have heart failure or recently had a heart attack.
- If you have a low level of potassium in your blood, which has not been treated.

Warnings and precautions

AMPERI 5 mg/mL can cause problems with your heart, problems controlling body or limb movements and a serious side effect called 'neuroleptic malignant syndrome'. You must be aware of serious side effects while you are using AMPERI 5 mg/mL because you may need urgent medical treatment.

Elderly people and people with dementia

A small increase in deaths and strokes has been reported for elderly people with dementia who are taking antipsychotic medicines. Talk to your doctor before being given AMPERI 5 mg/mL if you are elderly, particularly if you have dementia.

Talk to your doctor if you or your child have:

- Breathing problems.
- Myasthenia gravis (a muscle disorder causing muscle weakness).
- Prostate problems (enlarged prostate in men).
- A slow heartbeat, heart disease or anyone in your close family has died suddenly of heart problems.
- Low blood pressure, or feel dizzy upon sitting up or standing up.
- A low level of potassium or magnesium (or other 'electrolyte') in your blood. Your doctor will decide how to treat this.
- Ever had bleeding in the brain, or your doctor has told you that you are more likely than other people to have a stroke.
- Closed-angle glaucoma (increased pressure in your eyes).
- Epilepsy or have ever had fits (convulsions).
- Problems with your kidneys, liver or thyroid gland.
- Tardive dyskinesia (uncontrollable twitching or jerking movements of the arms and legs)

- A high level of the hormone 'prolactin' in your blood, or cancer that may be caused by high prolactin levels (such as breast cancer).
- Diabetes (high blood sugar levels in your body).
- A history of blood clots, or someone else in your family has a history of blood clots.
- Depression, or you have bipolar disorder and start to feel depressed.

You may need to be more closely monitored, and the amount of AMPERI 5 mg/mL you are given may have to be altered.

If you are not sure if any of the above applies to you, talk to your doctor or nurse before you are given AMPERI 5 mg/mL.

Medical check ups

Your doctor may want to take an electrocardiogram (ECG) before or during your or your child's treatment with AMPERI 5 mg/mL. The ECG measures the electrical activity of your heart.

Blood tests

Your doctor may want to check the levels of potassium or magnesium (or other electrolytes) in your or your child's blood before or during your treatment with AMPERI 5 mg/mL.

Eye tests

Your doctor may want you or your child to take regular eye tests when you are on AMPERI 5 mg/mL treatment.

Sun exposure

Your doctor may want you or your child to avoid direct exposure to sunlight if you are on long-term AMPERI 5 mg/mL treatment. This is because AMPERI 5 mg/mL treatment may make your skin more sensitive to sunlight.

Children

Children will generally receive a lowered dose of AMPERI 5 mg/mL. Your doctor will adjust the

amount of AMPERI 5 mg/mL your child will receive.

Other medicines and AMPERI 5 mg/mL

Always tell your health care provider if you or your child are taking any other medicine. (This includes all complementary or traditional medicines.)

Tell your doctor if you or your child are currently using medicines for:

- Problems with your heartbeat (such as amiodarone, dofetilide, disopyramide, dronedarone, ibutilide, quinidine and sotalol).
- Depression (such as citalopram and escitalopram).
- Bacterial infections (such as azithromycin, clarithromycin, erythromycin, levofloxacin, moxifloxacin and telithromycin).
- Psychoses (such as fluphenazine, levomepromazine, perphenazine, pimozide, prochlorperazine, promazine, sertindole, thioridazine, trifluoperazine, triflupromazine and ziprasidone).
- Fungal infections (such as pentamidine).
- Malaria (such as halofantrine).
- Nausea and vomiting (such as dolasetron).
- Cancer (such as toremifene and vandetanib).

Also tell your doctor if you are taking bepridil (for chest pain or to lower blood pressure) or methadone (a pain killer or to treat drug addiction).

Special monitoring may be needed if you or your child are using lithium and AMPERI 5 mg/mL at the same time.

Tell your doctor straight away and stop taking both medicines if you or your child get:

- Fever you can't explain or movements you can't control.
- Confused, disoriented, a headache, balance problems and feel sleepy.

These are signs of a serious condition.

Certain medicines may affect the way that AMPERI 5 mg/mL works or may make heart problems more likely.

Tell your doctor if you or your child are taking:

- Alprazolam or buspirone (for anxiety).
- Duloxetine, fluoxetine, fluvoxamine, nefazodone, paroxetine, sertraline, St John's Wort (Hypericum, perforatum) or venlafaxine (for depression).
- Bupropion (for depression or to help you stop smoking).
- Carbamazepine, phenobarbital or phenytoin (for epilepsy).
- Rifampicin (for bacterial infections).
- Itraconazole, posaconazole or voriconazole (for fungal infections).
- Ketoconazole tablets (to treat Cushing's syndrome).
- Indinavir, ritonavir or saquinavir (for human immunodeficiency virus (HIV)).
- Chlorpromazine or promethazine (for nausea and vomiting).
- Verapamil (for blood pressure or heart problems).

Also tell your doctor if you or your child are taking any other medicines to lower blood pressure, such as water tablets (diuretics).

Your doctor may have to change your or your child's dose of AMPERI 5 mg/mL if you are taking any of these medicines.

AMPERI 5 mg/mL can affect the way the following types of medicine work:

Tell your doctor if you or your child are taking medicines for:

- Calming you down or helping you to sleep (hypnotics, sedatives).
- Pain (strong pain killers).
- Depression ('tricyclic antidepressants').
- Lowering blood pressure (such as guanethidine and methyldopa).
- Severe allergic reactions (adrenaline).
- Attention deficit hyperactivity disorder (ADHD) or narcolepsy (known as 'stimulants').
- Parkinson's disease (such as levodopa).

- Thinning the blood (phenindione).

Talk to your doctor or nurse before being given AMPERI 5 mg/mL if you are taking any of these medicines.

AMPERI 5 mg/mL with food, drink and alcohol:

Drinking alcohol while you are using AMPERI 5 mg/mL might make you feel sleepy and less alert. It is advisable to avoid alcohol while on treatment with AMPERI 5 mg/mL.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before you receive AMPERI 5 mg/mL.

Safety of AMPERI 5 mg/mL during pregnancy and breastfeeding has not been established.

Your doctor may advise you not to use AMPERI 5 mg/mL while you are pregnant.

The following problems may occur in newborn babies of mothers that use AMPERI 5 mg/mL in the last 3 months of their pregnancy (the last trimester):

- Muscle tremors, stiff or weak muscles.
- Being sleepy or agitated.
- Problems breathing or feeding.

The exact frequency of these problems is unknown. If you received AMPERI 5 mg/mL while you were pregnant and your baby develops any of these side effects, contact your doctor.

Talk to your doctor if you are breastfeeding or planning to breastfeed your baby. This is because small amounts of AMPERI 5 mg/mL may pass into your breastmilk and on to your baby.

AMPERI 5 mg/mL may increase your levels of a hormone called 'prolactin', which may affect fertility in men and women. Talk to your doctor if you have any questions about this.

Driving and using machines

AMPERI 5 mg/mL can affect your ability to drive and use tools or machines. Side effects, such as feeling sleepy, may affect your alertness, particularly when you first start using it or after a high dose. Do not drive or use any tools or machines without discussing this with your doctor first.

3. How to use AMPERI 5 mg/mL

You will not be expected to give yourself AMPERI 5 mg/mL. AMPERI 5 mg/mL will always be given to you by a doctor or health care provider who are trained to administer AMPERI 5 mg/mL.

AMPERI 5 mg/mL will be for intramuscular use and is given as an injection into a muscle.

Your doctor will decide how much AMPERI 5 mg/mL you or your child need and for how long. It may be some time before you feel the full effect of the medicine. Your doctor will normally give you or your child a low dose to start, and then adjust the dose to suit you.

If you have the impression that the effect of AMPERI 5 mg/mL is too strong or too weak, tell your doctor or pharmacist.

If you receive more AMPERI 5 mg/mL than you should:

Since a health care provider will administer AMPERI 5 mg/mL, he / she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

If you forget to use AMPERI 5 mg/mL

Since a health care provider will administer AMPERI 5 mg/mL, it is unlikely that the dose will be missed. In case of a missed dose, this should not be given on the same day as a scheduled dose.

If you stop using AMPERI 5 mg/mL

Unless your doctor decides otherwise, AMPERI 5 mg/mL will be stopped gradually. Stopping treatment with AMPERI 5 mg/mL suddenly may cause effects such as:

- nausea and vomiting;

- difficulty sleeping.

Always follow your doctor's instructions carefully.

4. Possible side effects

AMPERI 5 mg/mL can have side effects.

Not all side effects reported for AMPERI 5 mg/mL are included in this leaflet. Should your or your child's general health worsen or if you experience any untoward effects while you are receiving AMPERI 5 mg/mL, please consult your doctor, pharmacist or other health care provider for advice.

If any of the following happens, stop receiving AMPERI 5 mg/mL and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of your hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing.
- Rash or itching.
- Fainting.

These are all very serious side effects. If you or your child have them, you may have had a serious allergic reaction to AMPERI 5 mg/mL. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- signs of recurrent infections such as fever or sore throat;
- bleeding or bruising more easily than normal;
- problems controlling movements of your body or limbs (extrapyramidal disorder), such as movements of your mouth, tongue, jaw and sometimes limbs (tardive dyskinesia), feeling restless or difficulty sitting still, increased body movements, slow or reduced body movements, jerking or twisting movements, muscle tremors or stiffness, being unable to move, lack of normal facial expression;
- neuroleptic malignant syndrome (NMS) (a life-threatening reaction in response to your antipsychotic medication with symptoms such as a high fever, confusion, rigid muscles,

variable blood pressure, sweating and a fast heart rate);

- fits (seizures);
- changes in the way your heart beats (beating faster or slower);
- liver failure, yellowing of your skin and eyes, dark urine, and tiredness which may be symptoms of liver problems;
- erythema multiforme (painful blistering skin rash which is potentially life-threatening);
- small, raised, acne-like bumps (usually on your face, scalp, chest, and upper back);
- being unable to pass urine or empty your bladder completely;
- rhabdomyolysis (rapid breakdown of muscle tissue causing muscle pain, muscle weakness or difficulty moving your arms or legs, pain of your stomach area, dark coloured urine, nausea or vomiting, fever, rapid heart rate, confusion, lack of consciousness);
- blood clots in your veins, usually in your legs (deep vein thrombosis (DVT)). These symptoms have been reported in people taking antipsychotic medicines. The signs of a DVT in your leg include swelling, pain and redness in your leg, but the clot may move to your lungs causing chest pain and difficulty in breathing.

These are all serious side effects. You or your child may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- feeling agitated;
- difficulty falling or staying asleep (insomnia);
- serious mental health problems, such as believing things that are not true (delusions) or seeing, feeling, hearing or smelling things that are not there (hallucinations);
- upward movements of your eye that you cannot control, visual problems;
- sleepiness, dizziness;
- tremors (involuntary trembling or shaking of hands and feet);
- low blood pressure, dizziness or light-headedness when getting up from a lying or sitting position;

- increased saliva;
- abnormal liver function results when blood tests are being done;
- the inability to develop or maintain an erection;
- weight gain or loss.

Less frequent side effects:

- decreased number of red blood cells which can make the skin pale and cause weakness or breathlessness;
- high level of the hormone 'prolactin' in your blood when blood tests are done;
- lack/loss of appetite (anorexia);
- too low levels of sodium in your blood (weakness, tiredness, headache, nausea (feeling sick), vomiting (being sick), muscle cramps or spasms, confusion);
- too high or too low sugar (glucose) levels in your blood;
- sexual problems, decreased or increased sex drive (libido);
- feeling confused, restless, anxious or depressed;
- feeling sedated;
- muscle spasms, twitching or contractions that you cannot control, including a spasm in your neck causing your head to twist to one side;
- blurred vision, unusual widening, or excessive constriction of your pupils;
- high blood pressure;
- shortness of breath, narrowed airways in your lungs, causing difficulty breathing;
- brief spasm of your vocal cords, which may cause difficulty speaking or breathing;
- blocked nose;
- diarrhoea, indigestion, constipation, dry mouth, nausea (feeling sick), vomiting (being sick);
- increased sensitivity of your skin to the sun;
- itchy rash (hives);
- increased sweating;
- redness and peeling of your skin;
- skin pigmentation (with prolonged sun exposure);

- skin sensitivity at the injection site;
- hair loss;
- joint pain, feeling tired;
- difficulty or being unable to open your mouth (lockjaw);
- changes in menstrual cycle (periods), such as no periods, or long, heavy, painful periods;
- unexpected production of breast milk;
- breast discomfort, swelling or pain, breast enlargement in men;
- ejaculation problems in men;
- persistent and painful erection of the penis;
- problems walking;
- abnormally high body temperature.

Frequency unknown side effects:

- high level of ‘antidiuretic hormone’ in your blood (syndrome of inappropriate antidiuretic hormone secretion);
- swelling around your voice box which may cause difficulty speaking;
- inflamed small blood vessels, leading to a skin rash with small red or purple bumps;
- abnormally low body temperature.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects:

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the “**6.04 Adverse Drug Reaction Reporting Form**”, found online under SAHPRA’s publications: <https://www.sahpra.org.za/Publications/Index/8>.

By reporting side effects, you can help provide more information on the safety of AMPERI 5 mg/mL.

5. How to store AMPERI 5 mg/mL

- Store at or below 25 °C.
- AMPERI 5 mg/mL should be used immediately after opening.
- Keep in the original carton in order to protect from light.
- Store all medicines out of reach of children.
- Do not use after the expiry date printed on the label / carton.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

6. Contents of the pack and other information**What AMPERI 5 mg/mL contains**

Each 1 mL of solution contains 5 mg haloperidol.

The other ingredients are lactic acid and water for injections.

What AMPERI 5 mg/mL looks like and contents of the pack

AMPERI 5 mg/mL is a clear, colourless solution.

AMPERI 5 mg/mL is packed in 1 mL amber (USP Type I) ampoules.

Pack size: 5 or 10 ampoules.

Holder of the certificate of registration

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