Applicant: MC Pharma (Pty) Ltd
Product name: Inapsin
Dosage form: Solution for injection
Strength: 2,5 mg/ml

06 March 2025

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S5

INAPSIN® 2,5 mg/ml injection

Droperidol

Read all of this leaflet carefully before you are given INAPSIN® 2,5 mg/ml injection

- 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 INAPSIN® is and what it is used for
2. What you need to know before you use INAPSIN®
3. How to use INAPSIN®
4. Possible side effects
5. How to store INAPSIN®
6. Contents of the pack and other information

1 What INAPSIN® 2,5 mg/ml injection is and what it is used for

Provided certain precautions are taken, INAPSIN® 2,5 mg/ml injection is indicated for the

reduction in the incidence of nausea and vomiting associated with surgical and diagnostic procedures in patients for whom other treatments are ineffective or inappropriate.

2 What you need to know before you use INAPSIN® 2,5 mg/ml injection

INAPSIN 2,5 mg/ml injection should not be administered to you:

- if you are hypersensitive (allergic) to Droperidol or any of the ingredients in INAPSIN® (listed in Section 6).
- If you are severely depressed
- If you have Parkinson's disease
- If you are comatose, or
- if you have a known hypersensitivity to the medicine or its metabolites.
- If anyone in your family have an abnormal electrocardiogram (ECG) heart tracing.
- If you have low levels of potassium or magnesium in your blood
- If you have a pulse rate of less than 55 beats per minute (the doctor or nurse will check this) or are taking any medicines that could cause this to happen.
- Safety in children under 2 years has not been established.
- INAPSIN® is not recommended for any use other than for the treatment of post-operative nausea and vomiting in patients for whom other treatments are ineffective or inappropriate.

Warnings and precautions

Tell your doctor or health care provider before being given the injection:

Special care should be taken with INAPSIN®:

- if you have problems with the working of your liver and kidney,
- if you have been diagnosed or suspect that you might have pheochromocytoma (a benign tumor of the adrenal gland associated with sudden, repeated attacks of high blood pressure causing heart palpitations, sweating and headache,
- if you have any risk factors for cardiac arrhythmia such as a history of significant cardiac disease, family history of sudden death, renal failure, significant chronic obstructive pulmonary disease, respiratory disease and risk factors for electrolyte disturbances),
- if you are receiving lithium or, anti-psychotic medications,
- if you are experiencing Tardive dyskinesia, characterised by rhythmical involuntary movements of the tongue, face mouth or jaw, or
- If you are experiencing the inability to move your muscles or if you have an abnormally high body temperature.

Children and adolescents

Do not give INAPSIN® to children under the age of two (2) years. Safe use in children under the age of two (2) years has not been established.

Other medicines and INAPSIN® 2,5 mg/ml injection

Always tell your healthcare provider if you are taking any other medicine.

- Concomitant use with metoclopramide and other neuroleptics may induce extrapyramidal symptoms, therefore should be avoided.
- Medicines known to prolong the QT interval are contraindicated. Examples include certain antiarrhythmics, such as those of Class A (such as quinidine, disopyramide and

procainamide) and Class III (such as amiodarone and sotalol); tricyclic antidepressants (such as amitriptyline); certain tetracyclic antidepressants (such as maprotiline); certain antipsychotic medications (such as phenothiazines, haloperidol, risperidone, pimozide and sertindole); certain antihistamines (such as astemizole and terfenadine); cisapride, bepridil, halofantrine and sparfloxacin. Please note that this list is not exhaustive.

- INAPSIN® may potentiate the action of sedative drugs medicines (barbiturates, benzodiazepines, morphinomimetics). The same applies to antihypertensive medicines eg. methyldopa, so that orthostatic hypotension may ensue.
- INAPSIN® may potentiate respiratory depression caused by opioids.
- INAPSIN® must be administered in reduced dosage (as low as ½ the dosage usually recommended) when other central nervous system depressants are prescribed concomitantly to avoid the possibility of potentiation.
- Since INAPSIN® blocks dopamine receptors, it may inhibit the action of dopamine agonists, such as bromocriptine, lisuride and of l-dopa. The dosage of anti-convulsants may need to be increased to take account of the lowered seizure threshold.
- Theoretically, certain medicines (eg. phenobarbital, carbamazepine, phenytoin), as well as smoking and alcohol consumption, which may stimulate metabolising enzymes in the liver, may enhance the metabolic breakdown of neuroleptics, possibly necessitating adjustment of the dose.

INAPSIN® 2,5 mg/ml injection with food and alcohol

Avoid drinking any alcohol for 24 hours before and after being given Droperidol.

Pregnancy, breastfeeding and fertility:

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please let your doctor, know. before taking this medicine.

Safety in pregnancy has not been established.

No fertility data is available.

Driving and using machines:

Patients should only drive or operate machinery if sufficient time after 24 hours has elapsed after the administration of INAPSIN® 2,5 mg/ml injection as sedation and impairment of alertness may occur particularly with higher doses and at the start of treatment and may be potentiated by alcohol.

3 How you will be given INAPSIN® 2,5 mg/ml injection

INAPSIN® will be administered to you by intramuscular or intravenous injection.

You will not be expected to give yourself INAPSIN®. It will be given to you by a person who is qualified to do so.

The dosage will be adapted to each individual case. Your doctor will consider your age, body weight, the use of other ~~drugs~~ medicines, the type of anesthesia to be used and the surgical or diagnostic procedure involved before administering INAPSIN® 2,5 mg/ml injection to you.

The usual adult dosage is 0.625 to 1.25 mg, reduced to 0.625 mg for the elderly (over 65 years) and those with renal and kidney impairment.

The dosage in children (2 to 11 years) and adolescents (12 to 18 years) is

based on their body weight (10 to 50 microgram/kg) but up to a maximum of 1.25 mg.

INAPSIN® 2,5 mg/ml injection is not recommended in children below 2 years.

If you have any further questions on the use of this medicine, please ask your doctor or nurse.

You will not be expected to give yourself INAPSIN® 2,5 mg/ml injection. It will be given to you by a person who is qualified to do so.

If you are given more INAPSIN than the recommended dosage:

Since a healthcare provider will administer INAPSIN®, he/she will control the dosage.

However, in the event of overdosage, your doctor will manage the overdosage.

If you forget to use INAPSIN®

Since a healthcare provider will administer INAPSIN®, it is unlikely that the dose will be missed.

4 Possible side effects:

INAPSIN® can have side effects.

Not all side effects reported for **INAPSIN®** are included in this leaflet. Should your general health worsen or if you experience any untoward effects after administration of this medicine, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, tell your doctor, nurse or pharmacist immediately.

- Swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing,

- Rash,
- Dizziness or fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to INAPSIN®. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Common side effects:

- Drowsiness,
- Hypotension (low blood pressure).

Uncommon side effects:

- Anxiety
- Rolling of the eyes
- Fast heartbeat e.g. more than 100 beats per minute
- Dizziness

Rare side effects (likely to affect less than 1 in 1,000 people and more than 1 in 10,000).

Serious allergic reaction known as anaphylaxis or anaphylactic shock

Torsade de pointes (life-threatening irregular heartbeat). Prolonged QT interval in ECG (a heart condition affecting the heartbeat)

Confusion

Agitation

Irregular heartbeat

Rash

Neuroleptic malignant syndrome, symptoms include fever, sweating, salivation, muscle stiffness and tremors.

Very Rare side effects (likely to affect less than 1 in 10,000 people)

Blood disorders (usually diseases affecting red blood cells or platelets). Your doctor can advise you.

Change in mood towards sadness, anxiety, depression and irritability

Heart attack (cardiac arrest)

Sudden death

Not known (other side effects which may occur are):

Inappropriate anti-diuretic hormone secretion (too much of the hormone is released leading to excess water and low sodium levels in the body)

Hallucinations

Epileptic seizures

Parkinson’s disease

Psychomotor hyperactivity

Coma

Fainting

Breathing difficulties

Blood clots in the veins especially in the legs (symptoms include swelling, pain and redness in the leg), which may travel through blood vessels to the lungs causing chest pain and difficulty in breathing.

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 nurse. You can also report side effects to SAHPRA via the "6.04 Adverse Drug 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 INAPSIN®.

5 How to store INAPSIN®:

Store all medicines out of reach of children.

Store at or below 25 °C. Protect from light.

Do not use after the expiry date stated on the label and carton.

6 Contents of the pack and other information

What INAPSIN® contains:

The active substance is droperidol.

Excipient with known effect: sodium < 23 mg per ml

The other ingredients are, D-Mannitol, dihydroxy-butanedoic acid and Water for injection.

What INAPSIN® looks like and contents of the pack

INAPSIN injection is supplied in 2 ml brown glass ampoules, packed in boxes of 5, 10 and 30 ampoules.

INAPSIN is a clear, colourless solution in 2 ml glass ampoules.

06 March 2025

Holder of Certificate of Registration

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This leaflet was revised in

06 March 2025

REGISTRATION NUMBER:

B/2.6.5/1012