

Applicant/PHCR: Innovata Pharmaceuticals (Pty) Ltd

Product Proprietary Name: INNOSPECT PEADIATRIC

Dosage Form & Strength: Syrup : Each 5 ml contains Triprolidine hydrochloride 0.6 mg,
Pseudoephedrine hydrochloride 12.0 mg, Codeine Phosphate 3.0 mg, Guaiphenesin 50,0 mg

PROPOSED PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S2

INNOSPECT PEADIATRIC

Each 5 mL contains:

Triprolidine hydrochloride: 0,60 mg

Pseudoephedrine hydrochloride: 12,00 mg

Codeine Phosphate: 3,00 mg

Guaiphenesin: 50,00 mg

Contains sugar: Glucose liquid: 250 mg, sucrose: 1,325 mg, Glycerol: 0,250 ml.

Read all of this leaflet carefully because it contains important information for you

INNOSPECT is available without a doctor's prescription, for you to treat a mild illness.

Nevertheless, you still need to use INNOSPECT carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share INNOSPECT with any other person.
- Ask your healthcare provider or pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve after 5 days.

What is in this leaflet

1. What **INNOSPECT** is and what it is used for
2. What you need to know before you take/use **INNOSPECT**
3. How to take **INNOSPECT**

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4. Possible side effects

5 How to store **INNOSPECT**

6. Contents of the pack and other information.

1. What INNOSPECT is and what is it used for:

INNOSPECT contains the active substances triprolidine hydrochloride; pseudoephedrine hydrochloride; guaiphenesin; codeine phosphate.

INNOSPECT is used for the relief of a cough.

2. What you need to know before you take INNOSPECT:

Do not take/give INNOSPECT:

- If you or your child are hypersensitive (allergic) to triprolidine hydrochloride, pseudoephedrine hydrochloride, guaiphenesin, codeine phosphate or any of the other ingredients of INNOSPECT (listed in section 6).
- To a child under the age of two years.
- If you or your child have taken medicines for depression (monoamine oxidase inhibitors) within the last two weeks.
- If you or your child have taken beta-blockers.
- If you or your child have taken nasal decongestants including sprays.
- If you or your child have heart disease.
- If you or your child have circulation problems
- If you or your child have severe or uncontrolled high blood pressure.
- If you have severe or chronic kidney disease/failure
- If you are pregnant or breastfeeding.

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- If you or your child have diabetes (high sugar levels in blood).
- If you or your child have an overactive thyroid gland.
- If you or your child have glaucoma (raised pressure inside the eye ball).
- If you or your child have phaeochromocytoma (tumour of the adrenal gland).
- If you or your child have a condition called porphyria.
- If you or your child have difficulty breathing, or any other chronic lung disease.
- If you are an alcoholic.
- If you or your child suffered a head injury or raised pressure in the skull (may cause painful eyes, changes in vision or headache behind the eyes).
- If you or your child have bowel disorders.
- If you or your child are younger than 18 years and had your tonsils or adenoids removed for obstructive sleep apnoea syndrome.
- If you or your child are 12 to 18 years old and have problems with breathing.
- If your doctor has informed you that you or your child are a rapid metaboliser of codeine into morphine or if you have CYP2D6 enzyme deficiency.
- If you or your child have liver problems.

Warnings and precautions

Take special care with INNOSPECT:

Exceeding the prescribed dose, together with prolonged and continuous use of INNOSPECT, may lead to dependency and addiction.

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- INNOSPECT may lead to drowsiness and a decrease in concentration. You should avoid alcohol and other medicines that depress the central nervous system. You should not drive, use machinery or perform any tasks that require concentration, until you are certain that INNOSPECT does not adversely affect your ability to do so (see Driving and using machinery).
- If you have an enlarged prostate or urinary retention (inability to completely empty the bladder).
- If you have an obstruction in your stomach or gut (for example, because of an ulcer).
- If you have epilepsy.
- If you are elderly as you are more likely to experience side effects.
- If you are taking medicines that may affect your hearing.
- If you are taking INNOSPECT and you experience the following, stop using INNOSPECT:
 - Hallucinations (seeing something that is not present).
 - Restlessness.
 - Sleep disturbances.
- If you suffer from a persistent cough such as that which occurs with smoking, asthma (a chronic disease of the lungs and airways), emphysema (a lung disease that makes it hard to breathe) or where cough is accompanied by excessive mucus or phlegm.

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- A persistent cough may be a sign of a serious condition. If your cough persists for more than one week, returns often or is accompanied by a high fever, rash or persistent headache, contact your doctor or pharmacist immediately.
- Do not take INNOSPECT for longer than directed by your healthcare provider as prolonged and continuous use of codeine may lead to dependency and addiction.
- If you suffer from any of the following conditions:
 - diseased adrenal glands;
 - an underactive thyroid gland;
 - muscle weakness (myasthenia gravis);
 - low blood pressure or are in shock;
 - alcoholism, drug abuse or dependence or mental illness.

Children

INNOSPECT should not be given to children younger than 2 years.

Other medicines and INNOSPECT:

Always tell your healthcare provider if you are taking any other medicine (this includes complementary or traditional medicines).

It is especially important to tell your doctor if you are taking any of the following:

- Alcohol and medicines that depress the central nervous system such as pain killers, tranquilisers and medicines to help you sleep.
- Antibacterials e.g. furazolidone: medicine used to treat bacterial infections.

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- Monoamine oxidase inhibitors (MAOIs) (e.g. moclobemide, selegiline): medicines used to treat depression.
- Anticholinergics (e.g. atropine and amitriptyline): medicines which are used as premedication before operations and to treat depression.
- Certain antibiotics such as gentamicin.
- Allergen tests: INNOSPECT should be stopped several days before testing.
- Anticonvulsants e.g. phenytoin: medicines used to treat epilepsy.
- Oral steroid contraceptives: medicine used to prevent pregnancy.
- Medicines to reduce your appetite.
- Medicines which stimulate the nervous system, e.g. amphetamines
- Medicines which lower your blood pressure.
- Medicines for mental illness.
- Beta blockers: medicines for a heart condition.
- Cardiac glycosides (digoxin): medicine for the heart.
- Anaesthetics (cyclopropane, halothane): medicine used during an operation to make you sleep.
- Ergotamine and methysergide: medicines used to treat migraines.
- Kaolin: medicine used to treat diarrhoea.
- Doxapram: medicine used to treat breathing problems.
- Oxytocin: medicine used during labour.
- Aluminium hydroxide: medicine used as an antacid.
- Medicines to treat allergies (antihistamines) that can cause drowsiness.

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- Antipsychotics (e.g. haloperidol, aripiprazole): medicines used to treat psychotic disorders.
- Hypnotics and anxiolytics (e.g. chlorpromazine, diazepam, temazepam): medicines which affect the nervous system.
- Cisapride, metoclopramide and domperidone: medicines used to treat nausea (feeling or being sick) and vomiting.
- Quinidine and mexiletine: medicines used to treat irregular heartbeats.
- Cimetidine: medicine used to treat stomach ulcers and indigestion.

Please advise your doctor or healthcare provider before you undergo any urine tests as INNOSPECT may affect the results of these tests.

Pregnancy, breastfeeding, and fertility.

You should not take INNOSPECT if you are pregnant or breastfeeding your baby.

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 healthcare provider for advice before taking INNOSPECT.

Driving and using machines:

Since adverse reactions such as dizziness, drowsiness and blurred vision have been reported in patients receiving INNOSPECT, you should not drive, use machinery or perform any tasks that require concentration, until you are certain that INNOSPECT does not adversely affect your ability to do so (see Possible side effects).

It is not always possible to predict to what extent INNOSPECT may interfere with the daily activities of a patient. Patients should ensure that they do not engage

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in the above activities until they are aware of the measure to which INNOSPECT affects them.

INNOSPECT contains glucose, sucrose, and sorbitol. INNOSPECT contains glucose and sucrose which may have an effect on the glycaemic control of patients with diabetes mellitus.

INNOSPECT contains sorbitol and may cause gastrointestinal discomfort and mild laxative effect.

3. How to take INNOSPECT

Do not share medicines prescribed for you with any other person. Always take INNOSPECT exactly as described in this leaflet or as your doctor, pharmacist or nurse has told you. Check with your doctor, pharmacist or nurse if you are not sure.

The usual dose of INNOSPECT is:

Children:

6 to 12 years: Take 5 ml to 10 ml three times a day.

2 to 5 years: Take 2,5 ml to 5 ml three times a day. If you have the impression that the effect of INNOSPECT is too strong or too weak, tell your doctor or pharmacist.

If you take more INNOSPECT than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you forget to take INNOSPECT

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Take your missed dose as soon as you remember, if within a few hours after missing a dose. Do not take a double dose to make up for forgotten individual doses.

4. Possible side effects

INNOSPECT can have side effects.

Not all side-effects reported for INNOSPECT are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking INNOSPECT, please consult your health care provider for advice.

If any of the following happens, stop taking INNOSPECT and tell your doctor immediately or go to the casualty department at your nearest hospital:

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

These are very serious side effects. If you have them, you may have had a serious reaction to INNOSPECT. 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:

- Seizures (fits),
- changes in the way your heart beats, for example, if you notice it beating faster,
- difficulty or pain in passing urine,
- trembling, shaking, irregular heartbeats (palpitations),
- increased pressure within your head (raised intracranial pressure).

These are serious side effects. You may need urgent medical attention.

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Tell your doctor if you notice any of the following

Frequent side effects:

- Drowsiness, unsteadiness, dizziness, lack of energy (lassitude), slowing down of thought and movement (psychomotor impairment), headache,
- blurred vision,
- thickening of airway mucous,
- dry mouth, constipation, stomach acid coming up from the stomach into the oesophagus (gastric reflux), inability to completely empty the bladder.

Less frequent side effects:

- Changes in the number and types of your blood cells,
- nausea, vomiting, diarrhoea, stomach pain,
- mental disorders (psychotic disorders) due to misuse,
- dizziness,
- skin rash with red, itchy bumps (urticaria).

Side effects of unknown frequency:

- Cross sensitivity to related medicines,
- confusion,
- increased energy, restlessness, nervousness especially in the elderly and in children,
- sleep disturbances, depression,

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- pins and needles (paraesthesia), shaking movements (extrapyramidal effects which include tremor), slurred speech, agitation and involuntary muscle movements
- ringing in the ears (tinnitus),
- decreased blood pressure (hypotension)
- decreased appetite (anorexia),
- sweating, hair loss,
- muscle pain (myalgia),
- seeing or hearing things that are not real (hallucinations),
- problem sleeping (insomnia), feeling worried (anxiety), irritability, excitability,
- restlessness, headache,
- raised pressure in the eyeball (angle-closure glaucoma),
- high blood pressure,
- poor circulation to hands and feet,
- dry mouth,
- skin rashes, lumps and red skin patches,
- gastrointestinal discomfort,
- fever,
- an enlarged spleen or swollen/enlarged lymph nodes,
- abnormally high levels of glucose in the blood (hyperglycaemia),
- mental clouding,
- mood changes such as depression and sadness,

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- a feeling or state of intense excitement and happiness (euphoria),
- a state of unease or generalized dissatisfaction with life (dysphoria),
- small pupils in the eye (myosis)
- a feeling of dizziness or being lightheaded (vertigo),
- inflammation of the pancreas (pancreatitis),
- biliary spasm (causing pain in the right side of your abdomen, particularly after eating a meal, which may spread towards your right shoulder),
- sweating, skin rash,
- uncontrolled muscle movements,
- painful or difficult urination (dysuria),
- reduced sexual drive or impotence,
- feeling unwell or tired,
- having abnormally low body temperature (hypothermia).
- Posterior reversible encephalopathy (PRES)
- Reversible vasoconstriction syndrome (RCVS)

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 or nurse. 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>.

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By reporting side effects, you can help provide more information on the safety of INNOSPECT.

5. How to store INNOSPECT

- Store all medicines out of reach of children.
- Store at or below 25° C and protect from light.
- Keep in original packaging until required for use.
- Do not store in a bathroom.
- Do not use after the expiry date stated on the label.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets)

6. Contents of the pack and other information

What INNOSPECT contains:

INNOSPECT PEADIATRIC:

The active substances are:

Triprolidine hydrochloride: 1,25 mg, Pseudoephedrine hydrochloride: 20,00 mg,

Codeine Phosphate: 7,50 mg, Guaiphenesin: 100,0 mg

The other ingredients are:

chloroform spirit, Citric acid monohydrate, dye lennon yellow, flavour cola imitation,

flavour peppermint, methylparaben, propylene glycol, purified water, sodium

benzoate, sodium citrate, sodium cyclamate, sorbitol solution 70%(non crystallising),

sucrose.

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What INNOSPECT looks like and contents of the pack

INNOSPECT PEADIATRIC is a bright red syrup with the odour and taste of raspberry.

Holder of certificate of registration

Innovata Pharmaceuticals

Crownwood Office Park

100 Northern Parkway

Ormonde

Johannesburg

2091

South Africa

The leaflet was revised in

09/12/2024

Registration number

INNOSPECT PEADIATRIC

Y/10.1/140