

**Applicant/PHCR:** Innovata Pharmaceuticals (Pty) Ltd

**Product Proprietary Name:** PAINCODEIN

**Dosage Form & Strength:** Tablets, Paracetamol 500 mg, Codeine Phosphate 8 mg  
CTD, Module 1

## PATIENT INFORMATION LEAFLET

**SCHEDULING STATUS:** S2

### PAINCODEIN TABLETS

**Paracetamol 500 mg**

**Codeine Phosphate 8 mg**

Powdered sucrose 20 mg

Nipastat 0, 07 % m/m & Benzoic acid 0,06 % m/m

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

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

Nevertheless, you still need to use **PAINCODEIN** carefully to get the best results from it. Keep this leaflet. You may need to read it again.

- Do not share **PAINCODEIN** with any other person.
- Ask your health care provider or pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve after 10 days.

### What is in this leaflet:

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

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## 1. What PAINCODEIN is and what it is used for

The name of your medicine is **PAINCODEIN**. It contains paracetamol and codeine which are indicated for the relief of mild to moderate pain and for the reduction of temperature in febrile conditions.

## 2. What you need to know before you take PAINCODEIN

### Do not take PAINCODEIN:

- If you are hypersensitive (allergic) to paracetamol or codeine or any other ingredients of **PAINCODEIN** (listed in section 6)
- If you have asthma or another lung disease which makes breathing difficult
- If you are an alcoholic.
- If you have increase pressure in the brain, e.g following a head injury
- If you have heart failure secondary to lung disease

### Warnings and precautions

#### Take special care with PAINCODEIN:

- If you going to use continuously for more than 10 days without consulting your doctor
- If you are taking monoamine oxidase inhibitors or within 14 days of stopping such treatment.
- If exceeding the prescribed dose, together with prolonged and continuous use of this medication, may lead to dependency and addiction
- If you have hypothyroidism(overactive thyroid), adrenocortical insufficiency(body does not produce enough of certain hormones) or myasthenia gravis(neuromuscular disease that causes weakness in skeletal muscles)
- If you have an impaired renal function, impaired liver function,

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- If you have an enlargement of the prostate
- If you have inflammation or obstructive bowel disorders.
- If you are elderly and a debilitated patients.
- If you are an alcoholic , taking anaesthetics, hypnotics and sedatives, phenothiazines, tricyclic antidepressants.
- If you are in labour as codeine may cause respiratory depression in the new born infant
- If you suffer from life threatening skin reactions such as Stevens- Johnson syndrome (SJS) and toxic epidermal necrolysis (TEN).
- If you develop a skin rash, swelling of lymph nodes and increase of eosinophils (a type of white blood cells). This is known as Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS).
- If you develop or have a history of Fixed Drug Eruptions (FDE) (may look like round or oval patches and swelling of the skin), blistering (hives), itching

#### **Other medicines and PAINCODEIN:**

Always tell your healthcare professional if you are taking any other medicine. (This includes all complementary or traditional medicines).

Tell your doctor if you are taking:

- medicines used to treat water retention or high blood pressure
- medicines to treat mental illness (anti-psychotics)
- medicines to prevent blood clotting, such as warfarin
- medicines to treat diarrhoea, such as loperamide and kaolin
- muscle relaxants, such as atropine

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- anaesthetics or other drug~ used in surgery (such as neuromuscular blocking agents)
- medicines that affect the liver e.g. carbamazepine, phenobarbital, phenytoin (anti-epileptics) or rifampicin (antibiotic)
- naloxone or naltrexone (used to treat drug abuse or overdose)
- colestyramine (used to reduce cholesterol in the blood)
- quinidine or mexiletine (used to treat certain heart conditions)
- metoclopramide or domperidone (used to treat nausea and vomiting)
- cimetidine (used to treat stomach ulcers)
- cisapride (used to treat heart burn)
- hydroxyzine (an anti-histamine)
- probenecid (used to treat gout)
- isoniazid (used to treat tuberculosis).

### **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 taking this medicine.

### **Driving and using machines**

**PAINCODEIN** contains codeine. Codeine may cause drowsiness if affected patients should be advised not to drive or operate machinery.

### **PAINCODEIN contains sucrose:**

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product

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**PAINCODEIN** contains benzoic acid

Benzoic acid may increase jaundice (yellowing of the skin and eyes) in newborn babies (up to 4 weeks old).

### 3. How to take PAINCODEIN

Do not share medicines prescribed for you with any other person.

Always take **PAINCODEIN** exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

#### The usual dose is:

Adults: One or two tablets every four to six hours. Children over 12 years: One tablet every four to six hours. Children 6 to 12 years: Half to one tablet every six hours. Do not exceed an adult dose of 8 tablets per day. Do not use continuously for longer than ten (10) days without consulting your doctor.

If you have the impression that the effect of **PAINCODEIN** is too strong or too weak, tell your doctor or pharmacist

#### If you take more PAINCODEIN than you should

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

#### If you forget to take PAINCODEIN

If you forget to take a dose take it as soon as you remember it and then take the next dose at the right time.

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Do not take a double dose to make up for forgotten individual doses.

#### 4. Possible side effects

**PAINCODEIN** can have side effects.

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

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

- An allergic reaction may include: Any kind of skin rash, flaking skin, boils or sore lips and mouth
- In rare cases, severe allergic reaction (anaphylactic shock) may occur which may include sudden itching of the skin, wheezing, fluttering or tightness of the chest, or collapse.

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

Tell your doctor if you notice any of the following:

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

#### Less frequent side effects:

- Steven Johnson Syndrome (serious disorder of the skin and mucous membrane)
- Exanthematous pustulosis (acute eruptions of pustules)

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- Fixed drug eruptions
- Allergic reactions including skin rash Frequency Unknown
- Agranulocytosis (low number of a type of white blood cells)
- Thrombocytopenia(low blood platelet count)
- Allergic reactions including rash, itching, difficulty in breathing including shock.
- Drug dependence
- Dizziness, light-headedness, confusion, drowsiness
- Upper abdominal pain, abdominal pain that radiates to back, tenderness when touching the abdomen, fever, rapid pulse, nausea, vomiting, which may be symptoms of inflammation of the pancreas (acute pancreatitis).
- Some of the listed side effects may be due to the diarrhoea, such as discomfort around the middle, feeling sick or being sick, dry mouth, feeling tired, drowsy or dizzy and wind.
- Constipation, nausea ,vomiting
- Urinary retention(unable to emptying all the urine from the bladder)
- Drug withdrawal syndrome
- Changes in mood
- Reslessness
- Pressure inside the skull
- Constriction of pupils of the eye
- Middle ear imbalance
- Slow heart rate,
- fast hear beat
- Low blood pressure
- Dry mouth

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- Spasm in the urethra
- Muscle rigidity
- Difficulty in urination, sweating.

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

### Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects via

<http://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of this medicine.

### 5. How to store PAINCODEIN

Store all medicines out of reach of children.

Store at or below 25 °C.

Store in the original package/container.

Keep the container in the outer carton.

Do not use after the expiry date stated on the carton/bottle.

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 **PAINCODEIN** contains

The active substance is paracetamol and codeine phosphate.

**PAINCODEIN:** each tablet contains 500 mg paracetamol & 8 mg codeine phosphate.

Contains Sugar: Powdered sucrose 20 mg

Contains preservatives: Nipastat 0, 07 % m/m & Benzoic acid 0,06 % m/m

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The other ingredients are:

Benzoic acid

Ethanol 90% v/v

Gelatin

Hexacol Red

Magnesium stearate

Modified starch

Nipastat

Powdered sucrose

Povidone

Purified water

Quinolone Yellow

Starch maize

### **What PAINCODEIN looks like and contents of the pack**

Flat green tablet, scored on the one side and plain on the other side.

HDPE white jar with a screw-on-cap. (Not lined).

Blister packs containing 2 x 10 and 10 x 10 tablets and plastic bottles containing 100, 500 and 1000 tablets.

### **HOLDER OF CERTIFICATE OF REGISTRATION**

Innovata Pharmaceuticals (Pty) LTD

Crownwood Office Park

100 Northern Parkway

Ormonde

28-04-2024



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Johannesburg

2091

South Africa

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**Registration number**

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