

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

**Product Proprietary Name:** HOPYN Tablet

**Dosage Form & Strength** Tablet, (Paracetamol 320 mg, Meprobamate 150 mg, codeine phosphate 8 mg and caffeine anhydrous 32 mg)

### 1.3.2 Clean Amended Patient Information Leaflet for HOPYN TABLETS

#### SCHEDULING STATUS

S5

#### HOPYN Tablets

Meprobamate, Codeine phosphate, Paracetamol and Caffeine anhydrous

Contains preservative(Nipastat): 0.025%

Sugar Free

#### Read all of this leaflet carefully before you start taking HOPYN TABLETS

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or pharmacist.
- HOPYN TABLETS** has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

#### What is in this leaflet

- 1.What **HOPYN TABLETS** is and what it is used for
- 2.What you need to know before you take **HOPYN**
- 3.How to take **HOPYN**
- 4.Possible side effects

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## 5. How to store HOPYN

## 6. Contents of the pack and other information

### 1. What HOPYN TABLETS is and what it is used for

HOPYN tablets contain the active ingredients Paracetamol 320 mg, Codeine phosphate 8 mg, Caffeine 32 mg and Meprobamate.

HOPYN is used for the short-term treatment of mild to moderate pain and fever, and pain associated with tension.

### 2. What you need to know before you take HOPYN TABLETS

#### Do not take HOPYN TABLETS

- if you have ever had an allergic reaction to paracetamol, codeine phosphate, caffeine, meprobamate or any of the other ingredients in the tablets (these are listed in section 6),
- if you have porphyria (a rare inherited blood disorder),
- if you have a history of fits (epilepsy),
- if you have any lung/airway (respiratory) problems, especially in the presence of cyanosis (condition where your skin or lips turn blue due to an insufficient level of oxygen in the blood) and excessive mucus and fluid secretion in the airways,

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- if you are experiencing an asthma attack or heart failure (secondary to a chronic lung disease),
- if you had an operation on the biliary tract (liver, gall bladder and bile ducts),
- if you had a kidney or liver disease,
- if you suffer from acute alcoholism (alcohol poisoning due to rapid and excessive alcohol intake),
- if you suffer from a head injury or any conditions in which intracranial pressure is raised (a rise in the pressure around your brain),
- if you are taking an antidepressant in the class called monoamine oxidase inhibitors or within fourteen days of stopping such treatment.

## **Warnings and precautions**

### **Take special care with HOPYN tablets and tell your doctor:**

- if you are pregnant or breastfeeding as **HOPYN** is not recommended for use during pregnancy or breastfeeding,
- if your symptoms do not improve on the recommended dosage as prescribed by your doctor,
- if you have a history of liver or kidney disease as paracetamol intake must then be carefully monitored and controlled by your doctor,

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- if you are suffering from hypothyroidism (underactive thyroid gland), adrenocortical insufficiency (condition in which the adrenal glands do not produce enough steroid hormones), prostatic hypertrophy (enlarged prostate gland) or shock,
- if you suffer from or have ever suffered from inflammatory or obstructive bowel disorders, such as ulcers (peptic ulceration), small bowel obstruction (blockage of the bowel), etc,
- if you are using anaesthetics, hypnotics, sedatives, phenothiazines and alcohol as these may, in combination with **HOPYN**, enhance impairment of judgement and coordination (feeling dizzy or drowsy). See “Other medicines and **HOPYN**”.

Do not use **HOPYN** for more than ten (10) days at a time without consulting your doctor. If you use **HOPYN** for too long or continuously, it may cause dependency and addiction. This can give you withdrawal symptoms from the medicine when you stop taking it. See section 3 “If you stop taking/using **HOPYN**”.

**HOPYN** contains paracetamol, which may be fatal or cause severe liver damage in overdose. Contact the nearest doctor, hospital or poison centre immediately following overdose or suspected overdose. See section 3

**The dosage of HOPYN TABLETS should be reduced in the elderly and in weakened (frail) patients.**

## **Children**

No data are available on the use of **HOPYN** in children.

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## **Other medicines and HOPYN TABLETS**

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

**Some medicines may increase or decrease the effects of HOPYN, and your doctor may wish to monitor you carefully if you are taking any of the following:**

- **Alcohol,**
- **Medication to numb sensation in certain areas of the body or induce sleep (anaesthetics),**
- **Sleeping pills (hypnotics),**
- **Tranquillisers (sedatives) used to make you feel more relaxed,**
- **Phenothiazines, such as chlorpromazine or prochlorperazine. This is a class of medicines used for mental disorders such as schizophrenia or psychotic disorders.**

## **Pregnancy and breastfeeding**

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 **HOPYN**. **HOPYN** is, however, not recommended for use by pregnant or breastfeeding women.

## **Driving and using machines**

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It is not always possible to predict to what extent **HOPYN** may interfere with your daily activities. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which **HOPYN** affects them. **HOPYN**, however, may cause drowsiness and care should be taken when driving or operating machinery.

### **3. How to take HOPYN TABLETS**

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

Always take **HOPYN** exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The usual adult dose of **HOPYN** is two tablets three to four times daily as required.

Take the tablets with a sufficient quantity of liquid (e.g., one glass of water).

Your doctor will tell you how long your treatment with **HOPYN** will last. However, it is not recommended to use continuously for more than ten days. If you have the impression that the effect of **HOPYN** is too strong or too weak, tell your doctor or pharmacist.

### **If you take more HOPYN TABLETS than you should**

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre even if you feel well. This is because

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too much paracetamol can cause delayed, serious liver damage. Specialised treatment is essential as soon as possible.

## Symptoms

The most common symptoms of **HOPYN** overdose is nausea and vomiting.

Additional symptoms resulting from meprobamate may include stupor (state of speechlessness, motionlessness, and unresponsiveness to stimulation, but are otherwise completely conscious), coma, convulsions (fits), shock, problems with your blood vessels (circulatory collapse) and breathing (respiratory system/respiratory collapse).

Symptoms of paracetamol overdose in the first 24 hours include pallor (unhealthy pale appearance), nausea, vomiting, loss of appetite and possibly abdominal pain.

Mild symptoms during the first two days of acute poisoning do not reflect the potential seriousness of the overdose. Liver damage may lead to brain damage, coma and death. Kidney failure may develop even in the absence of severe liver damage and heart rhythm problems (arrhythmias) have also been reported.

## If you forget to take / missed a dose of HOPYN TABLETS

If you miss a dose, take it as soon as possible. However, if it is almost time for the next dose, skip the missed dose and go back to your regular dosing schedule. Do not take a double dose to make up for forgotten individual doses.

## If you stop taking/using HOPYN TABLETS

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This medicine contains codeine and meprobamate and can cause addiction if you take it continuously for more than ten days. When you stop taking it you may get withdrawal symptoms.

**You should talk to your doctor or pharmacist if you think you are suffering from withdrawal symptoms.**

#### **4. Possible side effects**

**HOPYN** can have side effects.

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

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

- skin rashes, urticaria (red, itchy welts that result from a skin reaction) and purpura (blood spots, which are purple-coloured spots on the skin),
- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing,
- erythema multiforme (skin or mouth lesions that have a pink-red centre surrounded by a pale ring border and an outer pink-red ring).

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

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Tell your doctor if you notice any of the following:

- Mood changes,
- Drowsiness, confusion, vertigo (feeling off balance), orthostatic hypotension (a sudden drop in blood pressure when you stand from a seated or lying down position) and raised intracranial pressure (rise in pressure around your brain),
- Caffeine may cause restlessness, excitement, muscle tremor (spasms or twitching),
- Meprobamate may cause drowsiness, paraesthesia (tingling or pricking / “pins and needles”), weakness, headache, excitement, dizziness, ataxia (slurred speech, stumbling, falling, and incoordination),
- Miosis (constriction of the pupils / small pupils) and scintillating scotoma (visual aura or blind spot that affects a part of your vision), other vision disturbances,
- Ringing or buzzing noise in one or both ears,
- Codeine may cause nausea, vomiting, constipation, and dry mouth,
- Caffeine increases gastric secretions (such as stomach acid) and may cause stomach ulcers,
- Sweating, facial flushing (blushing), urticaria (skin rash) and pruritus (unpleasant itch),
- Difficulty in urination, spasms in urinary tract causing lower abdominal pain, spasm is the bile duct causing upper abdominal pain,
- Drop in body temperature (hypothermia),

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- Tachycardia (rapid heartbeat), extrasystoles (skipped heartbeats). Hypotension (low blood pressure), cardiac arrhythmias (improper heartbeat),
- Blood disorders including agranulocytosis (lowered white blood cell count), eosinophilia (high level of white blood cells), leukopenia (low level of white blood cells), thrombocytopenia (low blood plate count) and aplastic anaemia (a rare condition in which the body stops producing enough new blood cells).
- Skin and subcutaneous tissue disorders (see above hypersensitivity reactions that may occur).
- Steven Johnson Syndrome (serious disorder of the skin and mucous membrane)
- Exanthematous pustulosis (acute eruptions of pustules)
- Fixed drug eruptions

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. This includes any possible side effects not listed in this leaflet. 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 this medicine.

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## 5. How to store HOPYN TABLETS

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 HDPE bottle or blister.

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 HOPYN TABLETS contains

The active substances are paracetamol, codeine phosphate, caffeine and meprobamate.

The other ingredients of **HOPYN** are:

Apple green colourant ,colloidal silicone dioxide , magnesium stearate , nipastat, povidone, powdered acacia, purified talc and starch maize.

### What HOPYN TABLETS looks like and contents of the pack

Green, round, flat tablet.

**HOPYN TABLETS** is packaged into blister packs, or in a white HDPE jar with white HDPE screw cap.

Pack sizes: 20's, 100, 500's or 1 000 tablets. Not all pack sizes may be marketed.

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## **Holder of Certificate of Registration**

### **Innovata Pharmaceuticals (Pty) Ltd**

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### **This leaflet was last revised in**

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### **Registration number**

A28/2.8/0422

A copy of the professional Information is contained in the packaging of **HOPYN**.