

### **1.3.2 Patient Information Leaflet for NOCOMYPRO**

#### **SCHEDULING STATUS**

**S3**

#### **NOCOMYPRO 400 mg/325 mg film-coated tablets**

**Ibuprofen/Paracetamol**

**Sugar free**

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

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

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

- Keep this leaflet. You may need to read it again.
- Do not share NOCOMYPRO 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.

#### **What is in this leaflet**

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

## **1. What NOCOMYPRO is and what it is used for**

NOCOMYPRO contains two active ingredients. These are ibuprofen and paracetamol.

Ibuprofen belongs to a group of medicines known as non-steroidal anti-inflammatory drugs (NSAIDs). NSAIDs work by reducing pain, reducing swelling, and lowering high temperatures.

Paracetamol is an analgesic which works in a different way from ibuprofen to relieve pain and fever.

NOCOMYPRO is used to relieve mild and moderate pain and reduce swelling, with or without fever.

## **2. What you need to know before you take NOCOMYPRO**

### **Do not take NOCOMYPRO**

- if you are hypersensitive (allergic) to ibuprofen or paracetamol or any of the other ingredients of NOCOMYPRO.
- If you are pregnant, do not use NSAIDs at 20 weeks or later in your pregnancy unless specifically advised to do so by your health care professional because these medicines may cause problems in your unborn baby.
- if you have heart failure (a chronic condition in which the heart does not pump blood as well as it should).
- If you have or have had a stomach ulcer or have a history of inflammation and bleeding in the bowels.
- if you are sensitive to aspirin or another non-steroidal anti-inflammatory medicine.
- if you suffer from asthma or have ever had an allergic reaction or suffered from wheezing after taking ibuprofen, aspirin or any other anti-inflammatory pain killers.
- if you suffer from swelling and irritation inside the nose.
- if you have a condition which increases your tendency to bleed.
- if you have severe liver or kidney function impairment.
- if you are pregnant or breastfeeding.
- if you are taking blood thinners.

## **Warnings and precautions**

Special care should be taken with NOCOMYPRO:

- Higher than recommended doses of paracetamol may cause severe liver damage.  
Therefore, use NOCOMYPRO exactly as indicated (see section 3, How to take NOCOMYPRO).
- If you have an infection as NOCOMYPRO may mask the symptoms and the infection may get worse).
- if you have kidney or liver problems, including those due to drinking too much alcohol as you may be more at risk of the side effects of paracetamol (see Do not take NOCOMYPRO).
- If you have heart problems (see Do not take NOCOMYPRO) or high blood pressure.
- If you suffer from water retention (oedema).
- If you have asthma, a history of asthma or any other allergic disease (see Do not take NOCOMYPRO).
- If you are anaemic (feeling very weak, tired and looking pale).
- If you bleed easily (see Do not take NOCOMYPRO).
- If you have gastrointestinal problems (nausea, vomiting, stomach pain, heartburn, indigestion) and or stomach ulcer(s) (see Do not take NOCOMYPRO).
- If you are diabetic. NOCOMYPRO may influence your blood glucose results.
- If you are an elderly person. The elderly and patients with a history of stomach ulcers are more susceptible to develop side-effects affecting the bowels when using NSAIDs.  
Therefore, they should be carefully monitored for stomach ulcers and bleeding as it may be fatal.
- If you are going to have an operation. NOCOMYPRO may increase your risk of bleeding during surgery.

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NOCOMYPRO, film-coated tablets

*Contains 400 mg ibuprofen and 325 mg paracetamol per tablet*

- If you have or have had any allergies or allergic reactions (including hives, swelling of the face, lips, tongue, and/or throat which may cause difficulty in breathing or swallowing) which required hospital treatment.

Tell your doctor or health care provider if you are pregnant or plan to become pregnant. Taking NSAIDs at around 20 weeks of pregnancy or later may harm your unborn baby. If you need to take NSAIDs for more than 2 days when you are between 20 and 30 weeks of your pregnancy, your healthcare provider may need to monitor the amount of fluid in your womb around your baby. You should not take NSAIDs after around 30 weeks or later of pregnancy.

**Children**

NOCOMYPRO is not recommended for children under 12 years of age.

**Other medicines and NOCOMYPRO**

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

Tell your doctor or pharmacist if you are currently using:

- Hepatotoxic medicines (medicines that can cause damage to your liver).
- Enzyme inducing medicines.
- Metoclopramide (used to relieve feelings of sickness (nausea) or being sick (vomiting)).
- Cholestyramine (used to treat high cholesterol).
- Anticoagulant medicines which thin the blood (e.g., warfarin): if taken with NOCOMYPRO, you may be at an increased risk of bleeding, therefore your doctor is likely to monitor you more closely.
- Corticosteroids (used to treat inflammation in your body).
- Ticlopidine (used to thin your blood).
- Clopidogrel (used to prevent your blood from clotting).

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- Bisphosphonates (used to treat osteoporosis, a condition in which your bones become brittle and fragile).
- Pentoxifylline (used to treat muscle pain).
- Antidiabetic medicines (used to treat high sugar levels).
- Digoxin (used to treat heart failure and a fast heartbeat).
- Lithium, selective serotonin reuptake inhibitors (SSRIs) (used to treat depression).
- Methotrexate (used to treat rheumatoid arthritis, certain types of cancer and severe psoriasis).
- Ciclosporin (used to prevent organ rejection after a transplant).
- Antihypertensives (used to treat high blood pressure) or diuretics (water pills).
- Bone marrow depressants.
- Anti-platelet medicines and selective serotonin reuptake inhibitors (SSRIs) used for depression: if taken with NOCOMYPRO, you may be at an increased risk of bleeding if you suffer from stomach ulcers.
- Anti-inflammatory medicines such as NSAIDs (e.g., aspirin, diclofenac, etc.): if taken with NOCOMYPRO it may increase your side-effects.

**NOCOMYPRO with food, drink and alcohol**

NOCOMYPRO should be taken with food or after meals with sufficient water. The use of alcohol with NOCOMYPRO should be avoided as it increases the risk of stomach ulcers or gastrointestinal bleeding.

**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 this medicine.

Do not take NOCOMYPRO if you are pregnant as it may be harmful for your unborn baby and may delay the onset of labour and increase the duration.

Do not take NOCOMYPRO if you are breastfeeding your baby, as the safety and efficacy during breastfeeding has not been established.

### **Driving and using machines**

It is not always possible to predict to what extent NOCOMYPRO 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 NOCOMYPRO affects them.

### **3. How to take NOCOMYPRO**

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

Always take NOCOMYPRO exactly as described in this leaflet or as your doctor, pharmacist or nurse have told you. Check with your doctor, pharmacist or nurse if you are not sure.

NOCOMYPRO is not recommended for children under 12 years of age.

The usual dose is for adults and children over 12 years of age is: two (2) tablets every four (4) hours when necessary. Do not exceed six (6) tablets in 24 hours. Tablets are to be taken with food or after meals with sufficient water.

You should talk to your doctor if your symptoms worsen, if your pain does not go away within 7 days, or if your fever persists for longer than 3 days.

Your doctor will tell you how long your treatment will last. Your doctor will prescribe NOCOMYPRO for the shortest possible duration.

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

### **If you take more NOCOMYPRO 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 too much paracetamol can cause delayed, serious liver damage. Specialised treatment is essential as soon as possible.

### Symptoms

The most common symptoms of paracetamol overdosage is nausea, vomiting, loss of appetite and possible stomach pain. Additional symptoms resulting from ibuprofen may include tiredness, drowsiness, bleeding in the stomach or bowels, kidney failure, fits and coma.

Mild symptoms of paracetamol overdose during the first two days of acute poisoning do not reflect the potential seriousness of the overdosage. 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.

### Treatment

It is recommended that any adult person who has taken 5 to 10 g or more of paracetamol (or a child who has had more than 140 mg/kg) within a four-hour period, should have the stomach emptied by lavage (stomach pumping) and a single dose of 50 g activated charcoal given (by lavage tube).

N-acetylcysteine should be administered (preferably intravenously or less preferably, orally) to all cases of suspected overdose as soon as possible, preferably within eight hours of overdosage, although treatment up to 36 hours after ingestion may still be of benefit.

All patients treated for overdose should be monitored for at least ninety-six hours.

### **If you forget to take a dose of NOCOMYPRO**

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.

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

NOCOMYPRO can have side effects.

Not all side effects reported for NOCOMYPRO are included in this leaflet. Should you not experience pain relief, or your general health worsens, or if you experience any untoward effects while taking NOCOMYPRO, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, stop taking NOCOMYPRO 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.
- Fainting.

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

Tell your doctor if you notice any of the following:

#### Frequent side effects:

- Dizziness.
- Nausea, stomach pain, vomiting, diarrhoea, flatulence, constipation, indigestion, stomach ulceration, perforation, or bleeding, bloody stool, haematemesis (if you vomit blood), and gastritis (inflammation of the lining of the stomach).

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Less frequent side effects:

- Changes in your blood cell counts (agranulocytosis, thrombocytopenia, anaemia, neutropenia, eosinophilia)
- Nervousness, headache, ringing/buzzing noise in ear(s), depression, drowsiness, sleeplessness.
- Blurred vision, changes in visual colour perception and other toxic amblyopia (damage to optic nerve).
- Changes in the way your heart beats (beating faster), flushing, high blood pressure, and heart failure.
- Yellowing of your skin and eyes, also called jaundice or hepatitis.
- Kidney problems, which may lead to kidney failure (you may pass more or less urine, have blood in the urine or cloudy urine, feel breathless, very tired or weak, have no appetite, or have swollen ankles).
- Aseptic meningitis (infection around the brain or spinal cord with fever, nausea, vomiting, headache, stiff neck and extreme sensitivity to bright light).

Side effects with an unknown frequency:

- Crohn's disease (an inflammatory disease that can affect any part of the gastrointestinal track causing symptoms such as pain, fever, diarrhoea and loss of body mass).
- Painful, blistering or peeling skin rash, such as Stevens-Johnson syndrome, toxic epidermal necrolysis or erythema multiforme.
- Interstitial nephritis (passing more or less urine than is normal for you, dark urine, nausea, vomiting).

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 NOCOMYPRO.

## **5. How to store NOCOMYPRO**

- Store all medicines out of reach of children.
- Store at or below 30 °C. Protect from light and moisture.
- Do not use after the expiry date stated on the container 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 NOCOMYPRO contains**

The active substances are ibuprofen and paracetamol.

Each film-coated tablet contains 400 mg of ibuprofen and 325 mg of paracetamol.

The other ingredients are calcium hydrogen phosphate, Opadry 06G53189 orange (containing hypromellose, macrogol/PEG 6000, polyethylene glycol, sodium laurilsulfate, Sunset Yellow and titanium dioxide), povidone, pregelatinised starch, and purified talc.

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

NOCOMYPRO are orange coloured, oval, film-coated tablets.

The film-coated tablets are available in a carton containing 30, 60 or 100 tablets in blister strips of 10 tablets each, or a HDPE bottle containing 500 tablets.

Not all pack sizes may be marketed.

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NOCOMYPRO, film-coated tablets  
*Contains 400 mg ibuprofen and 325 mg paracetamol per tablet*

**Holder of Certificate of Registration and Manufacturer**

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