PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S2

NOMOPAIN tablets

Paracetamol / Doxylamine succinate / Caffeine / Codeine phosphate

Sugar free.

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

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

Nevertheless, you still need to take **NOMOPAIN** carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share **NOMOPAIN** 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 5 days.

What is in this leaflet

1. What NOMOPAIN is and what it is used for

NOMOPAIN contains caffeine, codeine phosphate, doxylamine succinate and paracetamol.

Paracetamol acts as an analgesic (painkiller) and an antipyretic (lowers body temperature), codeine phosphate is an analgesic, doxylamine succinate is an antihistamine, and caffeine is a mild stimulant.

NOMOPAIN is used for the short-term treatment of acute moderate pain which is not relieved by paracetamol, ibuprofen and aspirin alone such as headache, including muscle contraction or tension headache, migraine, neuralgia, period pain, toothache and other dental pain, muscular and rheumatic aches and pains and for pain relief following surgery or dental procedures.

2. What you need to know before you take NOMOPAIN

Do not take NOMOPAIN:

- If you are hypersensitive (allergic) to paracetamol, codeine or other opioid analgesics, doxylamine succinate, caffeine or any of the other ingredients of **NOMOPAIN** (see section 6).
- If you have liver problems.
- If you have been told by your doctor that you have a metabolic disorder called acute intermittent porphyria. Signs include severe abdominal pain, constipation or diarrhoea, nausea and vomiting, and pain in your chest, legs or back.
- If you are having an asthma attack or have severe breathing problems.
- If you have recently had an operation on your bile duct (biliary tract).
- If you are an alcoholic.
- If you have had a head injury or been told by your doctor that you have increased pressure in your head. Signs of this include headaches, being sick (vomiting) and blurred eyesight.
- If you are taking medicines to treat depression called monoamine oxidase inhibitors (MAOIs) or have recently taken them in the last two weeks.
- If you are pregnant or breastfeeding your baby.
- If you are at risk of blocked intestines (paralytic ileus).
- If you are under 18 years of age and have had your tonsils or adenoids removed due to obstructive sleep apnoea syndrome.
- If you have been told by your doctor that your body metabolises codeine to morphine very quickly.

Warnings and precautions

NOMOPAIN contains paracetamol which may be fatal in overdose.

Take special care with **NOMOPAIN**:

- If you have high blood pressure or any heart problems.
- If you have thyroid or hormonal problems.
- If you have an enlarged prostrate.
- If you have trouble to pass urine.
- If you have pressure in your eyes (glaucoma).
- If you have any bowel or abdominal problems (e.g. stomach ulcer).
- If you have had a recent operation on your gastrointestinal tract.
- If you have gall stones.
- If you have a condition known as myasthenia gravis which weakens the muscles.
- If you suffer from seizures.
- If you are in shock, have a history of medicine abuse or are emotionally not stable.
- If you have kidney problems or are elderly. You might need to reduce your dose.
- If you have asthma.
- If you develop any skin adverse reaction, such as toxic epidermal necrolysis (TEN), Steven-Johnson syndrome (SJS), acute generalised exanthematous pustulosis (AGEP), drug rash with eosinophilia and systemic symptoms (DRESS) or drug-induced hypersensitivity syndrome (DIHS) and fixed drug eruptions (FDE), treatment with **NOMOPAIN** must immediately be discontinued. These reactions can be life-threatening and are characterised by redness, inflamed or swollen skin, blisters, hives, itching and sometimes peeling or pain. Should you experience any of these symptoms, contact your health care provider immediately.

Paediatric population

NOMOPAIN can be used in children over 12 years of age for the short-term relief of moderate pain that is not relieved by other painkillers but not if they are under 18 years of age and have had their tonsils or adenoids removed due to obstructive sleep apnoea syndrome.

NOMOPAIN is not recommended in children with breathing problems, since the symptoms of morphine toxicity may be worse in these children.

Other medicines and NOMOPAIN

Always tell your health care 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:

- Metoclopramide or domperidone (used to treat nausea and vomiting).
- Colestyramine (used to lower your blood cholesterol levels).
- Medicines used to thin the blood such as warfarin (or other coumarins).
- Medicines which make you drowsy or sleepy (central nervous system (CNS) depressants) (e.g. barbiturates, anaesthetics, hypnotics, other opioid analgesics, anxiolytic sedatives, tranquillisers, antipsychotics, tricyclic antidepressants and phenothiazines) or a benzodiazepine used to treat anxiety or sleep disorders.
- Medicines called antimuscarinics (e.g. atropine).
- Medicines to treat or prevent clinical depression (antidepressants).
- Medicines for the treatment of high blood pressure (diuretics and antihypertensives).
- Hydroxyzine (used to treat anxiety, tension and allergies).
- Medicines called neuromuscular blockers.
- Quinidine (used to treat irregular heart rate).
- Kaolin or loperamide (used for the treatment of diarrhoea).
- Mexiletine (used to treat irregular heartbeat).
- Cisapride (used to treat gastro-oesophageal reflux disease).

- Cimetidine (used to treat stomach ulcers).
- Naloxone (used to treat a narcotic overdose).
- Naltrexone (used as part of a treatment program for medicine or alcohol dependence).
- Carbamazepine, phenytoin, phenobarbital and primidone (used to treat epilepsy).

Concomitant use of opioids and benzodiazepines increases the risk of drowsiness, difficulties in breathing (respiratory depression), coma and may be life-threatening. Because of this, you should only take these together if prescribed by a doctor. Please follow your doctor's dosage recommendation closely. It could be helpful to inform friends or relatives to be aware of signs and symptoms stated above. Contact your doctor when experiencing such symptoms.

NOMOPAIN with food and alcohol

NOMOPAIN should not be taken with alcohol.

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 **NOMOPAIN**.

Do not take **NOMOPAIN** during pregnancy and breastfeeding.

Driving and using machines

NOMOPAIN may cause drowsiness and impair your concentration.

If you experience these side effects, do not drive or operate machinery.

3. How to take NOMOPAIN

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

The usual dose is:

Adults and children 12 years and older: Take 2 tablets every 4 hours as needed.

Do not exceed 8 tablets per day.

Do not use continuously for longer than 5 days without consulting your doctor.

NOMOPAIN can be taken with or without food.

If you take more NOMOPAIN than you should

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

Take this leaflet and the rest of the remaining **NOMOPAIN** with you so the doctor will know what you have taken.

4. Possible side effects

NOMOPAIN can have side effects.

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

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

- Swelling of your hands, feet, ankles, face, lips, 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 allergic reaction to **NOMOPAIN**. 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:

- Bleeding or bruising more easily than normal.

- Frequent infections such as fever, severe chills, sore throat or mouth ulcers.
- Low number of red blood cells, white blood cells and cells involved with blood clotting (symptoms such as weakness, tiredness, skin problems such as rashes or bruising, rapid heart rate, shortness of breath).
- An excessive breakdown of red blood cells causing a type of anaemia (tiredness, headaches, shortness of breath, dizziness, looking pale and yellowing of the whites of the eyes).
- Difficulty breathing, tightness of the chest (bronchospasm).
- Slowing down of the central nervous system (slower heart rate and breathing, extreme confusion and memory loss and poor judgement).
- Fits (seizures).
- Increased pressure in the head (headache, blurred vision, feeling less alert than usual and vomiting).
- Changes in the way your heart beats, such as beating faster, slower or irregular, heart palpitations.
- Severe stomach pain, which may reach to your back. This could be a sign of inflammation of your pancreas (pancreatitis).
- Yellowing of your skin, whites of your eyes and mucous membranes (jaundice).
- Skin reactions such as toxic epidermal necrolysis (TEN), Stevens-Johnson syndrome (SJS), acute generalised exanthematous pustulosis (AGEP), drug rash with eosinophilia and systemic symptoms (DRESS) or drug-induced hypersensitivity syndrome (DIHS) and fixed drug eruptions (FDE). These reactions can be life-threatening and are characterised by redness, inflamed or swollen skin, blisters, hives, itching and sometimes peeling or pain (sometimes accompanied by fever) (see Take special care with **NOMOPAIN**).
- Difficulty in urinating, inability to empty all the urine from your bladder.
- Sudden drop in body temperature (hypothermia).

Tell your doctor if you notice any of the following:

Side effects occurring frequently:

- Feeling drowsy or confused.
- Changes in the way you move, talk or do regular activities (psychomotor impairment).
- Headache.
- Blurred vision.
- Thick phlegm.
- Dry mouth, nausea (feeling sick), vomiting (being sick), diarrhoea, constipation.

Side effects occurring less frequently:

- Seeing or hearing things that do not exist (hallucinations).
- Sleep problems, including difficulty falling and staying asleep (insomnia), nightmares.
- Nervousness, irritability, depression or very happy.
- Loss of appetite (anorexia).
- Dizziness.
- Tremors (involuntary trembling or shaking of hands and feet).
- Tingling or numbness of your hands and feet (pins and needles).
- Double vision.
- Vertigo (sensation of spinning or swaying).
- Ringing in your ears.
- Low blood pressure, including a drop in blood pressure when standing up (causing light-headedness or fainting).
- Shortness of breath (dyspnoea).
- Stomach pain.
- Feeling unwell or tired.

Side effects occurring with an unknown frequency:

- Restlessness, anxiety.

- Changes in mood.
- Decreased libido (sex drive).
- Lack of energy.
- Coordination problems.
- Increased sensitivity of your skin to the sun.
- Seeing flickering lights that obstructs your vision.
- Constricted pupils.
- Exacerbation of porphyria symptoms (inherited disorder where substances called porphyrins build up in your body, negatively affecting your skin or nervous system).
- Heartburn, stomach ulcer or cramps.
- Redness of your skin, small purple coloured spots caused by bleeding into the skin (purpura).
- Stiff muscles, muscle pain.
- Hair loss.
- Sweating, reddening of your face.
- Increased body temperature.

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. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reactions Reporting Form**", found online under SAHPRA's publications: http://www.sahpra.org.za/Publications/Index/8.

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

5. How to store NOMOPAIN

- Store at or below 25 °C.

- Store in a dry place.
- Protect from light.
- Store all medicines out of reach of children.
- Do not use after the expiry date printed on the container.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What NOMOPAIN contains

Each tablet contains:

Paracetamol	450 mg
Doxylamine succinate	5 mg
Caffeine	30 mg
Codeine phosphate	10 mg

The other ingredients are colloidal silicon dioxide, magnesium stearate, povidone K25, Quinoline yellow (E104), sodium starch glycollate, starch (maize) and talc.

What NOMOPAIN looks like and contents of the pack

A round yellow flat bevelled edge tablet, scored on one side.

Cardboard carton containing 20 or 40 tablets (2 or 4 aluminium/PVC blister packs of 10 tablets each).

Holder of certificate of registration

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This leaflet was last revised in

28 September 2023

Registration number

36/2.8/0270