1.3.2 PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S2

LENADOL 10 mg/5 mg/400 mg/50 mg TABLETS

Codeine phosphate, Diphenhydramine hydrochloride, Paracetamol, Caffeine anhydrous

Contains sugar: Lactose monohydrate 32,87 mg

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

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

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

- Keep this leaflet. You may need to read it again.
- Do not share LENADOL 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 LENADOL is and what it is used for

LENADOL is a combination of the medicines paracetamol, diphenhydramine hydrochloride, codeine and caffeine.

Paracetamol has both pain relieving (analgesic) and fever reducing properties. Codeine phosphate is used for pain (analgesia). Diphenhydramine hydrochloride has sedative and antihistaminic properties and, in combination with the above analgesics is of value, especially in tension states.

LENADOL is used for:

- The relief of fever and pain-tension states.

2. What you need to know before you take LENADOL

Do not take LENADOL:

- if you are hypersensitive (allergic) to codeine phosphate, diphenhydramine hydrochloride, paracetamol, caffeine anhydrous or any of the other ingredients of LENADOL (listed in section 6).
- if you are hypersensitive to other opioid painkillers.
- if you have severe liver or kidney problems.
- if you are pregnant and breastfeeding.
- if you have asthma attacks, respiratory depression especially in the presence of cyanosis (lack of oxygen in the blood that causes blue discoloration and/or numbness) or an excessive amount of mucus (phlegm) from the lungs.
- if you have had any head injuries, and in conditions where the pressure inside your head is raised.

- if you have any history of heart disease.
- if you have heart failure that is due to any longstanding (chronic) lung disease.
- if you suffer from fits (convulsions).
- if you have been using antidepressants called monoamine oxidase inhibitors or have just stopped using these medicines in the last 2 weeks.
- if you suffer from acute alcoholism.
- if the patient is in a coma.
- if the patient is under 12 years of age.
- in children that are having their tonsils and/or adenoids removed due to difficult/disturbed breathing during sleep.
- if you suffer from any condition where the impediment of bowel movements needs to be avoided e.g., paralytic ileus, swollen abdomen, runny stools due to inflammation of the lining of the gut, the use of antibiotics or poisoning.
- if you have been told that you are a CYP2D6 ultra-rapid metaboliser.
- if you suffer from porphyria.

Warnings and precautions

LENADOL contains codeine and exceeding the prescribed dose, together with prolonged and continuous use, may lead to dependence and addiction. The lowest effective dose should be used, and the duration of treatment should be as short as possible.

LENADOL contains paracetamol which may be fatal in overdose. In the event of overdosage or suspected overdose and notwithstanding the fact that the person may

be asymptomatic, the nearest doctor, hospital or Poison Centre must be contacted immediately.

Take special care with LENADOL:

- if you have been told that your adrenal glands do not function properly,
- if you are elderly,
- if you suffer from an underactive thyroid gland,
- if your kidneys or liver do not function properly,
- if you have been told that your prostate is enlarged,
- if you have a challenge passing urine,
- if you suffer from low blood pressure (hypotension),
- if you suffer from shock,
- if you have been told that you suffer from a disease that causes muscle weakness (myasthenia gravis),
- if you are or have ever been addicted to opioids, alcohol, prescription medicines, or illegal substances or if you suffer from major depression or if you have a family history of substance abuse or mental health disorders,
- if you overuse or misuse this medicine, you may need to use it more often than before to get the same results,
- if you have been using it on a regular basis, you will have to gradually decrease the amount of LENADOL you are taking over a period of weeks,
- if you experience an increased sensitivity to pain,
- if you feel that you are experiencing even more pain (hyperalgesia) or an increased sensitivity to pain (allodynia). You will need to inform your doctor,

- if you are using medicine for anxiety or to help you sleep, you are more likely to get severe side-effects, which could even lead to death,
- prolonged excessive use may cause damage to the kidneys and/or liver that may not be reversible upon discontinuation of LENADOL,
- if you suffer or are recovering from any form of liver disease,
- if you have been told that your body cannot produce a certain substance called glutathione (an antioxidant that may help to protect the body from diseases),
- if you develop very serious skin reactions that are potentially life threatening (see Possible side effects),
- If you are also taking flucloxacillin (an antibiotic) as the combination with paracetamol, as contained in LENADOL, has been associated with a condition where acid accumulates in the body (high anion gap metabolic acidosis), especially in patients with risk factors (see Other medicines and LENADOL),
- if you have been told that the pressure in your eye(s) is elevated (closed angle glaucoma),
- if you are already using other medicines that contain antihistamines including skin applications and medicine for colds and/or flu,
- if you are taking alcohol, as this may increase the drowsiness you experience due to LENADOL,
- if you have ever had stomach ulcers or excessive acid in your stomach.

Children and adolescents

LENADOL should not be given to children under the age of 12 years.

Other medicines and LENADOL

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

LENADOL SHOULD NOT BE TAKEN WITH SEDATIVES AND TRANQUILISERS.

Tell your doctor if you are taking any of the following:

- Monoamine oxidase inhibitors (MAOIs) e.g. phenelzine, moclobemide, selegiline, linezolid, that treat different forms of depression as well as other nervous system disorders. Avoid LENADOL use for 14 days after discontinuation of MAOIs.
- Tricyclic antidepressants e.g., imipramine, amitriptyline and clomipramine that are used to treat depression and other mental health disorders.
- Benzodiazepines e.g., diazepam, temazepam, lorazepam and related medicine used to treat anxiety and/or induce sedation.
- Anaesthetics, medicines used to cause a loss of sensation or pain and consciousness.
- Medicines used to treat irregular heartbeat including mexiletine and quinidine.
- Antipsychotics e.g., risperidone, quetiapine, olanzapine used to treat mental illness.
- Medicine that contains other antihistamines, usually found in allergy and cough and cold medicine.
- Medicines to control nausea and vomiting e.g., metoclopramide, domperidone.
- Medicine used to treat heartburn e.g., cisapride and cimetidine.
- Barbiturates e.g., phenobarbital used for sedation, anxiety and/or seizure disorders.
- Colestyramine, used to treat high fat levels in the blood, or instances where runny stools are due to issues with bile-acid malabsorption.
- Anticoagulants to thin your blood e.g., warfarin.

- Salicylates e.g., aspirin, medicine used to treat pain due to inflammatory conditions or fever.
- Isoniazid, a medicine used to treat tuberculosis.
- Probenecid, a medicine used to treat gout.
- Other opioid pain medicine e.g., tramadol, fentanyl, oxycodone, meperidine.
- Atropine, medicine found in certain eye drops to cause relaxation of a muscle in the eye or for diagnostic procedures.
- Aminoglycosides e.g., gentamicin, tobramycin are antibiotics used in hospital to treat infections.
- Flucloxacillin (antibiotic), as concurrent intake with paracetamol (as contained in LENADOL) has been associated with acid accumulating in the body, especially in patients with risk factors.
- Metoprolol, a medicine used to control the heart rate in high blood pressure, irregular heartbeat, heart attack or heart pain.
- Venlafaxine, a medicine used to treat depression and anxiety disorders.
- Sodium oxybate, a medicine used to treat a sleeping disorder that makes people very sleepy during the day known as narcolepsy.
- Lithium, a medicine used for bipolar mood disorder.
- Interference with laboratory tests: Opioids, such as codeine, as in LENADOL may interfere with gastric emptying studies.

LENADOL with alcohol

You should not drink alcohol whilst you are taking LENADOL, as LENADOL will increase the effects of the alcohol. Alcohol may increase the sedative effects of LENADOL and make you very sleepy.

Pregnancy, breastfeeding and fertility

LENADOL is contraindicated in pregnancy.

You should not take LENADOL 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 this medicine.

Driving and using machines

LENADOL is expected to influence your ability to drive.

LENADOL may lead to drowsiness and impaired concentration. You should not drive, use machinery or perform any tasks that require concentration until you are certain that LENADOL does not adversely affect your ability to do so safely.

It is not always possible to predict to what extent LENADOL may interfere with your daily activities. You should ensure that you do not engage in the above activities until you are aware of the measure to which LENADOL affects you (see section 4).

LENADOL contains lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking LENADOL.

LENADOL contains preservatives

LENADOL contains the preservatives methyl parahydroxybenzoate and propyl parahydroxybenzoate which may cause allergic reactions (possibly delayed).

3. How to take LENADOL

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

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

Adults and children over 12 years:

The usual dose of LENADOL is one or two tablets every 3 to 4 hours. Do not exceed 8 tablets per day.

If you take more LENADOL 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.

Symptoms of overdosage are constipation, nausea, vomiting, loss of appetite, dizziness, drowsiness, abdominal pain, stomach bleeding, potentially fatal liver damage, swelling in the brain and kidney failure, high or low blood sugar levels. Dry mouth, sweating, feeling very cold, confusion, nervousness or restlessness, excitement, slow heart rate, slow or troubled breathing, severe weakness, fits, especially in children.

Additional symptoms may include mydriasis (when the black centre of your eyes is larger than normal), fever, agitation, tremor, involuntary contractions of muscles in the face, neck, trunk, pelvis, extremities, and even the voice box, hallucinations (seeing things that are not there).

Large overdose may cause you to be in a mental state where you are confused, disoriented, and not able to think or remember clearly, toxic psychosis (psychosis due to substance use), dysrhythmias (abnormal heart rhythm).

If you forget to take LENADOL

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

If you stop taking LENADOL

If you have been taking LENADOL for an extended period, you may experience withdrawal symptoms when you stop taking LENADOL. Withdrawal symptoms can include: restlessness, difficulty sleeping, irritability, agitation, anxiety, feeling your heartbeat (palpitations), increased blood pressure, feeling or being sick, diarrhoea, loss of appetite, shaking, shivering or sweating.

4. Possible side effects

LENADOL can have side effects.

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

If any of the following happens, stop taking LENADOL 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,
- blistering of the skin, mouth, eyes and genitals as these may be due to a serious allergic reaction known as Stevens-Johnson Syndrome (SJS), Toxic Epidermal Necrolysis, Drug Rash with Eosinophilia and Systemic Symptoms (DRESS) or Acute Generalised Exanthematous Pustulosis (AGEP).

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

- Changes in the way your heart beats, for example, if you notice it beating faster, palpitations, slower or faster pulse.
- Abnormal laboratory results for white blood cell counts (neutropenia, leucopenia, agranulocytosis and eosinophilia) which may be associated with symptoms such as, but not limited to, high temperature, chills, sore throat, mouth sores, tiredness, flu-like symptoms.
- Tiredness, weakness, shortness of breath, irregular heartbeat, dizziness or light-headedness, chest pain and cold hands and feet could be a sign that your body is not producing enough new blood cells (aplastic anaemia).
- Easy bruising, including abnormal bleeding from nose and/or gums, the presence of blood in the urine or stool and cuts that continue bleeding could be due to a low platelet count (thrombocytopenia, pancytopenia).
- Convulsions (fitting).
- Hypothermia, a medical emergency that occurs when your body loses heat faster than it can produce heat, causing a dangerously low body temperature.

- Headache, blurred vision, vomiting, changes in your behaviour, weakness or problems with moving or talking and lack of energy or sleepiness could be a sign that the pressure inside your head is too high.
- Upper abdominal pain, nausea and vomiting, fat in stool, fast heartrate and sweating could be signs that there is inflammation in the pancreas (pancreatitis).
- Your skin and/or eyes become yellow, with possible nausea, abdominal pain, fatigue and fever as these could be signs that your liver is inflamed (hepatitis) or that your liver is not working (liver failure).
- Your urine output is possibly decreased or increased, and you retain fluid that causes swelling in your legs, ankles or feet could be a problem with your kidneys (renal failure or nephropathy).
- Inability to urinate (anuria).
- Seeing or hearing things that are not really there (hallucinations).
- Allergic skin conditions such as erythema multiforme, exfoliative or bullous dermatitis.
- Sharp intense pain around the abdominal area (renal colic).
- Exacerbation of porphyria (a rare hereditary disease in which there is abnormal metabolism of the blood pigment haemoglobin. Porphyrins are excreted in the urine, which becomes dark; other symptoms include mental disturbances and extreme sensitivity of the skin to light).

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

Tell your doctor if you notice any of the following:

Frequent side effects:

- Drowsiness or dizziness, disturbed attention, feeling unsteady,
- feeling sick or being sick (nausea), vomiting,
- constipation,

- confusion,
- a sudden reddening of the face due to increased blood flow (facial flushing),
- dry mouth,
- feeling of tiredness or lack of energy (fatigue).

Less frequent side effects:

- Tightening of the muscles that line the airways in your lungs (bronchospasms),
- restlessness, mood changes,
- feeling you are going to become unconscious (faintness), feeling like your environment is spinning in circles (vertigo),
- having small pupils (in the eyes),
- sweating,
- cloudy urine as this may be a symptom of sterile pyuria,
- drug withdrawal syndrome.

Side effects with an unknown frequency:

- Physical and mental weakness (lassitude), lack of energy or feeling unwell and weak (malaise),
- diarrhoea, stomach cramps and pain, development of stomach ulcers due to increased stomach secretions,
- headache,
- feeling faint on standing up,
- insomnia (inability to sleep),
- tingling or pricking (‘pins and needles’) feeling (paraesthesia),
- blurred vision, double vision or other changes in vision,
- depression and sadness,

- feeling extremely happy for no particular reason,
- feeling nervous, restless, or tense (anxiety), feeling frustrated or angry over small matters (irritability),
- feeling very unhappy, uneasy, or dissatisfied (dysphoria),
- nightmares,
- tinnitus (ringing in the ears),
- difficulty or pain in passing urine, passing less urine than usual,
- stinging or burning when emptying the bladder (dysuria),
- biliary spasm (causing pain in the right side of your abdomen, particularly after eating a meal, which may, spread towards your right shoulder),
- hyperglycaemia (abnormally high levels of sugar in the blood),
- fever (high body temperature),
- anorexia (an eating disorder),
- a painful, warm, or red lump under your skin could be due to enlarged lymph nodes (lymphadenopathy),
- pain or fullness in the left upper belly that can spread to the left shoulder could be due to an enlarged spleen (splenomegaly),
- uncontrolled muscle movements and restlessness, muscle rigidity, twitching and weakness,
- low blood pressure (on standing) (postural hypotension),
- reduced sexual drive or impotence (inability for a male to get an erection),
- involuntary body movements (dyskinesias),
- low blood pressure (hypotension),
- shortness of breath (dyspnoea), tight chest and thick mucus (phlegm) from lungs,
- purple or brownish-red spots on the skin or mucous membranes (purpura),

- a spot or flickering near the centre of your vision that prevents you from seeing (scintillating scotoma),
- headache, nausea, vomiting, confusion, dizziness, feeling week or tired, loss of appetite and increased heartbeat due to high acidity in the body (pyroglutamic aciduria (5-oxoprolinuria) and high-anion gap metabolic acidosis).

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, pharmacist or nurse. You can also report side effects to:

SAHPRA: via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.

Aspen Pharmacare:

E-mail: Drugsafety@aspenpharma.com

Tel: 0800 118 088/+27 (0) 11 239-6200

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

5. How to store LENADOL

Store all medicines out of reach of children.

Store at or below 25 °C.

Protect from light and moisture.

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 LENADOL contains

The active substance is 10 mg of codeine phosphate, 5 mg of diphenhydramine hydrochloride, 400 mg of paracetamol and 50 mg caffeine anhydrous.

The other ingredients are lactose monohydrate, magnesium stearate, maize starch, methyl parahydroxybenzoate, microcrystalline cellulose, polysorbate 80, povidone, propyl parahydroxybenzoate, purified talc, quinoline yellow, sodium starch glycollate.

Preservatives:

Methyl parahydroxybenzoate 0,019 % *m/m*

Propyl parahydroxybenzoate 0,003 % *m/m*

Contains sugar: Lactose monohydrate 32,87 mg

What LENADOL looks like and contents of the pack

Yellow, round, flat, bevelled edge tablet, bisected on one side, and debossed with “A79” on the other side.

18 or 40 tablets are packed in a white round polypropylene container with a white linear low density polyethylene closure with tamper evident seal, together with a rayon or white foam insert and a leaflet.

Not all pack sizes are necessarily marketed.

Holder of Certificate of Registration

PHARMACARE LIMITED

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Registration number

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Access to the corresponding Professional Information

SAHPRA Repository of Professional Information and Patient Information Leaflets:

https://www.sahpra.org.za/pi-pil-repository/

Aspen Pharmacare:

E-mail: Medinfo@aspenpharma.com

Tel: 0800 118 088

Botswana: BOT0400719 S3

Namibia: NS1 90/2.9/001018

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