PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S2

LENASPASM 35 mg/450 mg tablets

Orphenadrine citrate, paracetamol

Sugar free

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

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

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

- Keep this leaflet. You may need to read it again.
- Do not share LENASPASM 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 10 days.

What is in this leaflet

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

1. What LENASPASM is and what it is used for

LENASPASM is a combination of two active ingredients, orphenadrine and paracetamol. Orphenadrine belongs to a group of medicines called muscle relaxants and paracetamol to a group called analgesics (it relieves pain). LENASPASM is used in adults for the treatment of generalised mild to moderate pain and/or fever and to relieve muscle spasm associated with acute painful musculoskeletal conditions.

2. What you need to know before you take LENASPASM

Do not take LENASPASM if you:

- Have hypersensitivity (an allergy) to paracetamol, orphenadrine citrate or to any of the other ingredients in LENASPASM (listed in section 6).
- Have severe liver function impairment.
- Have an enlarged prostate or obstruction of the bladder neck.
- Have paralysis in your bowels or a thickening or obstruction of the opening between the stomach and small intestine or an obstruction in the small intestine.
- Suffer from a disorder called cardio-spasm/ mega-oesophagus which may prevent food and liquid from passing into the stomach.
- Suffer from a condition called porphyria (a group of disorders caused by an over-accumulation of porphyrin which helps haemoglobin, the protein that carries oxygen in the blood).
- Have a condition causing abnormal weakness of certain muscles (myasthenia gravis).

- Have a disease called glaucoma where there is increased pressure in your eye.
- Are at risk of a life-threatening increase in your body temperature when the air temperature immediately surrounding you is high.

Warnings and precautions

LENASPASM 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. Dosages of LENASPASM in excess of those recommended may cause severe liver damage.

Take special care with LENASPASM if you:

- Suffer from non-cirrhotic alcoholic liver disease or any liver disease.
- Are over the age of 65.
- Have problems with your thyroid gland (thyrotoxicosis).
- Suffer from any heart disease or will be having heart surgery (cardiac surgery).
- Are unable to completely empty your bladder.
- Suffer from kidney disease
- Experience a feeling of intense excitement and happiness when taking LENASPASM.

Other medicines and LENASPASM

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

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

- *Other medicines that contain paracetamol:* used to treat pain, fever and/or colds and flu. LENASPASM contains paracetamol, and this must be taken into account if other medicines containing paracetamol are taken, in order not to exceed the recommended daily dose.
- *Medicines that depress (slow down) the central nervous system (sedatives, tranquilisers, hypnotics):* The depressant (slowing down) effect on the central nervous system may be intensified when used with LENASPASM.
- *Anticonvulsant medicines used for seizures (fits):* These medicines may cause very high levels of paracetamol when used together with LENASPASM.
- *Cholestyramine:* medicine used to treat high cholesterol levels in the blood. The effect of LENASPASM may be weakened.
- *Other medicines such as amantadine (medicine used to treat Parkinson's disease), some antihistamines (used to treat allergies), butyrophenones and phenothiazine antipsychotics (used to treat psychotic disorders) and tricyclic antidepressants (used to treat depression) (e.g amitriptyline, nortriptyline):* The effect of LENASPASM may be intensified.
- *Antidepressant medicines such as selegiline and rasagiline:* The effect of LENASPASM may be intensified.
- *Gut motility enhancers (e.g. cisapride, domperidone, metoclopramide):* medicine used to increase muscular contractions of the gut and the movement of food through the intestines and to treat nausea. The effect of LENASPASM may be

intensified and LENASPASM can also diminish the effect of these medicines.

- *Medicines that decrease gut motility (e.g. propantheline, antidepressants with anticholinergic properties and narcotic agents).* These medicines may decrease the absorption of paracetamol in LENASPASM, thereby diminishing the effect of LENASPASM.

- *An antibiotic called chloramphenicol:* Paracetamol in LENASPASM may increase its effect.

- *Propoxyphene, a pain relieving medicine:* Confusion, anxiety and tremors (shaking) may occur. Your dose might need to be reduced or the medication stopped.
- *Bupropion:* medicine used to treat depression. LENASPASM may intensify the effect of bupropion.

- *Anticoagulants (e.g. warfarin) and anti-platelet medicines:* medicine used to prevent or treat blood clots. LENASPASM may intensify the effect of anticoagulants and increase bleeding risk.

- *Chlorpromazine:* LENASPASM, may weaken the effect of chlorpromazine.

- *Parasympathomimetics, medicines such as those used for the treatment of Alzheimer's disease and in certain heart conditions*. LENASPASM may counter the effects.

- *Other medicines*. LENASPASM slows down the movement of medicines along the gut and may therefore affect their absorption.

LENASPASM with alcohol

LENASPASM, may increase central nervous system depression (slowing down) and should not be taken with alcohol.

Alcohol may cause very high levels of paracetamol when used together with LENASPASM.

Pregnancy, breastfeeding and fertility

You should not take LENASPASM 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 LENASPASM.

Driving and using machines

Since adverse reactions such as dizziness, fainting, light-headedness, sleepiness and blurred vision have been reported in patients receiving LENASPASM, you should not drive, use machinery or perform any tasks that require concentration, until you are certain that LENASPASM does not adversely affect your ability to do so.

It is not always possible to predict to what extent LENASPASM may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which LENASPASM affects them (see section 4).

3. How to take LENASPASM

Do not share medicines prescribed for you with any other person. Always take LENASPASM exactly as described in this leaflet or as your doctor, pharmacist or nurse has told you.

Check with your doctor, pharmacist or nurse if you are not sure. The usual dose of LENASPASM is

Adults:

Two tablets three or four times a day.

DO NOT EXCEED THE RECOMMENDED DOSE.

LENASPASM is not recommended for children under 18 years of age.

If you take more LENASPASM 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.

Overdosage with LENASPASM can cause serious liver problems and death. Symptoms of overdosage include pallor, nausea, vomiting, stomach pain, fast or uneven heartbeat, rapid breathing, high fever, confusion, hallucinations, fits and fainting.

If you forget to take/use LENASPASM

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

4. Possible side effects

LENASPASM can have side effects.

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

If any of the following happens, stop taking LENASPASM 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 (hypersensitivity reactions, anaphylactic shock);
- rash (that is usually erythematous or urticarial, sometimes accompanied by fever and mucosal lesions) or itching (angioedema);
- fainting;
- rapid appearance of areas of red skin studded with pinhead-sized pus- filled blisters that starts on the face or in the armpits and groin and then becomes more widespread (acute generalised exanthematous pustulosis);
- peeling and/or blistering of the skin, mouth, eyes and genitals that spreads quickly as these may be due to a serious allergic reaction known as Stevens-Johnson Syndrome (SJS) or Toxic Epidermal Necrolysis (TEN).

These are all very serious side effects. If you have them, you may have had a serious reaction to LENASPASM. 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 or slower, heart attack with symptoms such as chest pain, shortness of breath, light-headedness and anxiety.
- Development of blood disorders that affect your blood cells as identified during laboratory testing.
- A reduction of blood cells (due to failure of the bone marrow) which can cause weakness, bruising or make infections more likely (aplastic anaemia).
- Upper abdominal pain, feeling bloated, nausea and vomiting.

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

Tell your doctor if you notice any of the following:

Side effects with an unknown frequency:

- Thirst;
- inability to sleep (insomnia);
- mental confusion (especially in the elderly);
- drowsiness;
- seeing or hearing things that are not really there (hallucinations);
- feeling extremely restless or irritated (agitation);
- staggering, light-headedness, giddiness (feeling faint or as if head is spinning);

- an unintentional muscle movement involving to- and-fro movements (oscillations) of one or more parts of the body. Shaking or quivering (tremor);
- dizziness;
- headache;
- dilated pupils, difficulty in focusing your eyes (loss of accommodation/blurred vision), sensitivity of the eyes to light (photophobia), increased pressure in the eye (increased intraocular pressure);
- reddening of the skin (flushing);
- fainting (syncope);
- reduced secretions from your lungs that may lead to mucus (phlegm) plugs;
- dry mouth, difficulty swallowing leading to constipation and pain caused by indigestion/reflux;
- nausea, gastric irritation;
- desire to urinate with the inability to do so, urinary hesitancy, urinary retention;
- dryness of the skin, pruritus, urticarial and other dermatoses;
- weakness.

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: https://www.sahpra.org.za/health-products-vigilance/

Aspen pharmacare:

E-mail: Drugsafety@aspenpharma.com

Tel: 0800 118 088

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

5. How to store LENASPASM

Store all medicines out of reach of children.

Store at or below 30 °C.

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 LENASPASM contains

The active substances are 35 mg orphenadrine citrate and 450 mg paracetamol.

The other ingredients are magnesium stearate, microcrystalline cellulose, povidone, pregelatinised starch.

Sugar free.

What LENASPASM looks like and contents of the pack

LENASPASM is a white to off white, oblong shaped tablet debossed with "E 47" on one side and a break line on the other side. The tablet can be divided into equal halves.

PVC/PE/PVDC/Al blisters with 12 tablets per blister strip. Two or four blister strips are packed into a carton in pack sizes of 24 or 48.

Holder of Certificate of Registration

PHARMACARE LIMITED

Healthcare Park

Woodlands Drive

Woodmead 2191

Hotline: 0800 122 912

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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

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