

1.3.2 PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S2

LENAZINE FORTE COUGH LINCTUS

Each 5 ml of LENAZINE FORTE COUGH LINCTUS contains:

Codeine phosphate 9,0 mg

Ephedrine hydrochloride 7,2 mg

Promethazine hydrochloride 3,6 mg

In a flavoured syrup base.

Preservative:

Methyl hydroxybenzoate 0,1 % *m/v*

Contains sugar: Sucrose 2 g, liquid glucose 2 g

Contains sweetener: Saccharin sodium 3,6 mg

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

LENAZINE FORTE COUGH LINCTUS is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use LENAZINE FORTE COUGH LINCTUS carefully to get the best results from it.

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

2. What you need to know before you take LENAZINE FORTE COUGH LINCTUS.
3. How to take LENAZINE FORTE COUGH LINCTUS.
4. Possible side effects.
5. How to store LENAZINE FORTE COUGH LINCTUS.
6. Contents of the pack and other information.

1. What LENAZINE FORTE COUGH LINCTUS is and what it is used for

LENAZINE FORTE COUGH LINCTUS is used for the alleviation of cough.

2. What you need to know before you take LENAZINE FORTE COUGH LINCTUS

Do not take for longer than directed by your pharmacist or doctor. Taking LENAZINE FORTE COUGH LINCTUS regularly for a long time can lead to addiction, which might make you feel restless and irritable when you stop taking the medicine.

Do not take LENAZINE FORTE COUGH LINCTUS:

- if you are hypersensitive (allergic) to codeine phosphate, ephedrine hydrochloride, promethazine hydrochloride or any of the other ingredients of LENAZINE FORTE COUGH LINCTUS (listed in section 6).
 - If you have respiratory depression (abnormally slow or shallow breathing).
 - If you are dependent on alcohol.
 - If you have head injuries, or conditions in which the pressure inside the skull is raised.
 - If you are taking medicines called mono-amine oxidase inhibitors, such as moclobemide and tranylcypromine, (used to treat conditions such as depression), or within 14 days of stopping such treatment.
 - During severe attacks of asthma.

- If you have heart failure caused by a lung condition.
- If you are pregnant or breastfeeding (see **Pregnancy and breastfeeding**).
- Do not use in premature infants or neonates (newborn babies).
- Do not use in children under 2 years of age.
- If you are between 12 and 18 and you are undergoing a procedure to remove your tonsils or adenoids for obstructive sleep apnoea syndrome.
- If you are an ultra-rapid metaboliser of CYP2D6 (see **Warnings and precautions**).
- If you have any of the following conditions where inhibition of contractions of the digestive tract (peristalsis) should be avoided: where there is a risk of a condition where the movement of the bowel is impaired (paralytic ileus), where bloating and swelling in the belly area (abdominal distension) develops, or in acute diarrhoeal conditions such as acute ulcerative colitis or antibiotic associated colitis (e.g. pseudomembranous colitis) or diarrhoea caused by poisoning.

Warnings and precautions

Take special care with LENZAINE FORTE COUGH LINCTUS:

This medicine may lead to drowsiness and impaired concentration, which may be worsened by the simultaneous intake of alcohol, or any calming or sleeping medication (central nervous system depressant agents).

Do not drive a motor vehicle, operate dangerous machinery or climb dangerous heights, as impaired decision making could lead to accidents.

- Taking more than the recommended dose and continuous use of this medicine for a long time may lead to dependency and addiction.
- If you have hypothyroidism (underactive thyroid gland) or hyperthyroidism (overactive thyroid gland).
- If you have a condition where your adrenal gland does not produce enough steroid hormones (such as cortisol).
- If your kidneys or liver are not functioning properly.
- If you have an enlarged prostate gland.
- If you have a sudden drop in blood pressure or shock (a condition where there is not enough blood flow through the body).
- If you have a condition where your bowel is blocked.
- If you have myasthenia gravis (disorder causing muscle weakness).
- If you are an ultra-rapid metabolizer of CYP2D6, you should not take LENA ZINE FORTE COUGH LINCTUS (see Do not take LENA ZINE COUGH FORTE LINCTUS). Even small doses of codeine can lead to increased formation of the active metabolite_morphine which can cause symptoms of morphine intoxication (see If you take more LENA ZINE FORTE COUGH LINCTUS than you should).
- If you have heart or blood vessel disease, occlusive vascular disorders (circulatory condition in which narrowed blood vessels reduces blood flow), or aneurysms (weakened area in a blood vessel).
- If you have angina (chest pain caused by reduced blood flow to_the heart), the chest pain may worsen.
- If you have diabetes mellitus (a condition where you have too much sugar in the blood).
- If you have closed-angle or narrow angle glaucoma (eye condition).

- If you undergo anaesthesia (where a halogenated anaesthetic, such as halothane or isoflurane, is given to make you unconscious during surgery).
- LENA ZINE FORTE COUGH LINCTUS may cause an increased risk of dysrhythmias (irregularity of the heartbeat) if you are taking cardiac glycoside medicines such as digoxin (used to treat heart conditions), quinidine (used to treat irregular heartbeat) or tricyclic antidepressants (such as amitriptyline).
- If you suffer from urinary retention (difficulty in emptying the bladder) or any bladder related obstructions.
- If you are taking antihypertensives (medicines to reduce your blood pressure), LENA ZINE FORTE COUGH LINCTUS may increase the blood pressure lowering effect of the antihypertensives.
- You should not take LENA ZINE FORTE COUGH LINCTUS if you have breathing problems or suffer from asthma.
- If you suffer from alcoholism, substance abuse or dependence or mental illness.
- Elderly patients are more likely to be affected by the adverse effects of LENA ZINE FORTE COUGH LINCTUS.
- If you are taking salicylates such as aspirin, used to treat pain due to inflammatory conditions or fever, LENA ZINE FORTE COUGH LINCTUS may mask warning signs of damage to your ears.
- If you have a head injury in which the pressure in your brain is raised (raised intracranial pressure) or intestinal blockage, LENA ZINE FORTE COUGH LINCTUS may delay early detection of the above due to the suppression of vomiting as a result of the promethazine hydrochloride as contained in LENA ZINE FORTE COUGH LINCTUS.

Children and adolescents

LENAZINE FORTE COUGH LINCTUS is contraindicated in children under 2 years of age.

LENAZINE FORTE COUGH LINCTUS should not be taken by children or adolescent with any signs suggestive of Reye's syndrome.

LENAZINE FORTE COUGH LINCTUS should not be given to children and adolescents under 18 years of age who undergo surgery to remove their tonsils (tonsillectomy) or surgery to remove their adenoids (adenoidectomy) (or both).

LENAZINE FORTE COUGH LINCTUS should not be given to children with breathing problems (compromised respiratory function), chest infections (upper respiratory or lung infections), any heart or lung related issue.

If you are taking salicylates such as aspirin, multiple trauma or extensive surgical procedures. These factors may worsen the symptoms of morphine toxicity.

Other medicines and LENAZINE FORTE COUGH LINCTUS

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

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

- Mono-amine oxidase inhibitors, such as moclobemide and tranylcypromine (used to treat conditions such as depression), or if you have taken such medicines within the last 14 days.
- Cardiac glycoside medicines such as digoxin (used to treat heart conditions).
- Medicines to treat allergies (antihistamines) that can cause drowsiness.
- Mexiletine (used to treat irregular heartbeat).
- Tricyclic antidepressants (such as amitriptyline).

- If you are to undergo anaesthesia (where an anaesthetic, such as halothane or isoflurane, is given to make you unconscious during surgery).
- Antihypertensives (medicines to reduce your blood pressure) as the blood pressure lowering effect may be increased.
- Alcohol or central nervous system depressants as the depressant or sedative effects may be enhanced.
- Antipsychotics (e.g. haloperidol, aripiprazole): medicines used to treat psychotic disorders.
- Hypnotics and anxiolytics (e.g. chlorpromazine, diazepam, temazepam): medicines which affect the nervous system.
- Cisapride, metoclopramide and domperidone: medicines used to treat nausea (feeling or being sick) and vomiting.
- Atropine (used to treat stomach conditions).
- Antibiotics, such as gentamicin, as LENA ZINE FORTE COUGH LINCTUS may hide the warning signs of damage to your ears.
- Interference with laboratory tests: Opioids, such as codeine, as in LENA ZINE FORTE COUGH LINCTUS may interfere with gastric emptying studies.

LENA ZINE FORTE COUGH LINCTUS with alcohol:

Do not take LENA ZINE FORTE COUGH LINCTUS 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 LENA ZINE FORTE COUGH LINCTUS.

The safety of LENA ZINE FORTE COUGH LINCTUS in pregnancy and breastfeeding has not been established.

You should not take LENAZINE FORTE COUGH LINCTUS if you are pregnant.

If you are pregnant or breastfeeding your baby, please consult your healthcare provider for advice before taking LENAZINE FORTE COUGH LINCTUS.

Driving and using machines

It is not always possible to predict to what extent LENAZINE FORTE COUGH LINCTUS may interfere with your daily activities.

LENAZINE FORTE COUGH LINCTUS may make you drowsy/sleepy and reduce your concentration. These effects may be made worse by taking alcohol, or any other central nervous system depressant agents at the same time.

Do not to drive a motor vehicle, operate dangerous machinery or climb dangerous heights, as impaired decision making could lead to accidents.

You should ensure that you do not engage in the above activities until you are aware of the measure to which LENAZINE FORTE COUGH LINCTUS affects you.

LENAZINE FORTE COUGH LINCTUS contains:

LENAZINE FORTE COUGH LINCTUS contains glucose and sucrose which may have an effect on the control of your blood sugar if you have diabetes mellitus.

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking LENAZINE FORTE COUGH LINCTUS.

3. How to take LENAZINE FORTE COUGH LINCTUS

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

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

DO NOT EXCEED THE RECOMMENDED DOSE.

The usual dose is:

Adults

Take one to two medicine measuresful (5 ml to 10 ml) 2 to 3 times a day.

Children

12 years and over: Take one to one and a half medicine measuresful (5 ml to 7,5 ml) 2 to 3 times a day.

7 to 11 years: Take half to one medicine measureful (2,5 ml to 5 ml) 2 to 3 times a day.

2 to 6 years: Take quarter to half a medicine measureful (1,25 ml to 2,5 ml) 2 to 3 times a day.

Do not use LENA ZINE FORTE COUGH LINCTUS for longer than 5 days.

If you take more LENA ZINE FORTE COUGH LINCTUS than you should

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

Signs and symptoms of overdosage include excitation, convulsions (fits), hallucinations, respiratory depression (very slow and/or shallow breathing), nausea, vomiting, drowsiness, hypotension (low blood pressure), hypertension (high blood pressure), excessive sleepiness (somnolence), circulatory failure and coma.

Overdose may cause death, especially in children.

If you forget to take LENA ZINE FORTE COUGH LINCTUS

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

4. Possible side effects

LENAZINE FORTE COUGH LINCTUS can have side effects.

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

If any of the following happens, stop taking / using LENAZINE FORTE COUGH LINCTUS 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 LENAZINE FORTE COUGH LINCTUS. 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:

- Cardiac arrest (sudden, unexpected loss of heart function, breathing and consciousness);
- angina (chest pain);
- changes in the way your heart beats, for example, if you notice it beating faster or

slower, or your heartbeat is irregular;

- difficulty breathing or shortness of breath;
- coma (state of unconsciousness in which a person cannot be awakened);
- convulsions (fits), especially in infants and children with high doses;
- increased pressure inside the skull (symptoms include headache, nausea, vomiting, increased blood pressure, confusion);
- circulatory failure (failure of the heart and blood vessels to supply the body with enough blood to function properly);
- yellowing of the skin or whites of the eyes which may be caused by liver or blood problems;
- serious blood disorders, such as severe decrease in a particular type of white blood cells which makes infections more likely, too few white blood cells, reduction in red blood cells which can make the skin pale yellow and cause weakness or breathlessness, reduction in blood platelets which increases risk of bleeding or bruising.
- inflammation of the pancreas, which causes severe pain in the abdomen and back (pancreatitis);
- increased heart rate (tachycardia), sensation that your heart is_pounding (palpitations);
- tightness of the chest;
- enlarged spleen (splenomegaly), swollen lymph nodes (lymphadenopathy);
- slow heart beat, sensation that your heart is pounding (palpitations).

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

Tell your doctor if you notice any of the following:

Frequent

- Drowsiness/sleepiness, confusion;
- miosis (pupil of the eye stays small, even in dim light);
- dry mouth, constipation;
- anxiety, restlessness, unable to sleep, headache;
- nausea;
- blurred vision;
- dizziness, lack of energy, lack of co-ordination;
- difficulty or pain in passing urine.

Less frequent

- Euphoria (false feeling of well-being);
- psychotic states (mental disorders);
- depression, confusion, mood changes;
- tinnitus (ringing in the ears);
- unusual brain stimulation, especially in high doses in children or elderly;
- low blood pressure, drop in blood pressure when standing up which can cause dizziness and fainting;
- itching, skin rash, sweating;
- muscle stiffness or cramps;
- spasm of the kidney duct, spasm of the bile duct and antidiuretic effect (water retention);
- facial flushing (redness);
- hypothermia (low body temperature);
- tremor, fear;
- diarrhoea, pain or discomfort below your ribs in your upper stomach;
- sensitivity to light.

The following side effects have been reported but the frequency is unknown:

- Changes in metabolism (physical and chemical processes in the body), including glucose metabolism;
- sudden spinning sensation (vertigo);
- loss of appetite (anorexia);
- inflammation of the pancreas, which causes severe pain in the abdomen and back (pancreatitis);
- sexual dysfunction;
- shortness of breath (dyspnoea);
- excess saliva in the mouth;
- irritability, weakness;
- unable to empty the bladder;
- muscle spasms, restlessness and contractions, rigid and slow movement, tremor, and irregular, jerky movements.

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 “6.04 Adverse Drug Reactions Reporting Form”, found online under SAHPRA’s publications: <https://www.sahpra.org.za/Publications/Index/8>.

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 LENZAINE FORTE COUGH LINCTUS.

5. How to store LENZAINE COUGH FORTE LINCTUS

Store all medicines out of reach of children.

Store at or below 25 °C.

Keep in original packaging until required for use.

Protect from light and keep container well closed.

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 LENZAINE FORTE COUGH LINCTUS contains

The active substances in each 5 ml are 9 mg codeine phosphate, 7,2 mg ephedrine hydrochloride, 3,6 mg promethazine hydrochloride.

The other ingredients are caramel 48000 or dye Lennon brown no. 112, chloroform spirit, flavour sweet orange essence, glycerol, hydrochloric acid (for pH adjustment), liquid glucose, methyl hydroxybenzoate, purified water, saccharin sodium, sucrose.

Preservatives:

Methyl hydroxybenzoate 0,1 % *m/v*

Contains sugar: Sucrose 2 g, liquid glucose 2 g

Contains sweetener: Saccharin sodium 3,6 mg

What LENZAINE FORTE COUGH LINCTUS looks like and contents of the pack

LENAZINE FORTE COUGH LINCTUS is a a bright orange-brown syrupy liquid with an orange odour.

100 ml is packed into a round, amber glass bottle and sealed with a round, flat topped white polypropylene screw-on child-lock cap with an expanded polyethylene liner and translucent polyethylene tamper evident band. The bottle is packed in an outer cardboard carton.

Holder of Certificate of Registration

PHARMACARE LIMITED

Healthcare Park

Woodlands Drive

Woodmead 2191

Hotline: 0800 122 912

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Registration number

G0533 (Act 101/1965)

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: B9322460 S3

Namibia: NS1 15/2.8/0125

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