PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S2

PHENERGAN 10 coated tablets

PHENERGAN 25 coated tablets

Promethazine hydrochloride

Contains sugar.

PHENERGAN 10: Each tablet contains 11,7 mg lactose monohydrate and 13,7 mg sucrose.

PHENERGAN 25: Each tablet contains 29,3 mg lactose monohydrate and 29,6 mg sucrose.

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

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

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

- Keep this leaflet. You may need to read it again.
- Do not share PHENERGAN with any other person.
- Ask your health care provider if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve after 7 days.

What is in this leaflet

1. What PHENERGAN is and what is it used for

PHENERGAN contains a medicine called promethazine hydrochloride. This belongs to a group of medicines called phenothiazines. It works by blocking a natural substance (histamine) that your body makes during an allergic reaction.

PHENERGAN is used to treat allergic conditions, such as hay fever, chronic sneezing, blocked or runny nose, skin rash and swollen, itchy areas.

2. What you need to know before you take PHENERGAN

Do not take PHENERGAN if:

- You are hypersensitive (allergic) to promethazine hydrochloride, other phenothiazines or any of the other ingredients of PHENERGAN listed in section 6 of this leaflet.
- The person taking PHENERGAN is younger than two years old.
- You or your child have signs and symptoms of a condition called Reye's syndrome, such as confusion, fatigue, fast breathing, nausea (feeling sick), vomiting (being sick), mental changes, loss of consciousness or seizures (fits).
- A child is very ill at present and might suffer from dehydration (increased thirst, dry mouth, swollen tongue, weakness, confusion).
- You have an acute asthma attack.
- The patient is unconscious (in a coma).
- You have any form of central nervous system depression.
- You are taking a medicine for depression called a monoamine oxidase inhibitor (MAOI). Also do not take PHENERGAN if you have stopped taking one of these MAOI medicines within the last 14 days. If you are not sure ask your doctor or pharmacist (see 'Other medicines and

PHENERGAN' below).

Warnings and precautions

Take special care with PHENERGAN:

- If you experience an allergic reaction (see section 4; 'Possible side effects'), seek medical help immediately.
- The use of PHENERGAN may lead to drowsiness and impaired concentration, which may be aggravated by simultaneous intake of alcohol (see 'PHENERGAN with food, drink and alcohol').
- If you develop a fever or infection, talk to your doctor immediately as laboratory tests to check your blood count may be required.
- If you have any personal or family history of heart disease.
- If you have irregular heartbeat.
- If you have liver or kidney problems.
- If you suffer from Parkinson's disease.
- If you have an underactive thyroid gland.
- If you have been diagnosed with pheochromocytoma (a tumour of your adrenal gland).
- If you have been diagnosed with myasthenia gravis (weakness of your muscles causing weakness in your legs and arms, mouth and throat, double vision, drooping eyelids or difficulty in swallowing).
- If you have a stomach blockage or difficulty passing water.
- If you have increased pressure in the eye (narrow angle glaucoma).
- If you have an enlarged prostate.
- If you have a seizure disorder (such as epilepsy/fits), talk to your doctor first before taking PHENERGAN.
- If you suffer from asthma, bronchitis (cough, fatigue, shortness of breath, chest discomfort,

chills) or bronchiectasis (chronic wet cough, wheezing, shortness of breath).

A very serious and sometimes deadly health problem called neuroleptic malignant syndrome (NMS) may happen. Stop treatment and call your doctor immediately if you have high fever, muscle cramps or stiffness, dizziness, very bad headache, fast heartbeat, confusion, agitation, hallucinations, or are sweating a lot.

PHENERGAN may increase your skin's sensitivity to the sun. Exposure to sunlight or ultraviolet (UV) light should be avoided during and shortly after treatment with PHENERGAN. It is advised to use sunscreen during this time.

Children and adolescents

PHENERGAN should not be used in children below two years of age. Because of the risk of choking, the tablets should be avoided in children who have difficulty swallowing tablets.

Other medicines and PHENERGAN

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

Tell your doctor or pharmacist if you are currently taking, have recently taken or might take any medicines, especially:

- Antidysrhythmic medicines (used to treat an irregular heartbeat).
- Antiepileptics (used for the treatment of epilepsy or seizures [fits]).
- Antipsychotics (used for the treatment of psychiatric illnesses).
- Antihypertensive medicines (used to treat high blood pressure).
- Antidepressants, monoamine oxidase inhibitors (MAOIs) (used to treat depression).
- Antimicrobial medicines (antibiotics used to treat infections).

- Atropine (used as an eye drop to dilate your pupils during eye examinations).
- Barbiturates, hypnotics, sedatives (used to treat sleeping disorders).
- Narcotic analgesic medicines (used to treat pain).
- Tranquillisers (used to reduce tension or anxiety).
- Aminoglycoside antibiotics (used to treat bacterial infections).

Tell your doctor if you are taking PHENERGAN, as it may interfere with skin allergy tests.

PHENERGAN may also interfere with pregnancy tests, giving false results.

PHENERGAN with food, drink and alcohol

PHENERGAN can be taken with or without food. If you experience any stomach pain or cramps, always take PHENERGAN with food or a well-sweetened drink.

PHENERGAN should not be taken with alcohol.

Do not take PHENERGAN within 2 hours of antacid medicines containing aluminium, magnesium or calcium salts.

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 PHENERGAN. Do not take PHENERGAN if you are pregnant or breastfeeding.

Driving and using machines

PHENERGAN may cause drowsiness, dizziness and blurred vision which may affect your ability to drive a vehicle and use machines (see ‘Possible side effects’). Do not drive a vehicle, operate machinery, or do anything else that requires your attention until you know how PHENERGAN affects you.

PHENERGAN contains lactose monohydrate and sucrose

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

3. How to take PHENERGAN

Do not share your medicines with any other person.

Always take PHENERGAN exactly as described in this leaflet or as your doctor or pharmacist has told you. You should check with your doctor or pharmacist if you are unsure.

Adults:

The usual dose is 25 mg at night, before bedtime, for the first evening. The dose may be increased to 50 mg (two 25 mg tablets) or 100 mg (four 25 mg tablets) on the following evenings.

If you have to take PHENERGAN during the day, the usual dose is 10 mg three times a day.

Use PHENERGAN only as recommended. Do not exceed the recommended dose. There have been case reports of promethazine abuse.

Do not take for longer than 7 days.

Children:

5 – 10 years of age:

The usual dose is 10 mg – 25 mg at night, before bedtime.

PHENERGAN 10 and PHENERGAN 25 are not suitable for children younger than 5 years.

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

If you take more PHENERGAN 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 remaining PHENERGAN tablets with you so the doctor will know what you have taken.

If you forget to take PHENERGAN

Do not take a double dose of PHENERGAN to make up for the forgotten dose.

4. Possible side effects

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

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

Allergic reactions (that can occur either immediately or within several days of PHENERGAN administration) that may be life-threatening. Symptoms may include:

- swelling of your hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing, shortness of breath;
- rash or itching;
- fainting.

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

- palpitations (very fast, irregular or forceful heartbeats);
- frequent infections such as fever, severe chills, sore throat or mouth ulcers;
- haemolytic anaemia (fatigue, loss of energy, pale skin, cramps in your legs, difficulty with concentration);
- yellowing of your skin and eyes, also called jaundice;
- eosinophilia (an increase in the number of white blood cells found in a blood test);
- thrombocytopenia (decrease in the number of platelets found in a blood test, which can lead to bleeding and bruising more easily than normal);
- changes in the way your heart beats;
- chest tightness;
- difficulty in passing urine;
- neuroleptic malignant syndrome (NMS) is a serious and potentially life-threatening condition that may happen. Stop treatment and call your doctor immediately if you have high fever, muscle cramps or stiffness, dizziness, severe headache, fast heartbeat, confusion, agitation, hallucinations or are sweating a lot.

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

Tell your doctor as soon as possible if you notice any of the following:

Frequent side effects:

- feeling tired or sleepy, dizziness, headache;
- loss of your sense of direction;
- twitching and jerking of your limbs at night;
- clumsiness and lack of coordination.

Less frequent side effects:

- drowsiness, restlessness, nightmares.

Side effects occurring with an unknown frequency:

- blurred vision, dry mouth;
- over-active behaviour, restlessness, nightmares, disorientation, sleeplessness, nervousness, tremors or fits in children;
- decreased appetite;
- feeling agitated, confused or anxious;
- tinnitus (ringing in your ears);
- confusion, especially in patients 65 years and older;
- low blood pressure (light-headedness);
- nausea (feeling sick), vomiting (being sick), diarrhoea or constipation, increased appetite, stomach pain or irritation;
- increased sensitivity of your skin to the sun;
- urge to move your legs when sitting or lying down, sudden jerking movements of the head and face;
- involuntary muscle movements;
- inability to empty your bladder completely;
- muscle weakness or spasms;
- blocked nose.

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:

- The Pharmacovigilance Unit at Sanofi: za.drugsafety@sanofi.com (email) or 011 256 3700 (tel), or

- 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 PHENERGAN.

5. How to store PHENERGAN

- Store at or below 25 °C.
- Protect from light.
- STORE ALL MEDICINES OUT OF REACH OF CHILDREN.
- Do not use after the expiry date printed on the carton / blister.
- 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 PHENERGAN contains

The active substance in PHENERGAN is promethazine hydrochloride.

PHENERGAN 10: Each tablet contains 10 mg promethazine hydrochloride.

PHENERGAN 25: Each tablet contains 25 mg promethazine hydrochloride.

The other ingredients are acacia powder, Brilliant Blue FCF (colourant) (E133), carnauba wax, dextrin white (technical), kaolin light, lactose monohydrate, magnesium stearate, sucrose, talcum powder, Vinnapas B60 (Vinac B7).

What PHENERGAN looks like and contents of the pack

PHENERGAN 10: Round, blue sugar-coated tablet, approximately 2,7 mm thick and approximately 4,5 mm in diameter.

PHENERGAN 25: Round, blue sugar-coated tablet, approximately 3,6 mm thick and

approximately 6,1 mm in diameter.

PHENERGAN 10 and 25 tablets are packed in securitainers of 100 and 500.

Holder of certificate of registration

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