PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S5

LARGACTIL 25 tablets

LARGACTIL 100 tablets

Chlorpromazine hydrochloride

Contains sugar (lactose and sucrose):

LARGACTIL 25 mg contains 79,7 mg lactose and 17,8 mg sucrose per tablet.

LARGACTIL 100 mg contains 318,8 mg lactose and 67,2 mg sucrose per tablet.

Read all of this leaflet carefully before you start taking LARGACTIL

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- LARGACTIL has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

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

1. What LARGACTIL is and what it is used for

LARGACTIL contains the active ingredient chlorpromazine which belongs to a group of medicines

known as phenothiazines, which act on the central nervous system of your body.

LARGACTIL is used in the management of mental and emotional disorders.

LARGACTIL is used in the management of psychotic conditions to manage excitement, agitation and other psychomotor disturbances (disturbances in movement due to conscious mental activity) in schizophrenic patients and in the treatment of the manic (excited) phase of bipolar depression.

It is also given to control hyperkinetic states (excessive amount of uncontrolled muscular action) and aggression and sometimes to control anxiety and tension in psychiatric conditions.

It may also be used for unstoppable hiccups.

2. What you need to know before you take LARGACTIL

Do not take LARGACTIL if:

- you are hypersensitive (allergic) to chlorpromazine hydrochloride or to any of the ingredients of LARGACTIL (listed in section 6).
- you or someone in your family has a history of circulatory problems or blood clots.
- you have a condition that causes depression of your central nervous system (decreased heart or breathing rate).
- you have a low number of blood cells (bone marrow suppression).
- you have kidney or liver disease.
- you have phaeochromocytoma (high blood pressure due to a tumour near the kidney).
- you have chronic respiratory disorders.
- you have glaucoma (increased pressure in the eye).
- you have a neurological disorder known as parkinsonism.
- you have diabetes mellitus.
- you have increased thyroid activity (hyperthyroidism).
- you have muscle weakness (myasthenia gravis).
- you have urine retention due to prostatic problems.
- you have epilepsy.
- you or your family have a heart condition known as QT-prolongation.

Warnings and precautions

Take special care with LARGACTIL:

- Before you take LARGACTIL, tell your doctor or health care professional if:
  - you are taking medicine for epilepsy.
  - you have heart problems or a family history of heart problems, especially if you or your family have a condition known as QT-prolongation, or if you are taking medicines which may affect the way your heart beats (medicines that can prolong the QT-interval). LARGACTIL should not be used if you have QT-prolongation (see Do not take LARGACTIL).
  - you have any known risk factors or a family history of stroke.
  - you are elderly (65 years of age or older) and if you suffer from dementia.
  - you have diabetes since your doctor may want to monitor your blood sugar levels when you start to take LARGACTIL tablets.
  - you are using a medicine which may suppress your central nervous system (causing drowsiness or sleepiness), e.g. opioid pain killers, sleeping tablets, sedatives or alcohol, or if you are going to have anaesthesia, since these effects may be enhanced when taken together with LARGACTIL.
- Tell your doctor if you develop any of the following symptoms while taking LARGACTIL: nausea (feeling sick), vomiting, loss of appetite (not eating well), stomach pain or yellow discoloration of the skin. These may indicate problems with your liver.
- You should avoid exposure to strong sunlight while taking LARGACTIL or wear suitable clothing if you cannot avoid sunlight.
- You should avoid very cold or very hot environments. LARGACTIL may make it difficult for your body to regulate its temperature.
- Before and during treatment your doctor may want to carry out some tests. These might include blood tests, an electrocardiogram (ECG) to check your heart is working properly and eye tests.

Children

LARGACTIL is not suitable for use in children.

Other medicines and LARGACTIL

Always tell your health care professional if you are taking any other medicine (including complementary or traditional medicine).

Before you take LARGACTIL, tell your doctor or health care professional if you are taking, or have recently taken, any of the following medicines:

- medicines which may increase the amount of LARGACTIL in your blood and lead to an increase in side effects, such as:
  - ciprofloxacin (an antibiotic to treat infections)
  - fluvoxamine (to treat mental disorders)
  - pipemidic acid (to treat kidney and bladder infections)
  - zafirlukast (to treat asthma)
  - oral contraceptives (for birth control in women)
  - phenylpropanolamine (to treat nasal congestion associated with colds, allergies or hay fever)
- amitriptyline (used to treat depression)
- medicines that reduce high blood pressure, such as propranolol and atenolol
- clonidine (for migraine and to lower blood pressure and may cause postural hypotension (light-headedness and fainting due to your blood pressure suddenly falling when you stand up)
- anticholinergic medicines – includes medicines used for motion-sickness, irritable bowel syndrome, asthma or incontinence
- antiparkinsonian medicines (medicines used to treat Parkinson’s disease), e.g. levodopa or carbidopa

- metoclopramide (used for the treatment of nausea)
- medicines which could affect your heart rhythm, including:
  - antidysrhythmic medicines (used to treat abnormal heart rhythm), such as amiodarone or disopyramide
  - medicines used for depression (e.g. citalopram or escitalopram)
  - medicines used to calm emotional and mental problems such as olanzapine or prochlorperazine
  - some non-sedating antihistamines (e.g. loratadine or cetirizine)
  - antimalarials (e.g. chloroquine)
  - diuretics (water tablets) or medicines which can alter electrolytes (salt levels) in your blood
  - medicines used for depression (e.g. imipramine, trimipramine)
- medicines that cause drowsiness or make you less alert, such as narcotic painkillers, sleeping tablets and medicines for anxiety (these effects may be worsened)
- general anaesthesia (used to put you in a sleep-like state before surgery or other medical procedures)
- medicines for diabetes (your dose may need to be adjusted)
- medicines for indigestion and heartburn (antacids) (LARGACTIL should be taken at least 2 hours before or after antacids)
- lithium (used for some types of mental illness)
- medicines for epilepsy (your dose may need to be adjusted).

LARGACTIL with food, drink and alcohol

Do not drink alcohol while being treated with LARGACTIL. This is because alcohol can increase the effects of LARGACTIL and cause serious breathing problems.

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

LARGACTIL.

Do not take LARGACTIL if you are pregnant or breastfeeding.

The following symptoms may occur in newborn babies, of mothers that have used LARGACTIL tablets in the last trimester (last three months) of their pregnancy: shaking, muscle stiffness and/ or weakness, sleepiness, agitation, breathing problems, and difficulty in feeding. If your baby develops any of these symptoms you may need to contact your doctor.

LARGACTIL may make it more difficult for a woman to get pregnant due to it reducing her fertility.

Driving and using machines

LARGACTIL may cause drowsiness. Take special care when driving or operating machinery.

LARGACTIL contains lactose and sucrose

LARGACTIL contains lactose and sucrose which may have an effect on the control of your blood sugar if you have diabetes mellitus. Patients with the rare hereditary conditions of lactose/fructose or galactose intolerance should not take LARGACTIL.

If you have been told by your doctor that you have an intolerance to some sugars or if you have diabetes mellitus, contact your doctor before taking LARGACTIL.

3. How to take LARGACTIL

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

Always take LARGACTIL exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are not sure.

Your doctor will tell you how long your treatment with LARGACTIL will last. Do not stop taking LARGACTIL early because you feel better or you have the impression that LARGACTIL is too strong or weak for you.

Always swallow the tablets whole with a full glass of water. Do not chew the tablets.

The usual starting oral dose for adults is 25 to 50 mg three times daily. Daily doses of 75 mg may be given as a single dose at night. Lower doses may be sufficient in some cases.

To treat intractable hiccups patients are given tablets orally: 25 to 50 mg three or four times a day for 2 to 3 days.

For elderly and weak or infirm patients, the recommended LARGACTIL dose is one-third to one-half the normal adult dose.

This formulation is not suitable for use in children.

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

If you take more LARGACTIL 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.

If you forgot to take LARGACTIL

If you forgot to take a dose, simply continue to take LARGACTIL as prescribed by your doctor or pharmacist. Do not take a double dose to make up for forgotten individual doses.

If you stop taking LARGACTIL

Do not stop taking LARGACTIL without talking to your doctor or pharmacist, even if you feel better. Withdrawal symptoms can occur after you stop treatment abruptly, such as feeling sick, vomiting, diarrhoea, not being able to sleep, sweating, restlessness, anxiety and tremor (see section 4). Your doctor will advise you on how to gradually withdraw your treatment with LARGACTIL.

4. Possible side effects

LARGACTIL can have side effects.

Not all side effects reported for LARGACTIL are included in this leaflet. Should your general

health worsen or if you experience any untoward effects while taking LARGACTIL, please consult your doctor, pharmacist or other health care professional for advice.

If any of the following happens, stop taking LARGACTIL immediately and tell your doctor or pharmacist immediately or go to the nearest hospital:

Less frequent:

- you have frequent infections such as fever, severe chills, sore throat or mouth ulcers (these could be signs of a blood problem called leucopenia or agranulocytosis).
- you bruise more easily than usual (this could be because of a blood disorder called thrombocytopenia).
- you feel tired and have a pale skin (this could be symptoms of anaemia (a deficiency of red cells in the blood)).

Frequency unknown:

- you have yellowing of the skin or eyes (jaundice) and your urine becomes darker in colour (these could be signs of liver damage which could be fatal if not treated).
- you have an allergic reaction. The signs may include: rash, itching, fever, difficulty in breathing or wheezing, chills, swollen eyelids, lips, tongue or throat.
- you have joint aches and pains, swollen joints, feel tired or weak, with chest pain and shortness of breath. These could be signs of an illness called ‘systemic lupus erythematosus’ (SLE).
- you have a fit (seizure).
- you have blood clots in the veins especially in the legs (symptoms include swelling, pain and redness in the leg), which may travel through blood vessels to the lungs causing chest pain and difficulty in breathing.
- you have movements that you cannot control, mainly of the tongue, mouth, jaw, arms and legs (dystonia).
- you have trembling, muscle stiffness or spasm, slow movement, producing more saliva than usual or feeling restless.

- you have a high temperature, sweating, stiff muscles, fast heartbeat, fast breathing and feel confused, drowsy or agitated (these could be signs of a serious but rare side effect called 'neuroleptic malignant syndrome').
- you have changes of the heart rhythm (called 'prolongation of QT-interval', seen on ECG, electrical activity of the heart).
- you have a very fast, uneven or forceful heartbeat (palpitations). You may also have breathing problems such as wheezing, shortness of breath, tightness in the chest and chest pain. These could be signs of very serious life-threatening heart problems which could lead to death if not treated.
- you are unable to move.
- you are breathing more slowly or less deeply than normal (CNS depression).
- you get a bloated feeling and cramping pain in the abdomen (stomach) be sick (vomit) have indigestion, heartburn, upset stomach, constipation and loss of appetite. This could be caused by an obstruction or blockage of the intestine.
- you have pain in your abdomen with vomiting or diarrhoea.
- you have a long lasting, painful erection of the penis.

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

Frequent:

- feeling dizzy, light-headed or faint when you stand or sit up quickly (due to low blood pressure).

Less frequent:

- difficulty seeing at night or reduced eyesight.

Frequency unknown:

- passing large amounts of urine, excessive thirst and having a dry mouth or skin. You may be

more likely to get infections, such as thrush. This could be due to too much sugar in your blood (hyperglycaemia).

- feeling tired, weak, confused and have muscles that ache, are stiff or do not work well. This may be due to low sodium levels in your blood.
- confused thinking and reduced awareness of your environment (delirium).
- feeling restless and not being able to keep still (akathisia).
- problems with eyesight (blurred vision, constricted or dilated pupils, opacities or cloudy areas in the eye).
- pigment deposits in the eye or skin which may affect vision, after having LARGACTIL for a long time.
- you have difficulty in passing water (urine).
- you feel too hot or too cold.
- your jaw is tight and stiff.

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

Tell your doctor if you notice any of the following:

Frequent:

- feeling drowsy or sleepy.

Less frequent:

- difficulty sleeping (insomnia).
- nightmares.
- feeling depressed (low mood).

Frequency unknown:

- abnormal production of breast milk in men and women.
- loss of menstrual periods.
- breast enlargement in men.
- elevated levels of a type of fat in your blood called triglycerides (hypertriglyceridaemia).
- putting on weight.

- feeling agitated.
- stuffy nose.
- dry mouth.
- constipation.
- being more sensitive to the sun than usual.
- difficulty in getting or keeping an erection (impotence).
- reduced sexual desire in women.
- skin rashes.
- withdrawal symptoms such as feeling sick, vomiting, diarrhoea, not being able to sleep, sweating, restlessness, anxiety and tremor may occur when LARGACTIL is stopped (see If you stop taking LARGACTIL).

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 LARGACTIL.

5. How to store LARGACTIL

Store at or below 25 °C, protected from light.

Store all medicines out of reach of children.

Do not take this medicine after the expiry date shown on the container.

Keep in the outer container until required for use.

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 LARGACTIL contains

The active substance of LARGACTIL 25 and 100 tablets is chlorpromazine hydrochloride. Each LARGACTIL 25 or 100 tablet contains 25 or 100 mg chlorpromazine hydrochloride, respectively. The 25 mg and 100 mg tablets also contain acacia powder, carnauba wax, dextrin white technical, gelatin, kaolin light, lactose, magnesium stearate, purified talc, polyethylene glycol, polyvinylpyrrolidone, stearic acid and sodium metabisulphite, sucrose, titanium dioxide and the 25 mg tablets also contain vinac B7.

What LARGACTIL looks like and contents of the pack

LARGACTIL 25: Round, off-white or very pale cream, sugar coated tablets, 4,05 mm thick and 7,4 mm in diameter.
LARGACTIL 100: Round, off-white or very pale cream, sugar coated tablets, 6,3 mm thick and 11,3 mm in diameter.

Tablets of 25 mg and 100 mg in containers of 28, 50, 56, 84 and 500.

Holder of certificate of registration

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