

PACKAGE LEAFLET:
INFORMATION FOR THE USER

Largactil® 25mg/ml Solution for Injection

Chlorpromazine
hydrochloride

SANOFI 

Is this leaflet hard to see or read? Phone 0800 035 2525 for help

Read all of this leaflet carefully before you are given this medicine

- Keep this leaflet. You may need to read it again
- If you have any further questions, ask your doctor, nurse or pharmacist
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor, nurse or pharmacist

In this leaflet:

1. What Largactil is and what it is used for
2. Before you are given Largactil
3. How Largactil is given
4. Possible side effects
5. How to store Largactil
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1. What Largactil is and what it is used for

Largactil contains a medicine called chlorpromazine. This belongs to a group of medicines called 'phenothiazines'. It works by blocking the effect of a chemical in the brain.

Largactil can be used for:

- Schizophrenia in adults and children
- Short term treatment of anxiety
- Hiccups
- Feeling or being sick (where other anti-sickness medicines have not worked)
- Autism

2. Before you are given Largactil

Do not have this medicine and tell your doctor if:

- X You are allergic (hypersensitive) to chlorpromazine or any of the other ingredients of Largactil (listed in Section 6). Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue
- X You have a low number of blood cells (bone marrow depression).
- X You have increased pressure in the eye (glaucoma)
- X You are taking a dopaminergic antiparkinsonism drug

- X You are breast feeding
- X You are taking citalopram or escitalopram
- X You have a history of a low white blood cell count
- X You have urine retention due to a prostate disorder
Do not have this medicine if any of the above apply to you. If you are not sure, talk to your doctor or nurse before being given Largactil

Take special care with Largactil Check with your doctor or nurse before you have this medicine if:

- ▲ You have liver or kidney problems
- ▲ You have thyroid problems
- ▲ You have heart problems or a family history of heart problems
- ▲ You have ever had a stroke
- ▲ You have Parkinson's disease
- ▲ You have epilepsy or have had fits (seizures)
- ▲ You have depression
- ▲ You have ever had alcohol problems
- ▲ You have an enlarged prostate gland
- ▲ You have had glaucoma (painful eyes with blurred vision)
- ▲ You have a tumour on the adrenal gland called 'phaeochromocytoma'

- ▲ You have a form of muscle weakness called 'myasthenia gravis'
- ▲ You have a low number of white blood cells (agranulocytosis). This means you may get infections more easily than usual
- ▲ You have low blood levels of potassium, calcium and magnesium. Your doctor may do blood tests to check on these
- ▲ You or someone else in your family has a history of blood clots, as medicines like these have been associated with formation of blood clots
- ▲ You are not eating properly
- ▲ You are allergic to other phenothiazine medicines such as prochlorperazine
- ▲ You are elderly (65 years of age or older)
- ▲ You are elderly, particularly during very hot or very cold weather. In these conditions, you could be at risk of hyperthermia or hypothermia
- ▲ You have low blood pressure or feel dizzy when you stand up
- ▲ You are diabetic or have high levels of sugar in your blood (hyperglycaemia). Your doctor may want to monitor you more closely

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before being given Largactil.



Taking other medicines

Please tell your doctor or nurse if you are taking or have recently taken any other medicines. This includes medicines you buy without a prescription, including herbal medicines. This is because Largactil can affect the way some other medicines work. Also some medicines can affect the way Largactil works.

In particular, check with your doctor if you are taking any of the following:

- Medicines for indigestion and heartburn (antacids)
- Medicines for diabetes
- Medicines for high blood pressure or prostate problems such as doxazosin and terazosin
- Medicines for Parkinson's disease such as levodopa
- Medicines for fits (epilepsy) such as carbamazepine or phenobarbital
- Medicines to control your heartbeat such as amiodarone, disopyramide or quinidine
- Medicines to help you sleep (sedatives)
- Medicines for depression
- Other medicines used to calm emotional and mental problems such as olanzapine or prochlorperazine
- Some medicines used for high blood pressure such as guanethidine, clonidine or propranolol
- Some medicines used for infections (antibiotics) such as moxifloxacin
- Some medicines used for cancer (cytotoxics)
- Medicines which can alter electrolytes (salt levels) in your blood
- Amphetamines - used for Attention Deficit Hyperactivity Disorder (ADHD)
- Anticholinergic medicines - includes some medicines used for irritable bowel syndrome, asthma or incontinence
- Adrenaline - used for life threatening allergic reactions
- Deferoxamine - used when you have too much iron in your blood
- Lithium - used for some types of mental illness
- Medicines that may interact in the metabolism of chlorpromazine; examples include ciprofloxacin, oral contraceptives.

Taking Largactil with food and drink

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 and breast-feeding and fertility

Talk to your doctor or nurse before having this medicine if you are pregnant, might become pregnant, or think you may be pregnant.

The following symptoms may occur in newborn babies, of mothers that have used Largactil 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.

Do not breast-feed if you are being given Largactil. This is because small amounts may pass into mothers' milk. If you are breastfeeding or planning to breast-feed talk to your doctor or nurse before taking this medicine.

Ask your doctor or nurse for advice before taking any medicine if you are pregnant or breastfeeding.

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



Driving and using machines

You may feel sleepy after having this medicine.

If this happens, do not drive or use any tools or machines.

Important information about some of the ingredients of Largactil

- **Sodium.** This injection contains 4.78mg of sodium in each 50mg dose and is essentially 'sodium-free'.
- **Small amounts of sulphites.** These may cause severe allergic reactions (hypersensitivity) and difficulty in breathing (bronchospasm). This is more likely to happen if you have a history of asthma or allergies. The chances of this happening are rare. Tell a doctor or nurse straight away if you get a rash, swallowing or breathing problems and swelling of your lips, face, throat or tongue.

3. How Largactil is given

Largactil is normally given by a doctor or nurse.

This is because it needs to be given as a deep injection into a muscle.

How much Largactil is given

If you are not sure why you are being given Largactil or have any questions about how much Largactil is being given to you, speak to your doctor or nurse.

The usual doses are:

	Schizophrenia
Adults:	25-50mg every 6-8 hours
Elderly:	25mg every 8 hours
Children 1-5 years:	0.5mg/kg body-weight every 6-8 hours (Maximum dose in a day is 40mg)
Children 6-12 years:	0.5mg/kg body-weight every 6-8 hours (Maximum dose in a day is 75mg)

Adults:	25-50mg every 6-8 hours
Elderly:	25mg every 8 hours
Children 6-12 years:	0.5mg/kg body-weight every 6-8 hours (Maximum dose in a day is 75mg)

Adults:	25-50mg
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Turn
Over

Feeling or being sick

- Adults: 25-50mg every 3-4 hours
Children 1-5 years: 0.5mg/kg body-weight every 6-8 hours (Maximum dose in a day is 40mg)
Children 6-12 years: 0.5mg/kg body-weight every 6-8 hours (Maximum dose in a day is 75mg)

Autism

- Children 1-5 years: 0.5mg/kg body-weight every 6-8 hours (Maximum dose in a day is 40mg)
Children 6-12 years: 0.5mg/kg body-weight every 6-8 hours. (Maximum dose in a day is 75mg)

Children under 1 year

Largactil is not usually given to children under 1 year.

Exposure to sunlight

Largactil can make your skin more sensitive to sunlight. Keep out of direct sunlight while having this medicine.

Tests

Before and during treatment your doctor may want to carry out some tests. These might include blood tests and an ECG to check your heart is working properly and eye tests. Your doctor may want to carry out tests every year during your child's treatment to evaluate your child's learning capacity.

If you have more Largactil than you should

It is unlikely that your doctor or nurse will give you too much medicine. Your doctor and nurse will monitor your progress, and check the medicine you are given. Always ask if you are not sure why you are getting a dose of medicine. Having too much Largactil may make you feel drowsy or dizzy with increased or rapid heartbeat. You may also feel very cold and restless, with writhing movements, stiffness or shaking. If you start getting any of these symptoms tell your doctor or nurse straight away. If you are away from the hospital, return straight away and speak to your doctor or nurse or go to the casualty department.

If you miss a dose of Largactil

Your doctor or nurse will have instructions on when to give you this medicine. It is unlikely that you will not be given the medicine as it has been prescribed. However, if you do think you have missed a dose, tell your doctor or nurse.

If you stop having Largactil

Keep having Largactil until your doctor tells you to stop. If you stop having Largactil your illness may come back and you may have other effects such as feeling or being sick and difficulty sleeping. Your doctor will gradually stop your medicine to prevent these effects happening.

4. Possible side effects

Like all medicines, Largactil can cause side effects, although not everybody gets them.

Tell a doctor or nurse or go to a hospital straight away if:

Very common (affects more than 1 in 10 people)

- You have movements that you cannot control, mainly of the tongue, mouth, jaw, arms and legs
 - Trembling, muscle stiffness or spasms, slow movement, producing more saliva than usual or feeling restless
- Common (affects 1 to 10 people in a 100 people)
- You have a fit (seizure)
 - Alteration of the heart rhythm (called 'prolongation of QT interval', seen on ECG, electrical activity of the heart)

Frequency unknown

- 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 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
- 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 yellowing of the skin or eyes (jaundice) and your urine becomes darker in colour. These could be signs of liver damage
- You have frequent infections such as fever, severe chills, sore throat or mouth ulcers. These could be signs of a blood problem called 'leucopenia'
- 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 get a bloated feeling and cramping pain in the abdomen (stomach) be sick (vomit) have indigestion, heartburn, upset stomach, constipation, loss of appetite, dry mouth. 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
- You bruise more easily than usual. This could be because of a blood disorder called 'thrombocytopenia'
- 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. If you notice any of these symptoms seek medical advice immediately

Tell a nurse or doctor as soon as possible if you have any of the following side effects:

Very common (affects more than 1 in 10 people)

- Feeling dizzy, lightheaded or faint when you stand or sit up quickly (due to low blood pressure)
- Frequency unknown
- You are breathing more slowly or less deeply than normal
 - Changes in skin or eye colour after having Largactil for a long time

- Problems with eyesight
- Rigid or stiff muscles, trembling or shaking, difficulty moving
- 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)
- Unusual eye movements (including rolling of the eyes)
- Your neck becomes twisted to one side
- Your jaw is tight and stiff
- You have difficulty in passing water (urine)
- 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

Talk to your doctor or nurse if any of the following side effects gets serious or lasts longer than a few days:

Very common (affects more than 1 in 10 people)

- Dry mouth
 - Feeling drowsy or sleepy
 - Putting on weight
- Common (affects 1 to 10 people in a 100 people)
- Abnormal production of breast milk in men and women
 - Loss of menstrual periods
 - Feeling anxious
- Frequency unknown
- Breast enlargement in men
 - Difficulty in getting or keeping an erection (impotence)
 - Reduced sexual desire in women
 - Difficulty sleeping (insomnia)
 - Feeling agitated
 - Being more sensitive to the sun than usual
 - Stuffy nose
 - Skin rashes
 - Tiredness, low mood

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Largactil

This medicine will be kept by your doctor or pharmacist in a safe place where children cannot see or reach it. Do not use Largactil after the expiry date which is stated on the label and carton. The expiry date refers to the last day of that month. Keep the Ampoules in the outer carton in order to protect from light. Discoloured solution should not be used. Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Further Information

What Largactil contains

- Each 1ml of solution contains 25mg of the active substance, chlorpromazine hydrochloride
- The other ingredients are: Sodium sulphite (E221), Sodium citrate, Sodium metabisulphite (E223), Sodium chloride, Water for Injection

What Largactil looks like and contents of the pack

- Largactil is a clear, colourless solution
 - Largactil is available in boxes containing 10 x 1ml or 10 x 2ml glass ampoules
- Not all pack sizes may be marketed

Marketing Authorisation Holder and Manufacturer

The Marketing Authorisation Holder for Largactil is: Sanofi, 410 Thames Valley Park Drive, Reading, Berkshire, RG6 1PT, UK

Tel: 0800 035 2525

email: uk-medicalinformation@sanofi.com

The Manufacturer of Largactil is:

Sanofi S.r.l., Via Valcanello, 4, 03012 – Anagni (FR), ITALY

This leaflet does not contain all the information about your medicine. If you have any questions or are not sure about anything, ask your doctor or nurse.

This leaflet was last revised in 10/2020.

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