

# Largactil®

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## Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

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### 1. Why am I using Largactil?

Largactil contains the active ingredient chlorpromazine hydrochloride, one of a group of medicines called phenothiazines. Largactil is used to treat several conditions and may be used either for a short time or for a long time.

Ask your doctor if you have any questions about why Largactil has been prescribed for you. Largactil is available only with a doctor's prescription. For more information, see Section [1. Why am I using Largactil?](#) in the full CMI.

### 2. What should I know before I use Largactil?

Do not use if you have ever had an allergic reaction to Largactil or any of the ingredients listed at the end of the CMI.

**Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.**

For more information, see Section [2. What should I know before I use Largactil?](#) in the full CMI.

### **3. What if I am taking other medicines?**

Some medicines may interfere with Largactil and affect how it works. A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

### **4. How do I use Largactil?**

- Your doctor or pharmacist will tell you how many tablets or how much syrup you will need to take each day. This depends on your condition and whether or not you are taking any other medicines.

More instructions can be found in Section [4. How do I use Largactil?](#) in the full CMI.

### **5. What should I know while using Largactil?**

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Remind any doctor, dentist or pharmacist you visit that you are using Largactil.</li><li>• If you become pregnant while taking Largactil,</li></ul>
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	<p>tell your doctor or pharmacist.</p> <ul style="list-style-type: none"> <li>● You should avoid very cold or very hot environments.</li> <li>● You should avoid exposure to strong sunlight while you are taking Largactil.</li> <li>● Call your doctor straight away if you notice any worm-like movements of the tongue, or other uncontrolled movements of the tongue, mouth, cheeks or jaw.</li> </ul>
<p><b>Things you should not do</b></p>	<ul style="list-style-type: none"> <li>● Do not take Largactil to treat any other complaints unless your doctor or pharmacist tells you to.</li> </ul>
<p><b>Driving or using machines</b></p>	<ul style="list-style-type: none"> <li>● Be careful before you drive or use any machines or tools until you know how Largactil affects you.</li> <li>● Largactil may cause drowsiness in some people.</li> </ul>

<p><b>Drinking alcohol</b></p>	<ul style="list-style-type: none"> <li>● Be careful when drinking alcohol while taking Largactil. Combining Largactil and alcohol can make you more sleepy, dizzy or light headed.</li> </ul>
<p><b>Looking after your medicine</b></p>	<ul style="list-style-type: none"> <li>● Follow the instructions in the carton on how to take care of your medicine properly.</li> </ul>

For more information, see Section [5. What should I know while using Largactil?](#) in the full CMI.

## 6. Are there any side effects?

Less serious side effects include dizziness or light headedness, headache, nausea, dry mouth, drowsiness or tiredness, weight gain, constipation, nasal congestion, agitation, skin discolouration, blurred vision, difficulty urinating and impotence.

Serious side effects include sore throat, fever or any sign of infection, breathing difficulty, seizures or fits, unwanted muscle movements of the mouth, tongue, jaw, cheeks or arms and legs, uncontrolled bleeding or bruising more easily than usual.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.



# Largactil®

**Active ingredient:** *chlorpromazine hydrochloride*

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## Consumer Medicine Information (CMI)

This leaflet provides important information about using Largactil. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Largactil.**

**Where to find information in this leaflet:**

- [1. Why am I using Largactil?](#)
- [2. What should I know before I use Largactil?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use Largactil?](#)
- [5. What should I know while using Largactil?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

## 1. Why am I using Largactil?

Largactil contains the active ingredient **chlorpromazine hydrochloride**, one of a group of medicines called phenothiazines. Largactil is used to treat several conditions and may be used either for a short time or for a long time. **Largactil is used to treat various problems such as severe depression or behavioural disturbances. Largactil can also be**

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**used to treat nausea, vomiting, severe pain and unstoppable hiccups.**

Your doctor may have prescribed Largactil for another reason. Ask your doctor if you have any questions about why Largactil has been prescribed for you.

## **2. What should I know before I use Largactil?**

### **Warnings**

#### **Do not use Largactil if:**

- you have ever had an allergic reaction to Largactil or any of the ingredients listed at the end of the CMI. Always check the ingredients to make sure you can use this medicine.
- you have taken any other 'phenothiazine' medicine before, which caused your face, lips, tongue, throat, hands or feet to swell up, or made it hard for you to breathe. If you have had an allergic reaction to a phenothiazine before, you may be allergic to Largactil. If you experience an allergic reaction, seek medical help right away.
- you have circulatory, blood or bone marrow problems, high blood pressure, liver problems, depression of the central nervous system and phaeochromocytoma (a rare tumour of the adrenal gland which sits near the kidney).

- the packaging is torn or shows signs of tampering or if the tablet, syrup or ampoule doesn't look quite right.

## **Check with your doctor or pharmacist if you:**

- take any medicines for any other condition
- have any other medical conditions especially the following:
  - asthma
  - chronic respiratory disorders
  - kidney or liver disease
  - heart disease
  - blood clots
  - decreased parathyroid activity
  - low blood calcium levels
  - Parkinson's disease
  - prostate problems
  - epilepsy - fits and seizures
  - glaucoma - high pressure in the eye
  - muscle weakness (myasthenia gravis)
  - diabetes
  - dementia

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

## **Use in children**

Do not use in children less than 1 year of age.

Because of the risk of choking, the tablets should be avoided in children who have difficulty swallowing tablets.

## **Pregnancy and breastfeeding**

Use of Largactil is not recommended during pregnancy.

Check with your doctor or pharmacist if you are a woman of childbearing age and not using effective contraception, or if you are pregnant or intend to become pregnant.

Babies exposed to antipsychotic medicines including Largactil during the third trimester of pregnancy are at risk of experiencing breathing problems, difficulty in feeding, spasms, restlessness, involuntary movements and/or withdrawal symptoms following delivery.

Use of Largactil is not recommended during breastfeeding.

Talk to your doctor or pharmacist if you are breastfeeding or intend to breastfeed.

Your doctor or pharmacist will discuss the possible risks and benefits of using Largactil during pregnancy and during breastfeeding.

### **3. What if I am taking other medicines?**

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

**Some medicines may interfere with Largactil and affect how it works.** These include:

- benztropine and levodopa - drugs used to treat Parkinson's disease
- antimicrobials – used to treat infections
- antacid - used to treat stomach upsets
- lithium - used to treat mood disorders
- barbiturates - a group of drugs used as sedatives
- tricyclic antidepressants
- benzodiazepines - a group of drugs used to treat anxiety and muscle spasms
- other antipsychotics
- medicines that are CYP1A2 inhibitors e.g. ciprofloxacin, fluvoxamine, oral contraceptives, vemurafenib
- medicines used to treat a fast or irregular heart beat e.g. amiodarone, quinidine, disopyramide
- medicines that can slow your heart beat e.g. diltiazem, verapamil, propranolol
- medicines that can reduce potassium levels in the blood e.g. diuretics, laxatives
- other medicines that can affect your heart rate e.g. methadone, pentamidine
- anaesthetics
- opioids - a group of pain killing drugs
- antidiabetic agents - a group of drugs used to treat diabetes
- amphetamines
- anticoagulants

- anticholinergics
- guanethidine
- clonidine
- thiazides - diuretics (fluid tablets)
- MAOI - a group of drugs used to treat depression
- adrenaline
- suxamethonium, atropine and organophosphorous insecticides
- anticonvulsants - a group of drugs used to treat epilepsy e.g. phenytoin, valproic acid
- prochlorperazine - a drug used to treat nausea and vomiting
- desferrioxamine - a drug used to treat iron poisoning

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Largactil.**

## **4. How do I use Largactil?**

### **How much to take**

- Follow the instructions provided and use Largactil until your doctor tells you to stop.
- Your doctor or pharmacist will tell you how many tablets or how much syrup you will need to take each day. This depends on your condition and whether or not you are taking any other medicines.

**Follow all directions given to you by your doctor and pharmacist carefully.**

If you do not understand the instructions on the pack, ask your doctor or pharmacist for help.

## **When to take Largactil**

**Take Largactil at about the same time each day.**

Continue taking Largactil until your doctor or pharmacist tells you to stop. Do not stop using it unless your doctor or pharmacist tells you to, even if you feel better.

Taking your tablets or syrup at the same time each day will have the best effect. It will also help you remember when to take the tablets or syrup.

## **How to take Largactil**

- Swallow the prescribed dose of Largactil tablets whole with a full glass of water. Do not chew the tablets.
- Swallow the prescribed dose of Largactil syrup and follow with a glass of water.
- Largactil may be given as an injection into a muscle or as a slow injection into a vein. Largactil injections should only be given by a doctor, nurse or other trained person.

## **If you forget to use Largactil**

**If you miss a dose, simply continue to take Largactil as advised by your doctor or pharmacist. You do not need to make up for the missed dose.**

**Do not take a double dose to make up for the dose that you missed.** This may increase the chance of you getting an unwanted side effect.

If you are not sure what to do, ask your doctor or pharmacist. If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

## **If you use too much Largactil**

If you think that you have used too much Largactil, you may need urgent medical attention.

### **You should immediately:**

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

### **You should do this even if there are no signs of discomfort or poisoning.**

You may need urgent medical attention. If you take too much Largactil, you may experience:

- drowsiness
- low body temperature
- low blood pressure
- twisting your limbs
- stiffness
- shaking
- unusual heart beats

- muscle twitching
- difficulty in swallowing and breathing
- convulsions
- loss of consciousness leading to coma

## **5. What should I know while using Largactil?**

### **Things you should do**

Tell any other doctors, dentists, and pharmacists who are treating you that you are taking Largactil.

If you plan to have surgery that needs a general anaesthetic, tell your doctor or dentist that you are taking Largactil.

If you become pregnant while taking Largactil, tell your doctor or pharmacist.

You should avoid very cold or very hot environments. Largactil may make it difficult for your body to regulate its temperature.

You should avoid exposure to strong sunlight while you are taking Largactil. Do not use a sunlamp or tanning bed or booth.

Largactil may cause your skin to be much more sensitive to sunlight than it is normally. Exposure to sunlight may cause a skin rash, itching, redness or severe sunburn. If your skin does appear to be burning, tell your doctor. If exposure to strong sunlight is unavoidable, suitable

clothing, including a hat, should be worn. A sunscreen with a high level of protection should also be used.

All mentions of suicide must be taken seriously. Tell your doctor or a mental health professional immediately if you have any suicidal thoughts or other mental/mood changes.

### **Call your doctor straight away if you:**

- notice any worm-like movements of the tongue, or other uncontrolled movements of the tongue, mouth, cheeks or jaw which may progress to the arms and legs.

These are symptoms of a condition called tardive dyskinesia, which may develop in people taking phenothiazine medicines, including Largactil.

This condition is more likely to occur during long term treatment with Largactil, especially in elderly women. In very rare cases, this may be permanent. However, if detected early, these symptoms are usually reversible.

### **Things you should not do**

- Do not give Largactil to anyone else, even if they have the same condition as you.
- Do not take Largactil to treat any other complaints unless your doctor or pharmacist tells you to.

### **Driving or using machines**

**Be careful before you drive or use any machines or tools until you know how Largactil affects you.**

Largactil may cause drowsiness, dizziness, and blurred vision in some people. Make sure you know how you react to Largactil before you drive a car, operate machinery, or do anything else that could be dangerous if you are dizzy or light-headed. If this occurs, do not drive. If you drink alcohol, dizziness or light-headedness may be worse.

**If Largactil makes you feel light-headed, dizzy or faint, be careful when getting up from a sitting or lying position.** Getting up slowly may help.

## **Drinking alcohol**

**Tell your doctor if you drink alcohol.**

Be careful when drinking alcohol while taking Largactil. Combining Largactil and alcohol can make you more sleepy, dizzy or light headed. Your doctor may suggest you avoid alcohol while you are being treated with Largactil.

## **Looking after your medicine**

Follow the instructions in the carton on how to take care of your medicine properly.

- Store tablets below 30°C.
- Store syrup below 25°C. Protect from light.
- Store ampoules below 25°C. Protect from light.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or

- in the car or on window sills.

**Keep it where young children cannot reach it.**

## **Getting rid of any unwanted medicine**

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

## **6. Are there any side effects?**

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

If you are over 65 years of age, you may have an increased chance of getting side effects.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

### **Less serious side effects**

<b>Less serious side effects</b>	<b>What to do</b>
<p><b>General</b></p> <ul style="list-style-type: none"> <li>• dizziness or light headedness</li> <li>• headache</li> <li>• nausea</li> <li>• dry mouth</li> </ul>	<p><b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b></p>

<b>Less serious side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"> <li>• drowsiness or tiredness</li> <li>• weight gain</li> <li>• constipation</li> <li>• nasal congestion</li> <li>• weakness</li> </ul> <p><b>Nervous System related</b></p> <ul style="list-style-type: none"> <li>• agitation</li> <li>• confusion</li> </ul> <p><b>Skin related</b></p> <ul style="list-style-type: none"> <li>• skin problems or discolouration</li> </ul> <p><b>Eye related</b></p> <ul style="list-style-type: none"> <li>• blurred vision</li> </ul> <p><b>Genito-urinary related</b></p> <ul style="list-style-type: none"> <li>• difficulty in urinating</li> <li>• impotence</li> </ul>	

## **Serious side effects**

<b>Serious side effects</b>	<b>What to do</b>
<p><b>General</b></p> <ul style="list-style-type: none"> <li>• sore throat, fever or any sign of infection</li> <li>• hypersensitivity, fever, rash, facial swelling,</li> </ul>	<p><b>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you</b></p>

<b>Serious side effects</b>	<b>What to do</b>
<p>swollen lymph nodes (which could be symptoms relating to raised levels of infection fighting cells (these could be symptoms relating to eosinophilia)</p> <p><b>Allergic reaction</b></p> <ul style="list-style-type: none"> <li>● breathing difficulty, rash, itching, shortness of breath, swelling of throat, face, lips or tongue, clammy skin, palpitations, fainting</li> </ul> <p><b>Nervous system related</b></p> <ul style="list-style-type: none"> <li>● seizures or fits</li> <li>● unwanted muscle movements of the mouth, tongue, jaw, cheeks or arms and legs.</li> <li>● hardness or rigidity of the muscles.</li> <li>● high fever, muscle cramps or stiffness, severe headache, fast heartbeat, hallucinations, or are sweating a lot</li> </ul>	<p><b>notice any of these serious side effects.</b></p>

<b>Serious side effects</b>	<b>What to do</b>
<p>(symptoms relating to Neuroleptic malignant syndrome)</p> <ul style="list-style-type: none"> <li>● involuntary movement of tongue, face, mouth or jaw (symptoms relating to Tardive Dyskinesia)</li> <li>● high fever, muscle cramps or stiffness, dizziness, severe headache, fast heartbeat, confusion, agitation, hallucinations or if you are sweating a lot (symptoms relating to neuroleptic malignant syndrome)</li> </ul> <p><b>Heart related</b></p> <ul style="list-style-type: none"> <li>● fast heartbeat</li> <li>● alteration of the heart rhythm (electrical activity of the heart).</li> <li>● very fast, uneven or forceful heartbeat (palpitations), weakness, fainting (symptoms relating to QT prolongation)</li> </ul> <p><b>Bleeding related</b></p>	

<b>Serious side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"> <li>● uncontrolled bleeding or bruising more easily than usual</li> </ul> <p><b>Liver related</b></p> <ul style="list-style-type: none"> <li>● yellowing of the skin and/or eyes (jaundice) and urine becomes darker in color</li> </ul> <p><b>Blood related</b></p> <ul style="list-style-type: none"> <li>● bleeding and bruising (thrombocytopenic purpura)</li> </ul>	

**Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.**

Other side effects not listed here may occur in some people.

## **Reporting side effects**

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems). By reporting side effects, you can help provide more information on the safety of this medicine.

**Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.**

## 7. Product details

This medicine is only available with a doctor's prescription.

### What Largactil contains

#### Tablets

<b>Active ingredient (main ingredient)</b>	<ul style="list-style-type: none"><li>● chlorpromazine hydrochloride 10mg, 25mg, or 100mg (active ingredient)</li></ul>
<b>Other ingredients (inactive ingredients)</b>	<ul style="list-style-type: none"><li>● lactose monohydrate</li><li>● maize starch</li><li>● colloidal anhydrous silica</li><li>● magnesium stearate</li><li>● hypromellose</li><li>● macrogol 200</li></ul>
<b>Potential allergens</b>	<ul style="list-style-type: none"><li>● Contains lactose</li></ul>

#### Syrup

<b>Active ingredient (main ingredient)</b>	<ul style="list-style-type: none"><li>● chlorpromazine hydrochloride 25mg/5mL (active ingredient)</li></ul>
<b>Other ingredients (inactive ingredients)</b>	<ul style="list-style-type: none"><li>● sucrose</li><li>● caramel</li></ul>

	<ul style="list-style-type: none"> <li>● citric acid</li> <li>● polysorbate 20</li> <li>● peppermint oil</li> <li>● spearmint oil</li> <li>● sodium citrate dihydrate</li> <li>● ascorbic acid</li> <li>● sodium sulphite</li> <li>● sodium metabisulphite</li> <li>● sodium benzoate</li> <li>● fruit cup essence</li> <li>● purified water</li> </ul>
<b>Potential allergens</b>	<ul style="list-style-type: none"> <li>● Contains benzoates</li> <li>● Contains sulfites</li> </ul>

### **Ampoules**

<b>Active ingredient (main ingredient)</b>	<ul style="list-style-type: none"> <li>● chlorpromazine hydrochloride 50mg/2mL (active ingredient)</li> </ul>
<b>Other ingredients (inactive ingredients)</b>	<ul style="list-style-type: none"> <li>● sodium sulfite</li> <li>● sodium metabisulphite</li> <li>● sodium chloride</li> <li>● sodium citrate dihydrate</li> <li>● water for injections</li> </ul>
<b>Potential allergens</b>	<ul style="list-style-type: none"> <li>● Contains sulfites</li> </ul>

**Do not take this medicine if you are allergic to any of these ingredients.**

## What Largactil looks like

Largactil tablets are white film coated tablets with embossing on one side:

- 10mg tablet: LG / 10
- 25mg tablet: LG / 25
- 100mg tablet: LG / 100

Tablets are available in blister packs of 100.

Largactil syrup is a dark orange syrupy liquid with the odour of spearmint / peppermint, and is slightly fruity. Syrup is available in an amber glass 100mL bottle with a childproof cap.

Largactil for injection is a clear liquid in a 2mL glass ampoule, in a pack of 10 ampoules.

## Who distributes Largactil

sanofi-aventis australia pty ltd

12-24 Talavera Road

Macquarie Park NSW 2113

Toll Free Number (medical information): 1800 818 806

Email: [medinfo.australia@sanofi.com](mailto:medinfo.australia@sanofi.com)

Largactil® is a registered trademark.

Australian Registration Numbers:

10mg tablet AUST R 51620

25mg tablet AUST R 51618

100mg tablet AUST R 51619

25mg/5mL syrup AUST R 118128

50mg/2mL ampoule AUST R 27511

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