

Vallergan® and Vallergan Forte

Alimemazine (trimeprazine) tartrate

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Vallergan.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor or pharmacist has weighed the risks of you taking Vallergan against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What Vallergan is used for

Vallergan can be taken to treat hives or pinkish itchy swellings on the skin. This condition is called urticaria.

Vallergan can also be taken to relieve itching due to sunburn, photosensitivity, measles and chicken pox.

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

Vallergan should not be used in children under 2 years of age because safety of such use had not been established.

Before you take Vallergan

When you must not take it

Do not take Vallergan if you have an allergy to Vallergan or any of the ingredients listed at the end of this leaflet.

Symptoms of an allergic reaction to Vallergan may include swelling of the face, lips, tongue or other parts of the body, shortness of breath, wheezing or trouble breathing

Do not take Vallergan if you have, or have had, any of the following medical conditions:

- asthma
- severe liver or kidney disease
- epilepsy
- Parkinson's disease
- hypothyroidism (underactive thyroid gland)
- myasthenia gravis (disease causing muscle weakness)
- pheochromocytoma (tumour of adrenal glands)
- agranulocytosis (lack of white blood cells)
- closed-angle glaucoma
- unusual heart beats
- prostate problems
- difficulty passing urine
- a narrowing or blockage between the stomach and small intestine which causes vomiting of undigested food

Do not give Vallergan to a child under 2 years.

The safety of Vallergan in children under 2 years has not been established.

Do not take Vallergan after the expiry date printed on the pack.

Do not take Vallergan if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking Vallergan, talk to your doctor or pharmacist.

Before you start to take it

Tell your doctor or pharmacist if you have allergies to:

- any other medicines
- any other substances, such as foods, preservatives or dyes

Tell your doctor or pharmacist if you have or have had any medical conditions, especially the following:

- epilepsy
- liver or kidney disease
- breathing problems, including asthma or bronchitis
- thyroid problems
- heart disease
- high blood pressure
- prostate problems
- chronic constipation
- raised pressure in the eye

Vallergan should be used with caution in the elderly, particularly during very hot or very cold weather, as there is a risk of hyper or hypothermia. The elderly are also particularly susceptible to postural hypotension.

Exposure to sunlight should be avoided during treatment with Vallergan.

The sugar content of Vallergan Syrup and Vallergan Forte Syrup should be considered in patients with diabetes or on low sugar diets.

This medicine contains sulfites that may cause or worsen anaphylactic (allergic) reactions.

Tell your doctor or pharmacist if you are pregnant or intend to become pregnant.

Like most antihistamine medicines, Vallergan is not recommended for use during pregnancy. If there is a need to consider Vallergan during your pregnancy, your doctor or pharmacist will discuss with you the benefits and risks of using it.

Tell your doctor or pharmacist if you are breast-feeding or plan to breast-feed.

Vallergan passes into breast milk and therefore there is a possibility that the breast-fed baby may be affected.

Taking other medicines

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

Some medicines should not be taken with Vallergan. These include:

- itraconazole, ketoconazole or miconazole, medicines used to treat fungal infections
- erythromycin or roxithromycin, medicines used to treat bacterial infections
- quinine, a medicine used to treat muscle cramps or prevent malaria
- medicines used to treat unusual heart beats
- monoamine oxidase inhibitor (MAOI) medicines, including moclobemide, phenelzine and tranylcypromine, which are used to treat depression

Some medicines and Vallergan may interfere with each other. These include:

- alcohol or medicines containing alcohol, such as some cough syrups

- tricyclic antidepressants, medicines used to treat depression
- lithium, a medicine used to treat mood and some types of depression
- anticholinergics, medicines used to relieve stomach cramps or spasms, prevent travel sickness or treatment of an overactive bladder
- amphetamines (stimulants)
- adrenaline
- levodopa (a drug used to treat Parkinson's disease)
- clonidine (a medicine used to treat high blood pressure, attention deficit disorders, anxiety)
- strong / narcotic pain killers, such as codeine, morphine and dextropropoxyphene
- some medicines used for sedation or to help you sleep
- antacids (medicines used to treat heartburn and indigestion)
- some medicines used to treat anxiety
- some medicines used to stop blood clotting, such as warfarin

These medicines may be affected by Vallergan, or may affect how well it works. You may need different amounts of your medicine, or you may need to take different medicines. Your doctor or pharmacist will advise you.

Your doctor and pharmacist may have more information on medicines to be careful with or avoid while taking Vallergan.

How to take Vallergan

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

They may differ from the information contained in this leaflet.

Your doctor or pharmacist will tell you how many tablets you will need to take each day. This depends on

your condition and whether or not you are taking any other medicines.

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

How much to take

For urticaria:

- Adults should take 10mg, (approximately 6.5mL of Vallergan Syrup: approximately 1.6mL of Vallergan Forte Syrup) 3 or 4 times daily.
- Children above 2 years of age should take between 2.5 and 5mg three to four times daily.

For sedation in children:

- 3-6 years: 2.5 to 10mL (Vallergan Forte Syrup) 15 - 60mg per day in divided doses
- 7-12 years: 10 to 15mL (Vallergan Forte Syrup) 60 - 90mg per day in divided doses.

How to take it

Carefully measure the dose using a medicine cup or spoon. Swallow the Vallergan syrup.

When to take it

Take Vallergan at several evenly spaced times throughout the day.

It does not matter if you take Vallergan before or after food.

How long to take it

Stop taking Vallergan when the itching and redness have gone.

If you forget to take it

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Otherwise, take it as soon as you remember, and then go back to taking your medicine as you would normally.

Do not take a double dose to make up for the dose you missed.

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 take too much (overdose)

Immediately telephone your doctor or pharmacist or the Poisons Information Centre (telephone 13 11 26 in Australia or 0800 764 766 in New Zealand), or go to Accident and Emergency at your nearest hospital, if you think that you or anyone else may have taken too much Vallergan. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

If you take too much Vallergan, you may feel drowsy, or perhaps lose consciousness. An overdose of Vallergan can also cause your heart to beat fast or an increase in the size of your blood vessels which could lead to circulatory collapse. You may also experience high temperature, excessive thirst, muscle stiffness and altered mental status.

While you are using Vallergan

Things you must do

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

If you are about to be started on any new medicine, tell your doctor, dentist or pharmacist that you are taking Vallergan.

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

If you become pregnant while taking Vallergan, stop taking it and tell your doctor or pharmacist immediately.

Things you must not do

If your Doctor has prescribed Vallergan for you, do not give it to anyone else, even if they have the same condition as you.

Do not take Vallergan to treat any other complaints unless your doctor or pharmacist tells you to.

Things to be careful of

Make sure you know how you react to Vallergan before you drive, operate machinery, or do anything else that could be dangerous if you are tired, drowsy, dizzy or light-headed.

Vallergan is a known sedative. If you are drowsy, do not drive a car or operate machinery.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Vallergan.

Vallergan helps most people with urticaria, but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

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

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- drowsiness
- nasal stuffiness
- dry mouth
- insomnia
- agitation
- headache
- constipation

These side effects are usually mild.

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

- wheezing or being short of breath
- fast, pounding or irregular heart beats
- slow heart beat
- frequent infections such as fever, severe chills, sore throat or mouth ulcers
- yellowing of the skin and/or eyes
- problems passing urine
- hallucinations
- spinning sensation
- fainting
- unusual or uncontrolled muscle movements
- tingling or numbness in the hands or feet, also known as 'pins and needles'.

These may be serious side effects. You may need medical attention. (Serious side effects are rare.)

If any of the following happen, stop taking/using Vallergan and tell your doctor or pharmacist immediately or go to Accident and Emergency at your nearest hospital:

- chest pain
- sudden signs of allergy such as rash, itching or hives on the skin, swelling of the face, lips, tongue or other parts of the body, shortness of breath, wheezing or trouble breathing.
- convulsions, fits or seizures
- loss of consciousness
- high temperature
- muscle stiffness
- altered mental status

These are very serious side effects. You may need urgent medical attention or hospitalisation. (These side effects are very rare.)

Other side effects not listed above may occur in some patients. Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

After using Vallergan

Storage

Keep your medicine in the bottle and protected from light until it is time to take it.

Keep your medicine in a cool dry place where the temperature stays below 25°C.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor or pharmacist tells you to stop taking Vallergan or the tablets has passed their expiry date, ask your pharmacist what to do with any that are left over.

Product description

What it looks like

Vallergan Syrup (7.5mg/5mL) is clear bright straw coloured liquid with an apricot odour. It is available in a 100mL bottle*

Vallergan Forte (30mg/5mL) is a clear to yellow liquid with an apricot odour. It is available in a 100mL bottle.

Ingredients

Active ingredient:

- Alimemazine (trimeprazine) tartrate

Other ingredients:

- sucrose, ethanol, citric acid, sodium citrate dihydrate, sodium benzoate, sodium sulfite, sodium metabisulfite, ascorbic acid, apricot flavour 91 and purified water. Vallergan syrup also contains caramel.

Sponsor

sanofi-aventis australia Pty Ltd
12-24 Talavera Rd
Macquarie Park NSW 2113

Vallergan Forte Syrup is supplied in New Zealand by:

sanofi-aventis new zealand limited
Level 8,
56 Cawley Street
Ellerslie, Auckland

Australian Registration Numbers:

Vallergan Syrup AUST R 164306

Vallergan Forte AUST R 164298

* Not available in New Zealand

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