

## DATA SHEET

### 1 VALLERGAN FORTE® 30MG/5ML SYRUP

### 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5mL of syrup contains alimemazine tartrate 30mg.

For the full list of excipients, see section 6.1.

### 3 PHARMACEUTICAL FORM

Vallergan Forte syrup is a clear, colourless to pale yellow coloured, apricot flavoured liquid.

### 4 CLINICAL PARTICULARS

#### 4.1 THERAPEUTIC INDICATIONS

Vallergan Forte is used in:

1. Urticaria and pruritus.
2. Premedication for anaesthesia.

#### 4.2 DOSE AND METHOD OF ADMINISTRATION

Vallergan is contraindicated for use in children less than 2 years of age due to the risk of marked sedation and respiratory depression.

#### Urticaria and Pruritus

##### *Adults*

10 mg two or three times daily. Up to 100 mg per day has been used in intractable cases.

### *Elderly*

Dosage should be reduced to 10 mg once or twice daily.

### *Children*

2.5 to 5 mg three or four times daily.

### Pre-anaesthetic Medication

#### *Children (2 to 7 years of age)*

The maximum dosage of Vallergan Forte syrup recommended for this indication is 2 mg/kg bodyweight.

For instructions on dilution of medicine before administration see section 6.6.

## **4.3 CONTRAINDICATION**

Vallergan Forte should be avoided in patients with liver or renal dysfunction, epilepsy, Parkinson's disease, hypothyroidism, phaeochromocytoma, myasthenia gravis, and prostate hypertrophy.

It should be avoided in patients known to be hypersensitive to phenothiazines or any of the excipients or with a history of narrow angle glaucoma or a history of agranulocytosis.

Vallergan is contraindicated for use in children less than 2 years of age due to the risk of marked sedation and respiratory depression.

## **4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE**

QT interval prolongation has been reported with phenothiazines.

Alimemazine should be used with caution in:

- elderly or volume depleted patients who are more susceptible to orthostatic hypotension
- elderly patients presenting chronic constipation (risk of paralytic ileus)
- elderly patients with possible prostatic hypertrophy
- elderly patients in hot and cold weather (risk of hyper/hypothermia)
- patients with certain cardiovascular diseases, due to the tachycardia-inducing, arrhythmia-inducing and hypotensive effects of phenothiazines

Patients are strongly advised not to consume alcoholic beverages or medicines containing alcohol throughout treatment.

Exposure to sunlight should be avoided during treatment.

Caution must be exercised in patients with a history of seizures.

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

This medicine contains sulfites that may cause or exacerbate anaphylactic reactions.

There is a risk of post-operative restlessness especially if the child is in pain.

#### **4.5 INTERACTION WITH OTHER MEDICINES AND OTHER FORMS OF INTERACTION**

The CNS depressant actions of phenothiazine agents may be intensified (additively) by alcohol, anxiolytics and hypnotics, barbiturates, opiates and other sedatives. There may be increased antimuscarinic and sedative effects of phenothiazines with tricyclic antidepressants and monoamine oxidase inhibitors (MAOIs), including moclobemide. Respiratory depression may occur.

The hypotensive effect of most antihypertensive drugs, especially alpha-adrenoceptor blocking drugs may be exaggerated by phenothiazines. The use of antimuscarinics in conjunction with antihistamines will increase the risk of antimuscarinic side effects.

The mild anticholinergic effect of phenothiazines may be enhanced by other anticholinergic drugs possibly leading to constipation, heat stroke, etc.

The action of some drugs may be opposed by phenothiazines. These include amphetamine, levodopa, clonidine, guanethidine, adrenaline.

Anticholinergic agents may reduce the antipsychotic effect of phenothiazines.

Some drugs interfere with absorption of phenothiazine agents: antacids, anti-Parkinson, lithium. Increases or decreases in the plasma concentrations of a number of drugs, e.g. propranolol, phenobarbitone have been observed but were not of clinical significance.

High doses of phenothiazines reduce the response to hypoglycaemic agents, the dosage of which might have to be raised. Adrenaline must not be used in patients overdosed with phenothiazines.

#### **4.6 PREGNANCY AND LACTATION**

##### Pregnancy

Category C

There is inadequate evidence of the safety of Vallergan Forte in human pregnancy. Some phenothiazines have shown evidence of harmful effects in animals.

Vallergan Forte, like other drugs, should be avoided in pregnancy unless the physician considers it essential. Neuroleptics may occasionally prolong labour and at such a time should be withheld until the cervix is dilated 3-4 cm. Possible adverse effects on the neonate include lethargy or paradoxical hyperexcitability, tremor and low Apgar score.

#### Breast-feeding

Phenothiazines may be excreted in milk. Breastfeeding should be suspended during treatment.

### **4.7 EFFECTS ON ABILITY TO DRIVE AND USE MACHINES**

Patients should be warned about drowsiness during the early days of treatment, and advised not to drive or operate machinery.

### **4.8 UNDESIRABLE EFFECTS**

Minor side effects of phenothiazines are nasal stuffiness, dry mouth, insomnia and agitation. In long term use, dry mouth may cause damage to teeth and oral mucous membranes. Constipation, dizziness, headache and retention of urine have been reported.

#### Liver Function

Jaundice, usually transient, occurs in a very small percentage of patients taking phenothiazines. A premonitory sign may be a sudden onset of fever after one to three weeks of treatment followed by the development of jaundice.

Neuroleptic jaundice has the biochemical and other characteristics of obstructive jaundice and is associated with obstructions of the canaliculi by bile thrombi. The frequent presence of an accompanying eosinophilia indicates the allergic nature of this phenomenon. Treatment should be withheld on the development of jaundice.

#### Cardiorespiratory

Hypotension, or pallor, may occur in children. Elderly or volume-depleted subjects are particularly susceptible to postural hypotension.

Cardiac arrhythmias, including atrial arrhythmia, A-V block, ventricular tachycardia and fibrillation have been reported during phenothiazine therapy, possibly related to dosage. Pre-existing cardiac disease, old age, hypokalaemia and concurrent tricyclic antidepressants may predispose. ECG changes, usually benign, include widened QT interval, ST depression, U-waves and T-wave changes. Respiratory depression is possible in susceptible patients.

#### Blood Picture

A mild leucopenia occurs in up to 30% of patients on prolonged high dosages of phenothiazines. Agranulocytosis may occur rarely; it is not dose related. The occurrence of unexplained infections or fever requires immediate haematological investigation.

### Extrapyramidal

Acute dystonias or dyskinesias, usually transitory, are more common in children and young adults, and usually occur within the first 4 days of treatment or after dosage increases. Akathisia characteristically occurs after large initial doses. Parkinsonism is more common in adults and the elderly. It usually develops after weeks or months of treatment. One or more of the following features of Parkinsonism may be seen: tremor, rigidity, akinesia or other. Commonly just tremor is visible. If tardive dyskinesia occurs it is usually, but not necessarily, after prolonged or high dosage. It can even occur after treatment has been stopped. Dosage should therefore be kept low whenever possible.

### Skin and Eyes

Contact skin sensitisation is a serious but rare complication in those frequently handling preparations of certain phenothiazines. The greatest care must be taken to avoid contact of the drug with the skin. Skin rashes of various kinds may also be seen in patients treated with the drug. Patients on high dosage should be warned that they may develop photosensitivity in sunny weather and should avoid exposure to direct sunlight.

Ocular changes and the development of a metallic greyish-mauve colouration of the exposed skin have been noted in some individuals, mainly females, who have received chlorpromazine continuously for long periods (four to eight years).

Accommodation disorder has also been reported.

### Endocrine

Hyperprolactinaemia, which may result in galactorrhoea, gynaecomastia, amenorrhoea; impotence.

### Neurological Effects

Neuroleptic malignant syndrome (hyperthermia, rigidity, autonomic dysfunction and altered consciousness) may occur with any neuroleptic. Paradoxical excitement has been noted.

### Nervous System Disorders

Convulsions have been reported.

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare professionals are asked to report any suspected adverse reactions <https://nzphvc.otago.ac.nz/reporting/>.

## **4.9 OVERDOSE**

Symptoms of phenothiazine overdosage include drowsiness or loss of consciousness, hypotension, tachycardia, ECG changes, ventricular arrhythmias and hypothermia. Severe extrapyramidal dyskinesias may occur.

If the patient is seen sufficiently soon (up to 6 hours) after ingestion of a toxic dose, gastric lavage may be attempted. Pharmacological induction of emesis is unlikely to be of any use. Activated charcoal should be given. There is no specific antidote. Treatment is supportive.

Generalised vasodilatation may result in circulatory collapse. Raising the patient's legs may suffice, in severe cases, volume expansion by intravenous fluids may be needed. Infusion fluids should be warmed before administration in order not to aggravate hypothermia.

Positive inotropic agents such dopamine may be tried if fluid replacement is insufficient to correct circulatory collapse. Peripheral vasoconstrictor agents are generally not recommended. Avoid the use of adrenaline.

Ventricular or supraventricular tachyarrhythmias usually respond to restoration of normal body temperature and correction of circulatory or metabolic disturbances. If persistent or life threatening, appropriate anti-arrhythmic therapy may be considered. Avoid lignocaine and, as far as possible, long-acting anti-arrhythmic drugs.

Pronounced central nervous system depression requires airway maintenance or, in extreme circumstances, assisted respiration. Severe dystonic reactions usually respond to procyclidine (5-10 mg) or orphenadrine (20-40 mg) administered intramuscularly or intravenously. Convulsions should be treated with intravenous diazepam.

Neuroleptic malignant syndrome has been reported in the context of alimemazine overdose. Symptoms include a combination of hyperthermia, muscle rigidity, altered mental status and autonomic instability. Since this syndrome is potentially fatal, the use of Vallergan Forte must be discontinued immediately, and intensive clinical monitoring and symptomatic treatment must be initiated.

Neuroleptic malignant syndrome should be treated with cooling. Dantrolene sodium may be tried. Strict adherence to the recommended dose is critical.

Contact the Poisons Information Centre on 0800 POISON OR 0800 764 766 for advice on the management of overdosage.

## **5 PHARMACOLOGICAL PROPERTIES**

### **5.1 PHARMACODYNAMIC PROPERTIES**

Vallergan Forte has a central sedative effect comparable to that of chlorpromazine, but largely devoid of the latter's anti-adrenaline action. It has powerful anti-histamine and anti-emetic actions.

## **5.2 PHARMACOKINETIC PROPERTIES**

There is little information about blood levels, distribution and excretion in humans. The rate of metabolism and excretion of phenothiazines decreases in old age.

## **5.3 PRECLINICAL SAFETY DATA**

There are no pre-clinical data of relevance to the prescriber which are additional to that already included in other sections of the Data Sheet.

# **6 PHARMACEUTICAL PARTICULARS**

## **6.1 LIST OF EXCIPIENTS**

Sucrose  
Apricot flavor  
Ethanol  
Citric acid  
Sodium citrate dehydrate  
Sodium metabisulfite  
Sodium sulfite  
Sodium benzoate  
Purified water

## **6.2 INCOMPATIBILITIES**

This medicine must not be mixed with other medicines except those mentioned in section 6.6.

## **6.3 SHELF LIFE**

3 years.

Discard Vallergan Forte syrup one month after first opening the bottle.

## **6.4 SPECIAL PRECAUTIONS FOR STORAGE**

Protect from light.

Vallergan Forte syrup should be stored below 25°C.

For storage conditions after first opening of the medicine, see section 6.3.

## **6.5 NATURE AND CONTENTS OF CONTAINER**

100 mL bottles

## **6.6 SPECIAL PRECAUTIONS FOR DISPOSAL AND OTHER HANDLING**

Vallergan Forte syrup may be diluted, if required, using Syrup B.P.

No special requirements for disposal.

## **7 MEDICINE SCHEDULE**

Prescription Medicine

## **8 SPONSOR**

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

Freecall: 0800 283 684

## **9 DATE OF FIRST APPROVAL**

31 December 1969

## **10 DATE OF REVISION OF THE TEXT**

16 June 2017

## SUMMARY OF CHANGES

Section changed	Summary of new information
2	Added excipient reference.
4.2	Added reference to section 6.6 re dilution.
4.3	Added contraindication: history of agranulocytosis.
4.4	Added the precaution to exercise caution in patients with a history of seizures.
4.5	Added opiates to list of medicines capable of intensifying the CNS depressant actions of phenothiazines.
4.8	Added the following new adverse events: constipation, dizziness, headache, retention of urine, accommodation disorder and damage to teeth and oral mucous membranes with long term use. Added adverse event reporting details.
5.3	Added statement re no pre-clinical data.
6.1	Added excipients as per TPDR
6.2	Added reference to section 6.6 re mixing.
6.3	Added shelf life as per TPDR
6.4	Added reference to 6.3 re storage after opening.
6.6	Added no special requirements for disposal.
8	Added Freecall number.
9	Added date of first approval as per TPDR.
10	Updated date of revision to: 16 June 2017