

# **Nausicalm**

## **Cyclizine lactate 50 mg/mL solution for injection**

### **Presentation**

Nausicalm solution for injection is a clear colourless solution, presented in 1 mL ampoules.

### **Uses**

#### ***Actions***

Cyclizine is a piperazine derivative with the general properties of H<sub>1</sub>-blocking drugs including antimuscarinic activity, but is used as an anti-emetic in a variety of clinical situations including drug-induced and motion sickness, vertigo, post-operative vomiting and radiation sickness. The mechanism of the anti-emetic effect is unclear. Cyclizine also possesses anticholinergic activity but does not have marked sedative effects.

#### ***Pharmacokinetics***

Cyclizine produces its antiemetic effect within 2 hours and lasts approximately 4 hours.

Cyclizine is metabolised in the liver. It is extensively N-demethylated to the inactive metabolite norcyclizine which is widely distributed throughout the tissues with a plasma half-life of approximately 20 hours.

#### ***Indications***

Nausicalm is indicated for the prevention and treatment of nausea and vomiting including:

motion sickness,  
nausea and vomiting caused by narcotic analgesics and by general anaesthetics in the post-operative period  
vomiting associated with radiotherapy, especially for breast cancer since cyclizine does not elevate prolactin levels.

Intravenous Nausicalm is indicated pre-operatively in patients undergoing emergency surgery to reduce the hazard of regurgitation and aspiration of gastric contents during induction of general anaesthesia.

Nausicalm may be of value in relieving vomiting and attacks of vertigo associated with Meniere's disease and other forms of vestibular disturbance.

### **Dosage and Administration**

For adult administration only.

The recommended dose is 50 mg administered intramuscularly (IM) or intravenously (IV), which may be repeated up to three times a day.

When used intravenously, Nausicalm injection should be injected slowly, undiluted, into the bloodstream with only minimal withdrawal of blood into the syringe.

To prevent post-operative vomiting the first dose should be given by slow IV injection 20 minutes before the anticipated end of surgery.

Cyclizine given IV, in half the recommended dose, increases the lower oesophageal sphincter tone thus reducing the hazard of regurgitation and aspiration of gastric contents when given to patients undergoing emergency surgery before the induction of general anaesthesia.

There have been no specific studies of cyclizine in the elderly. Experience has indicated that the normal adult dosage is appropriate.

## **Contraindications**

Nausicalm should not be given to individuals with known hypersensitivity to cyclizine.

## **Warnings and Precautions**

As with other anticholinergic agents, Nausicalm should be used with caution and appropriate monitoring in patients with glaucoma, obstructive disease of the gastrointestinal tract, hepatic disease, epilepsy and in males with possible prostatic hypertrophy.

Nausicalm should be used with caution in patients with severe heart failure. In such patients, cyclizine may cause a fall in cardiac output associated with increases in heart rate, mean arterial pressure and pulmonary wedge pressure.

There have been no specific studies of cyclizine in patients with hepatic and/or renal dysfunction.

There have been reports of abuse of cyclizine for its euphoric or hallucinatory effects. The concomitant use of cyclizine with large amounts of alcohol is particularly dangerous as the anti-emetic effect of the cyclizine may increase the toxicity of the alcohol.

There have been isolated case reports of transient paralysis occurring in patients using intravenous cyclizine. Two of the patients mentioned in these reports had an underlying neuromuscular disorder. Thus intravenous cyclizine should be used with caution in all patients in general, and in patients with underlying neuromuscular disorders in particular.

## **Pregnancy and Lactation [Category A]**

Some animal studies are interpreted as indicating that cyclizine may be teratogenic.

In a study involving prolonged administration of cyclizine to male and female rats there was no evidence of impaired fertility after continuous treatment for 90 to 100 days. There is no experience of the effect of cyclizine on human fertility.

It is not known whether cyclizine or its metabolites are excreted in human milk.

## **Effects on ability to drive and use machines**

Studies designed to detect drowsiness did not reveal sedation in healthy adults who took a single oral therapeutic dose (50 mg) of cyclizine.

Patients should not drive or operate machinery until they have determined their own response.

Although there are no data available, patients should be cautioned that cyclizine may have additive effects with alcohol and other central nervous system depressants, e.g. hypnotics and tranquillisers.

## **Adverse Effects**

**Eye disorders:** oculogyric crisis

**General disorders and administration site conditions:** asthenia. Injection site reactions including vein tracking, erythema, pain, thrombophlebitis and blisters. A sensation of heaviness, chills and pruritus have been reported rarely.

**Hepatobiliary disorders:** hepatic dysfunction, hypersensitivity hepatitis, cholestatic jaundice and cholestatic hepatitis.

**Musculoskeletal and connective tissue disorders:** twitching, muscle spasms

**Nervous System Disorders:** somnolence, headache, dystonia, dyskinesia, extrapyramidal motor disturbances, tremor, convulsions, dizziness, decreased consciousness, transient speech disorders, paraesthesia

**Psychiatric disorders:** disorientation, agitation

**Respiratory, thoracic and mediastinal disorders:** bronchospasm, apnoea

**Skin and subcutaneous tissue disorders:** urticaria, drug rash, angioedema

**Vascular Disorders:** hypertension, hypotension

Drowsiness, dryness of the mouth, nose and throat, blurred vision, tachycardia, urinary retention, constipation, restlessness, nervousness, insomnia and auditory and visual hallucinations have been reported, particularly when dosage recommendations have been exceeded.

Following oral administration, single case reports have been documented of:

fixed drug eruption;  
generalised chorea;  
hypersensitivity hepatitis;  
agranulocytosis.

A single case of anaphylaxis has been recorded following intravenous administration of cyclizine co-administered with propanidid in the same syringe.

An increase in excitatory phenomena (tremor and muscle movements) has been reported when cyclizine has been given before propanidid and methohexitone anaesthesia.

## Interactions

Cyclizine may have additive effects with alcohol and other central nervous system depressants e.g. hypnotics, tranquillisers. Cyclizine enhances the soporific effect of pethidine. Because of its anticholinergic activity cyclizine may enhance the side-effects of other anticholinergic drugs.

## Overdosage

**Symptoms:** Symptoms of acute toxicity from cyclizine arise from peripheral anticholinergic effects and effects on the central nervous system.

Peripheral anticholinergic symptoms include, dry mouth, nose and throat, blurred vision, tachycardia and urinary retention. Central nervous system effects include drowsiness, dizziness, inco-ordination, ataxia, weakness, hyperexcitability, disorientation, impaired judgement, hallucinations, hyperkinesia, extrapyramidal motor disturbances, convulsions, hyperpyrexia and respiratory depression.

**Treatment:** In the management of acute overdosage with cyclizine, gastric lavage and supportive measures for respiration and circulation should be performed if necessary. Convulsions should be controlled in the usual way with parenteral anticonvulsant therapy.

## Pharmaceutical Precautions

Store below 25 °C. Protect from light.

## Medicine Classification

Prescription Only Medicine.

## Package Quantities

Packs of 5 ampoules.

## Further Information

Other ingredients of the injections are lactic acid and water for injections.

## Name and Address

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