

## **SUMMARY OF PRODUCT CHARACTERISTICS**

### **1 NAME OF THE MEDICINAL PRODUCT**

Cyclizine lactate 50mg/ml solution for injection

### **2 QUALITATIVE AND QUANTITATIVE COMPOSITION**

Each 1ml ampoule contains 50mg cyclizine lactate.  
For the full list of excipients, see section 6.1.

### **3 PHARMACEUTICAL FORM**

Clear, colourless to slightly yellowish solution for injection

### **4 CLINICAL PARTICULARS**

#### **4.1 Therapeutic indications**

Cyclizine is indicated in adults for the prevention and treatment of nausea and vomiting including:

- Motion sickness when the oral route cannot be used.
- 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.

Cyclizine injection, by the intravenous route, is also indicated pre-operatively in patients undergoing emergency surgery in order to reduce the hazard of regurgitation and aspiration of gastric contents during induction of general anaesthesia.

Cyclizine may be of value in relieving vomiting and attacks of vertigo associated with Menière's disease and other forms of vestibular disturbance when the oral route cannot be used.

#### **4.2 Posology and method of administration**

Posology

For the prevention of postoperative nausea and vomiting, administer the first dose by slow intravenous injection 20 minutes before the anticipated end of surgery.

#### Adults

- 50mg intramuscularly or intravenously up to three times daily.
- When used intravenously, cyclizine should be injected slowly into the bloodstream, with only minimal withdrawal of blood into the syringe.
- For the prevention of post operative nausea and vomiting, administer the first dose by slow intravenous injection 20 minutes before the anticipated end of surgery.
- Cyclizine given intravenously, in half the recommended dose, increases the lower oesophageal sphincter tone and thereby reduces the hazard of regurgitation and aspiration of gastric contents if given to patients, undergoing emergency surgery, before induction of general anaesthesia.

#### Elderly

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

#### Paediatric population

- Not licensed for use in children.

#### Method of administration

Intramuscularly or intravenously

### **4.3 Contraindications**

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

Cyclizine is contraindicated in the presence of acute alcohol intoxication. The anti-emetic properties of cyclizine may increase the toxicity of alcohol.

### **4.4 Special warnings and precautions for use**

As with other anticholinergic agents, cyclizine may precipitate incipient glaucoma and it should be used with caution and appropriate monitoring in patients with glaucoma, urinary retention, obstructive disease of the gastrointestinal tract, hepatic disease, pheochromocytoma, hypertension, epilepsy and in males with possible prostatic hypertrophy. Cyclizine injection may have a hypotensive effect.

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

Cyclizine should be avoided in porphyria.

There have been reports of abuse of cyclizine, either oral or intravenous, for its euphoric or hallucinatory effects. The concomitant misuse of cyclizine with large amounts of alcohol is particularly dangerous, since the antiemetic effect of cyclizine may increase the toxicity of alcohol (see also Section 4.5).

Case reports of paralysis have been received in patients using intravenous cyclizine. Some of the patients mentioned in these case reports had an underlying neuromuscular disorder. Thus, intravenous cyclizine should be used with caution in all patients and with particular care in patients with underlying neuromuscular disorders.

#### **4.5 Interaction with other medicinal products and other forms of interaction**

Cyclizine may have additive effects with alcohol and other central nervous system depressants, e.g. hypnotics, tranquilisers, anaesthetics, antipsychotics, barbiturates.

Cyclizine enhances the soporific effect of pethidine.

Cyclizine may counteract the haemodynamic benefits of opioid analgesics.

Because of its anticholinergic activity, cyclizine may enhance the side-effects of other anticholinergic drugs, and may have an additive antimuscarinic actions with other antimuscarinic drugs, such as atropine and some antidepressants (both tricyclic and MAOIs).

Cyclizine may mask the warning signs of damage caused by ototoxic drugs such as aminoglycoside antibacterials.

#### **4.6 Fertility, pregnancy and lactation**

##### Pregnancy

In the absence of any definitive human data, the use of cyclizine in pregnancy is not advised

##### Breast-feeding

Cyclizine is excreted in human milk; however, the amount has not been quantified.

### Fertility

In a study involving prolonged administration of cyclizine to male and female rats, there was no evidence of impaired fertility after continuous treatment for 90-100 days at dose levels of approximately 15 and 25 mg/kg/day. There is no experience of the effect of cyclizine on human fertility.

## **4.7 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 (50mg) of cyclizine. Sedation of a short duration was reported by subjects receiving intravenous cyclizine.

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

Although there is 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.

## **4.8 Undesirable effects**

Adverse reactions are ranked under heading of frequency, the most frequent first, using the following convention: Very common: ( $\geq 1/10$ ); Common ( $\geq 1/100$  to  $< 1/10$ ); Uncommon ( $\geq 1/1,000$  to  $< 1/100$ ); Rare ( $\geq 1/10,000$  to  $< 1/1,000$ ); Very rare ( $< 1/10,000$ ); Not known: cannot be estimated from the available data.

The following undesirable effects have been reported with a frequency of Not known.

<b>System Organ Class</b>	<b>Frequency</b>	<b>Adverse reactions</b>
Blood and lymphatic system disorders	Not known	Agranulocytosis, leucopenia, haemolytic anaemia, thrombocytopenia.
Cardiac disorders	Not known	Tachycardia palpitations, arrhythmias (see section 4.4)
Ear and labyrinth disorders	Not known	Tinnitus. There have been rare case reports of patients experiencing depressed levels of consciousness/loss of consciousness.
Eye disorders	Not known	Blurred vision, oculogyric crisis
Gastrointestinal system disorders	Not known	Dryness of the mouth, nose and throat, constipation, increased gastric reflux, nausea, vomiting, diarrhoea, stomach pain, loss of appetite.

General disorders and administration site conditions	Not known	Asthenia, malaise Injection site reactions including vein tracking, erythema, pain, thrombophlebitis and blisters. A sensation of heaviness, <u>chills</u> and <u>pruritus</u> have been reported rarely. Rapid IV administration can lead to symptoms similar to overdose.
Hepatobiliary disorders	Not known	Hepatic dysfunction (see section 4.4), hypersensitivity hepatitis, cholestatic jaundice and cholestatic hepatitis have occurred in association with cyclizine.
Immune system disorders	Not known	Hypersensitivity reactions, including anaphylaxis have occurred.
Musculoskeletal and connective tissue disorders	Not known	Twitching, muscle spasms
Nervous system disorders	Not known	Effects on the central nervous system have been reported with cyclizine these include somnolence, drowsiness, incoordination, headache, dystonia, dyskinesia, extrapyramidal motor disturbances, restless leg syndrome, tremor, convulsions, dizziness, decreased consciousness, transient speech disorders, paraesthesia, paralysis* and generalised chorea.
Psychiatric disorders	Not known	Disorientation, restlessness or agitation, nervousness, euphoria, insomnia and auditory and visual hallucinations have been reported, particularly when dosage recommendations have been exceeded.
Renal and urinary disorders	Not known	Urinary retention
Respiratory, thoracic and mediastinal disorders	Not known	Bronchospasm, apnoea
Skin and subcutaneous tissue disorders	Not known	Urticaria, pruritus, drug rash, angioedema, allergic skin reactions, fixed drug eruption, photosensitivity
Vascular disorders	Not known	Hypertension, hypotension

\*Case reports of paralysis have been received in patients using intravenous cyclizine. Some of the patients mentioned in these case reports had an underlying neuromuscular disorder (see section 4.4).

#### Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme website [www.mhra.gov.uk/yellowcard](http://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

## 4.9 Overdose

### 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, incoordination, ataxia, weakness, hyperexcitability, disorientation, impaired judgement, hallucinations, hyperkinesia, extrapyramidal motor disturbances, convulsions, hyperpyrexia and respiratory depression.

An oral dose of 5 mg/kg is likely to be associated with at least one of the clinical symptoms stated above. Younger children are more susceptible to convulsions. The incidence of convulsions, in children less than 5 years, is about 60% when the oral dose ingested exceeds 40 mg/kg.

### Management

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.

## 5 PHARMACOLOGICAL PROPERTIES

### 5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Piperazine derivatives  
ATC code: R06AE03

#### Mechanism of action:

Cyclizine is a histamine H<sub>1</sub> receptor antagonist of the piperazine class which is characterised by a low incidence of drowsiness. It possesses anticholinergic and antiemetic properties. The exact mechanism by which cyclizine can prevent or suppress both nausea and vomiting from various causes is unknown. Cyclizine increases lower oesophageal sphincter tone and reduces the sensitivity of the labyrinthine apparatus. It may inhibit the part of the midbrain known collectively as the emetic centre.

#### Pharmacodynamics effects:

Cyclizine produces its antiemetic effect within two hours and lasts approximately four hours.

### 5.2 Pharmacokinetic properties

Distribution: In healthy adult volunteers, the administration of a single oral dose of 50mg cyclizine resulted in a peak plasma concentration of approximately 70ng/mL occurring at about two hours after drug administration. The plasma elimination half-life was approximately 20 hours.

Biotransformation: The N-demethylated derivative, norcyclizine, has been identified as a metabolite of cyclizine. Norcyclizine has little antihistaminic (H<sub>1</sub>) activity compared to cyclizine and has a plasma half-life of approximately 20 hours.

Elimination: After a single dose of 50mg cyclizine given to a single adult male volunteer, urine collected over the following 24 hours contained less than 1% of the total dose administered.

### **5.3 Preclinical safety data**

Mutagenicity: cyclizine was not mutagenic in a full Ames test, including use of S9-microsomes but can nitrosate *in vitro* to form mutagenic products.

Carcinogenicity: No long term studies have been conducted in animals to determine whether cyclizine has a potential for carcinogenesis. However, long-term studies with cyclizine administered with nitrate have indicated no carcinogenicity.

Teratogenicity: Some animal studies are interpreted as indicating that cyclizine may be teratogenic at dose levels up to 25 times the clinical dose level. In another study, cyclizine was negative at oral dose levels up to 65mg/kg in rats and 75mg/kg in rabbits. The relevance of these studies in humans is not known.

Fertility: In a study involving prolonged administration of cyclizine to male and female rats there was no evidence of impaired fertility after continuous treatment for 90-100 days at dose levels of approximately 15 and 25 mg/kg/day. There is no experience of the effect of Cyclizine on human fertility.

## **6 PHARMACEUTICAL PARTICULARS**

### **6.1 List of excipients**

Lactic acid  
Water for injections

## **6.2 Incompatibilities**

None known. In the absence of compatibility studies, this medicinal product must not be mixed with other medicinal products.

## **6.3 Shelf life**

18 months

## **6.4 Special precautions for storage**

Store below 25°C.

Keep the ampoules in the outer carton in order to protect from light

## **6.5 Nature and contents of container**

1ml clear glass type I ampoules. Five ampoules in the outer carton.

## **6.6 Special precautions for disposal**

For single use only. Discard any unused product.

## **7 MARKETING AUTHORISATION HOLDER**

Strandhaven Limited t/a Somex Pharma  
600 High Road,  
Ilford, Essex,  
IG3 8BS, UK

## **8 MARKETING AUTHORISATION NUMBER(S)**

PL 15764/0209

## **9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

30/04/2026

**10 DATE OF REVISION OF THE TEXT**

30/04/2026