- Antihistamine -

Homoclomin® Tablets 10mg

<Homochlorcyclizine hydrochloride preparation>

CONTRAINDICATIONS (HOMOCLOMIN is contraindicated in the following patients.)

1. Patients with glaucoma
   [HOMOCLOMIN may increase intraocular pressure due to its anticholinergic action.]
2. Patients with obstructive diseases of the lower urinary tract such as a prostatic hypertrophy
   [HOMOCLOMIN may cause dysuria, urinary retention or other symptoms due to its anticholinergic action.]

DESCRIPTION

1. Composition
   Each white plain tablet contains 10 mg of homochlorcyclizine hydrochloride.
   It also contains calcium stearate, corn starch, lactose hydrate and hydroxypropylcellulose as inactive ingredients.

2. Product description
<table>
<thead>
<tr>
<th>Brand name</th>
<th>Dosage form and identification code</th>
<th>Appearance</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>HOMOCLOMIN</td>
<td>Tablets 10 mg</td>
<td>White, bitter taste, scored</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Diameter (mm) 7.1</td>
<td>Weight (mg) 120</td>
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<tr>
<td></td>
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<td>Thickness (mm) 2.4</td>
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</tbody>
</table>

INDICATIONS

Itching sensation resulting from skin diseases (eczema or dermatitis, pruritus, drug eruption, toxic erythema and infant staphylus), urticaria and allergic rhinitis

DOSAGE AND ADMINISTRATION

The usual adult dosage for oral use is 1 to 2 tablets (10 - 20 mg of homochlorcyclizine hydrochloride) three times daily. The dosage may be adjusted depending on the patient’s age and symptoms.

PRECAUTIONS

1. Important Precautions
   Since HOMOCLOMIN may produce sleepiness, patients should be cautioned against engaging in potentially hazardous activities requiring alertness, such as operating machinery or driving a car.

2. Drug Interactions
   Precautions for coadministration (HOMOCLOMIN should be administered with care when coadministered with the following drugs.)

<table>
<thead>
<tr>
<th>Drugs</th>
<th>Signs, Symptoms, and Treatment</th>
<th>Mechanism and Risk Factors</th>
</tr>
</thead>
<tbody>
<tr>
<td>Central nervous system suppressants</td>
<td>They may mutually potentiate each other’s action. They should be coadministered with care, such as by reducing in dosage.</td>
<td>Their actions are potentiated due to the central nervous system supressing action of HOMOCLOMIN.</td>
</tr>
<tr>
<td>Barbituric acid derivatives</td>
<td>Monoamine oxidase inhibitor (MAO-I)</td>
<td></td>
</tr>
<tr>
<td>Phenothiazine derivatives</td>
<td>Alcohol</td>
<td></td>
</tr>
<tr>
<td>Alcohol</td>
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</tr>
</tbody>
</table>

3. Adverse Reactions

Adverse reactions were reported in 376 of 1,941 patients (19.37%). (At the end of reevaluation period)

<table>
<thead>
<tr>
<th>Hypersensitivity</th>
<th>Rash</th>
</tr>
</thead>
<tbody>
<tr>
<td>Psychoneurologic</td>
<td>Sleeplessness</td>
</tr>
<tr>
<td>Gastrointestinal</td>
<td>Nausea/vomiting, thirst and anorexia</td>
</tr>
<tr>
<td>Urinary</td>
<td>Dysuria</td>
</tr>
<tr>
<td>Respiratory</td>
<td>Difficulty of sputum excretion</td>
</tr>
</tbody>
</table>

Note) In the event of such symptoms, treatment should be discontinued.
4. **Use in the Elderly**
Since the elderly often have a physiological hypofunction, it is advisable to take measures, such as reduction in dosage under careful observation.

5. **Use during Pregnancy, Delivery or Lactation**
HOMOCLOMIN is not recommended for pregnant women or women suspected of being pregnant.
[The safety of HOMOCLOMIN in pregnant women has not been established.]

6. **Precautions concerning Use**
Caution in handing over drug
For drugs that are dispensed in a press-through package (PTP), instruct the patient to remove the drug from the package prior to use. [It has been reported that, if the PTP sheet is swallowed, the sharp corners of the sheet may puncture the esophageal mucosa, causing perforation and resulting in serious complications such as mediastinitis.]

7. **Other Precautions**
Since hematological, hepatic or other abnormalities have been reported to be associated with the use of HOMOCLOMIN in animal studies, the patient should be carefully observed. In the event of such symptoms, treatment should be discontinued. Long-term or high-dose administration should be avoided.

**CLINICAL STUDIES**

**Clinical efficacy**
The efficacy rate of HOMOCLOMIN for the treatment of eczema (acute, chronic, dry, nummular or seborrheic), dermatitis (acute, contact, atopic or neurotic), pruritus, toxic erythema, infant strophulus and urticaria, etc. was 68.9% (918/1,333) in open labeled clinical trials.

**PHARMACOLOGY**

1. **Anti-bradykinin action**
Homochlorcyclizine hydrochloride inhibits bradykinin-induced contractions of isolated guinea pig ileum using the Schultz-Dale method at a concentration as low as 0.1 μg/mL, and this effect is nearly complete at concentrations of 1 to 2 μg/mL. 1)

2. **Antagonism to SRS-A (slow-reacting substance of anaphylaxis)**
Homochlorcyclizine hydrochloride partially blocks SRS-A-induced contractions in isolated guinea pig ileum at a concentration of 4μg/mL. 2)

3. **Anti-histamine, anti-serotonin and anti-acetylcholinergic actions**
In isolated guinea-pig ileum using the Schultz-Dale method, homochlorcyclizine hydrochloride completely inhibits histamine-induced contractions at a concentration of 0.1μg/mL, while it completely inhibits serotonin or acetylcholine-induced contractions at a concentration of 1μg/mL. 1)

4. **Anti-anaphylactic effect**
Passive anaphylaxis in guinea pigs is prevented by intraperitoneal injection of 20 mg/kg of homochlorcyclizine hydrochloride. 3)

**PHYSICOCHEMISTRY**

**Nonproprietary name:**
Homochlorcyclizine Hydrochloride (JAN)

**Chemical name:**
1-[(RS)-(4-Chlorophenyl) (phenyl) methyl]-4-methylhexahydro - 1H-1, 4-diazepine dihydrochloride

**Molecular formula:**
C₁₉H₂₃ClN₂ ⋅ 2HCl

**Molecular weight:**
387.77

**Structural formula:**

![Structural formula](image)

**Description:**
Homochlorcyclizine hydrochloride occurs as white to pale brown crystals or powder.
It is very soluble in water, freely soluble in acetic acid (100), slightly soluble in ethanol (99.5), very slightly soluble in acetonitrile and in acetic anhydride.
It dissolves in 0.1 mol/L hydrochloric acid TS.
It is hygroscopic.
It slightly colored by light. A solution of homochlorcyclizine hydrochloride in water (1 in 10) shows no optical rotation.

**Melting point:**
about 227°C (with decomposition)

**PACKAGING**

HOMOCLOMIN Tablets 10mg:
Boxes of 100 and 1,000 in press-through packages

**REFERENCES**


**REQUESTS FOR LITERATURE AND PRODUCT INFORMATION SHOULD BE MADE TO:**
Customer Information Service
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