SUPRASTIN
Active material: Xloropiramin
When ATH: R06AC03 CCF: Gistaminovy blocker H₁-receptors.
Allergy medication ICD-10 codes (testimony): H10.1, J06.9, J30.1, J30.3, L20.8, L23, L24, L29, L30.0, L50, T14.0, T78.3, T80.6, T88.7 When CSF: 13.01.01.01 Manufacturer: EGIS

PHARMACEUTICALS Plc (Hungary)

DOSAGE FORM, COMPOSITION AND PACKAGING
◊ Pills white or grayish white color, in the form of a disk with a chamfer, Engraved “Understand” on one side, with little or no odor.

<table>
<thead>
<tr>
<th>1 tab.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chloropyramine hydrochloride</td>
</tr>
</tbody>
</table>

Excipients: stearic acid, gelatin, sodium carboxymethyl (Type A), talc, potato starch, lactose monohydrate (116 mg).
10 PC. – blisters (2) – packs cardboard.
20 PC. – vials of dark glass (1) – packs cardboard.

Solution for in / and the / m clear, colorless, with a faint characteristic odor.

<table>
<thead>
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<th>1 amp.</th>
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</tr>
</tbody>
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Excipients: water d / and.
1 ml – ampoule (5) – packings Valium planimetric (1) – packs cardboard.

Pharmacological action
Gistaminovy blocker H₁-receptors, ethylenediamine derivative. It prevents the development and facilitates the allergic reactions. It has a mild sedative and antipruritic effect pronounced. It has antiemetic effect, peripheral anticholinergic activity, moderate inflammatory properties. The therapeutic effect develops within 15-30 minutes after ingestion, It reaches a maximum during the first hour after administration and lasts for at least 3-6 no.

Pharmacokinetics
Absorption
Once inside Chloropyramine hydrochloride is rapidly and completely absorbed from the gastrointestinal tract. 
$C_{max}$ plasma levels achieved during the first 1-2 no, therapeutic level of concentration is maintained for a 3-6 no.

Distribution
Regardless of the route of administration are well distributed in the body, including CNS. Binding Chloropyramine plasma protein is 7.9%.
Metabolism
It is extensively metabolized in the liver.  
*Deduction*  
Introduced primarily in the urine as metabolites.  
*Pharmacokinetics in special clinical situations*  
In children, excretion of the drug faster, than in adults.

**INDICATIONS**
- Urticaria;  
- Angioedema (angioedema);  
- Serum sickness;  
- Seasonal and perennial allergic rhinitis;  
- Conjunctivitis;  
- Contact dermatitis;  
- Itching;  
- Acute and chronic eczema;  
- Atopic dermatitis;  
- Food and drug allergy;  
- An allergic reaction to insect bites.

**DOSAGE**
Assign inside, / m and / in.  
Inside **adult** appoint 25 mg (1 tab.) 3-4 times / day (75-100 mg / day).  
**Babies** the drug is prescribed in the following doses:

<table>
<thead>
<tr>
<th>Age</th>
<th>Single dose</th>
<th>Reception frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>from 1 to 12 months</td>
<td>1/4 tab.</td>
<td>2-3 times / day (Pounded into a powder to form along with baby food)</td>
</tr>
<tr>
<td></td>
<td>(6.25 mg)</td>
<td></td>
</tr>
<tr>
<td>from 1 Year to 6 years</td>
<td>1/4 tab.</td>
<td>3 times / day</td>
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<td></td>
<td>1/2 tab.</td>
<td>2 times / day</td>
</tr>
<tr>
<td></td>
<td>(12.5 mg)</td>
<td></td>
</tr>
<tr>
<td>from 6 to 14 years</td>
<td>1/2 tab.</td>
<td>2-3 times / day</td>
</tr>
<tr>
<td></td>
<td>(12.5 mg)</td>
<td></td>
</tr>
</tbody>
</table>

The dose can be gradually increased in the absence of side effects in patients, but the maximum dose should not exceed 2 mg / kg body weight.  
The tablets should be taken orally with meals, not chewing and drinking plenty of water.  
Parenteral drug products should be entered in the / m.  
In / in the introduction is used only in severe cases of acute under medical supervision.  
**Adults** the drug is introduced into / m 20-40 mg (1-2 amp.)/d.  
**Babies** / m of drug administered in the following doses:

<table>
<thead>
<tr>
<th>Age</th>
<th>Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>from 1 to 12 months</td>
<td>1/4 amp. (5 mg)</td>
</tr>
</tbody>
</table>
from 1 Year to 6 years | 1/2 amp. (10 mg)
from 6 to 14 years | 1/2-1 amp. (10-20 mg)

The dose can be gradually increased in the absence of side effects in patients, but the maximum dose should not exceed 2 mg / kg body weight.

In severe and acute cases of allergic and anaphylactic reactions, treatment can begin with a slow I / injection, then continue to the / m introduction of the drug, then go to the reception of the drug inside.

At abnormal liver function, it may require dose reduction due to reduction of metabolism of the active ingredient.

At impaired renal function, also may require a reduction in dose.

SIDE EFFECT

CNS: drowsiness, fatiguability, dizziness, jitters, tremor, headache, euphoria.

From the digestive system: abdominal discomfort, dry mouth, nausea, vomiting, diarrhea, constipation, loss or increase in appetite, epigastric pain.

Cardio-vascular system: decrease in blood pressure, tachycardia, arrhythmia (It was not always a direct relationship between these side effects to the drug intake).

From the hematopoietic system: rarely – leukopenia, agranulocytosis.

Other: strangury, muscular weakness, increased intraocular pressure, photosensitivity.

Side effects occur, usually, rarely, are temporary and disappear after drug withdrawal.

CONTRAINDICATIONS

- An acute attack of asthma;
- Pregnancy;
- Lactation (breast-feeding);
- Infants (incl. Premature);
- Hypersensitivity to the drug or other derivatives of ethylene diamine.

FROM caution use in patients with angle-closure glaucoma, in patients with urinary retention and hypertrophy of the prostate, for violations of the liver and / or kidney, cardiovascular diseases, in elderly patients.

Pregnancy and lactation

There have been no adequate and well-controlled studies of the use of antihistamines in pregnancy. Therefore, use of the drug in pregnant women (especially in the I trimester and last month of pregnancy) possibly only, if the potential benefit to the mother outweighs the potential risk to the fetus.

If necessary, use during lactation should stop breastfeeding.
Cautions
With extreme caution should be used drug in the elderly, malnourished patients, tk. such patients often experience side effects (dizziness, drowsiness).
Precautions should be prescribed Suprastin® simultaneously with sedatives, tranquilizatorami, analgesics, MAO inhibitors, tricyclic antidepressants, atropine and / or sympatholytic.
During treatment should eliminate the use of alcohol.
Each tablet contains 116 mg lactose monohydrate. This amount can cause unwanted reactions in patients with lactase deficiency or rare metabolic disorders – galactosemia and malabsorption syndrome glucose / galactose.
Effects on ability to drive vehicles and management mechanisms
In the initial, individually defined period of application suprastin® not permitted driving vehicles and other classes of potentially hazardous activities, requiring quickness of psychomotor reactions. In the course of further treatment degree of limitation is determined depending on the individual tolerability.

OVERDOSE
Symptoms: hallucinations, anxiety, ataxia, dystaxia, athetosis, convulsions, midria; in infants – excitation, anxiety, dry mouth, fixed dilated pupils, facial flushing, sinus tachycardia, urinary retention, fever, coma; adult – fever and flushing of the skin faces seen impermanent, after a period of excitement followed by depression, convulsions and poslesudorozhnaya, coma.
Treatment: prior to 12 h after dosing – gastric lavage (should be considered, that the emptying of the stomach prevents the anticholinergic effect of the drug), appointment of activated carbon, parameter control of blood pressure and respiration, symptomatic therapy, if necessary – resuscitation. Spetsificheskiy no known antidote.

Drug Interactions
In an application Suprastin® enhances the effects of sedatives, tranquilizatorov, analgesics, MAO inhibitors, tricyclic antidepressants, atropyna, simpatolitikov and ethanol.
While the use of ototoxic drugs Suprastin® may mask the early signs of ototoxicity.

Conditions of supply of pharmacies
A preparation in the form of solution for injection by prescription. The drug is in the form of tablets is approved for use as a means of non-prescription.
TERMS AND CONDITIONS OF STORAGE

The drug should be stored out of reach of children at temperature from 15 ° to 25 ° C. Shelf life – 5 years.

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Online Medicina: http://omedicine.info/es/suprastin.html