

### 1.3.1.1 PROFESSIONAL INFORMATION FOR MEDICINES FOR HUMAN USE

#### SCHEDULING STATUS:

**S2**

#### PROPRIETARY NAME AND DOSAGE FORM:

ELIXIROL (syrup)

#### COMPOSITION:

Each 5 ml medicine measure contains:

Diphenhydramine Hydrochloride	12,5 mg	
Ammonium Chloride	125 mg	
Preservative:	Nipasept	0,06 % <i>m/v</i>

#### PHARMACOLOGICAL CLASSIFICATION:

A 10.1 Antitussives and expectorants.

#### INDICATIONS:

Alleviation of cough.

#### CONTRA-INDICATIONS:

Sensitivity to any of the ingredients.

Antihistamines should not be given to premature infants or neonates, and are also contra-indicated during acute attacks of asthma.

Impaired liver and renal function.

Safety in pregnancy and lactation has not been established.

**WARNINGS:**

This medicine may lead to drowsiness and impaired concentration, which may be aggravated by simultaneous intake of alcohol or other central nervous system depressant agents. Patients should be warned against taking charge of vehicles or machinery or performing potentially hazardous tasks where loss of concentration may lead to accidents.

**DOASAGE AND DIRECTIONS FOR USE:**

**Adults:** One or two medicine measures (5 - 10 ml) every four hours.

**Infants 2-5 years:** One quarter to one half medicine measure (1,25 - 2,5 ml) every four hours.

**Children 6-2 years:** One half to one medicine measure (2,5 - 5 ml) every four hours.

**SIDE-EFFECTS AND SPECIAL PRECAUTIONS:****Side-effects:**

The most common effect is sedation, varying from slight drowsiness to deep sleep, and including lassitude, dizziness, and inco-ordination.

Other side-effects include gastro-intestinal disturbances such as nausea, vomiting, diarrhoea or constipation, anorexia or increased appetite, and epigastric pain.

Antihistamines may also produce antimuscarinic effects including blurred vision, difficulty in micturition, dysuria, dryness of the mouth, and tightness if the chest. Other central effects include hypotension, muscular weakness, tinnitus, euphoria or depression, headache, irritability and nightmares.

Paradoxical CNS stimulation may occur especially in children, with insomnia, nervousness, tachycardia, tremors, and convulsions. Antihistamines may precipitate epileptiform seizures in patients with focal lesions of the cerebral cortex.

Systemic or topical therapy may produce allergic reactions and cross-sensitivity to related drugs.

Blood disorders, including agranulocytosis, leucopenia, and haemolytic anaemia, have been reported.

**Special Precautions:**

Elderly patients are more susceptible to the CNS depressant and hypotensive effects even at therapeutic doses.

Because of their antimuscarinic properties antihistamines should be used with care in conditions such as narrow angle glaucoma, urinary retention and prostatic hypertrophy.

Antihistamines may suppress positive skin test results and should be stopped several days before the test.

Use with care in cardiac failure, hypertension, oedema and cardiovascular disease.

**Interactions:**

Antihistamines may enhance the sedative effects of central nervous system depressants including alcohol, tricyclic antidepressants, barbiturates, hypnotics, narcotic analgesics, sedatives, and tranquillisers.

MAOI's may enhance the antimuscarinic effects of antihistamines, and antihistamines have an additive antimuscarinic action with other antimuscarinic drugs, such as atropine and tricyclic anti-depressants.

It has been suggested that antihistamines could mask the warning signs of damage caused by ototoxic drugs such as aminoglycoside antibiotics.

**KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:**

**Ammonium Chloride:**

Overdosage may cause nausea, vomiting, thirst, headache, hyperventilation, progressive drowsiness, mental confusion, hyperchloraemic acidosis and hypokalaemia.

**Diphenhydramine Hydrochloride:**

Overdose may be fatal especially in infants and children in whom the main symptoms are CNS stimulation and antimuscarinic effects, including ataxia, excitement, hallucinations, muscle tremor, convulsions, dilated pupils, dry mouth, flushed face, and hyperpyrexia. Deepening coma, cardiorespiratory collapse, and death may occur within 18 hours. In adults, the usual symptoms are of CNS depression with drowsiness, coma and convulsions. Hypotension may also occur.

**Treatment:**

Treatment is supportive and symptomatic and may include artificial respiration, external cooling for hyperpyrexia, and intravenous fluids.

**IDENTIFICATION:**

A dark brown liquid.

**PRESENTATION:**

Bottles of 100 ml, 200 ml and 2,5 litres.

**STORAGE INSTRUCTIONS:**

Store below 25°C

Keep the bottle tightly closed and protect from light.

KEEP OUT OF REACH OF CHILDREN.

**REGISTRATION NUMBER:**

J/10.1/207

**NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:**

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