

## DIMESTIL

Drops

### Composition

Each 1 ml contains Dimethindene Maleate 1 mg

### Action

#### Mechanism of Action

Dimestil is an antihistamine anti-allergic and antipruritic remedy. *Dimestil* works by blocking H1-histamine receptors and thereby lowers the increased permeability of the capillaries and itching associated with histamine effects. *Dimestil* also exerts antikinin and moderate anticholinergic action. After oral administration, operation preparation begins after 30-60 minutes, and maintained by 8 to 12 hours.

#### Pharmacokinetics

- The half of the blood plasma -10-11 hours
- The maximum concentration in blood plasma after 6 - 8 hrs
- Binding to human plasma protein is approximately 90%
- Drug Metabolism occurs in the liver- hydroxylation and methoxylation.
- Dimethindene and its metabolites are eliminated in bile and urine

### Indications

Dimestil drops are used for the treatment of allergic reactions such as nettle rash, upper respiratory allergies (e.g. hay fever and vasomotoric rhinitis), as well as drug and food allergies. Dimestil drops are suitable for the treatment of itching caused by skin diseases connected to various rashes (e.g. varicella), and for insect bites. They can also be used as an additional treatment for eczema and other non-inflammatory skin diseases of allergic origin.

### Contraindications

- Hypersensitivity to Dimethindene maleate
- Postnatal period up to one month
- Narrow-angle glaucoma
- 1st trimester of pregnancy

### Adverse Reactions

There are possible side effects associated with this medicine that can affect individuals in different ways. The most common side effects include:

- Drowsiness
- Excitation
- Headache,
- Nausea,
- Dry mouth,
- Edemas,
- Fatigue

## Warnings and Precautions

Observe the customary precautions in case of narrow - angle glaucoma, of urinary retention linked with urethroprostatic disorders and of chronic obstructive pulmonary disorders. Antihistamines can cause excitation in young children. Caution is recommended in case of administration of the drops to children below the age of 1 year: the sedative effect can be associated with episodes of sleep apnea.

## Pregnancy

### *Category B*

Animal reproduction studies have failed to demonstrate a risk to the fetus and there are no adequate and well-controlled studies in pregnant women.

## Nursing Mothers

A study performed in animals has shown that very small amounts of Dimethindene and/or of its metabolites are secreted in the mother's milk. The use of Dimethindene is not recommended during breast-feeding.

## Driving and using machines

The administration of Dimethindene can impair wakefulness; for concerned patients, caution is recommended in case of car driving or tasks requiring alertness (such as for instance the operation of machines).

## Drug Interactions

The sedative effect of central nervous system depressants, such as that of tranquillizers, hypnotic drugs and alcohol, can be enhanced. The simultaneous ingestion of alcohol can result in a more marked slowing down of reflexes. The concomitant administration of MAO inhibitors can increase the antimuscarinic and the CNS-depressor effect of antihistaminics; their simultaneous use is not recommended. Tricyclic antidepressants and anticholinergic drugs can have an antimuscarinic effect additional to that of antihistaminics, thus increasing the risk of decompensation or of urine retention.

## Dosage and Administration

***Adults and children above the age of 12 years:*** the usual daily dose is 3 to 6 mg of Dimethindene maleate, divided over 3 intakes, this corresponds to: ***Drops 1 mg/ml:*** 20 to 40 drops, 3 times a day. ***Children:*** the usual dose is approximately 0.1 mg/kg body weight per day. Accordingly, the usual daily dosages for children between the ages of 1 month and 12 years are the following:

Age	Dose in mg 3 times a day	Drops 1 mg/ml (0.05 mg/drops) 3 times a day
1 month - 1 year	0.15 - 0.5 mg	3 - 10 drops
1 - 3 years	0.5 - 0.75 mg	10 - 15 drops
3 - 12 years	0.75 - 1.0 mg	15 - 20 drops

Dimetil drops should not be exposed to high temperatures; they should be poured at the last minute into the lukewarm feeding bottle. If the baby is already being fed with a spoon, the drops should be administered as such in a teaspoon; the drops have a pleasant taste.



## **Over Dosage**

### ***Symptoms***

As with other antihistamines, overdosage can produce the following symptoms: CNS depression accompanied by drowsiness (especially in adults), CNS stimulation and antimuscarinic effects (especially in children) including excitation, ataxia, tachycardia, hallucinations, tonic or clonic spasms, mydriasis, dryness of the mouth, redness of the face, urine retention and fever.

Blood hypotension is also possible. In its terminal phase, coma can be aggravated by cardiorespiratory collapse and death.

There have been no reports of fatal outcome of Dimethindene overdosage.

### ***Treatment***

There is no specific antidote in case of overdosage with antihistamines. The customary emergency measures should be taken: provocation of vomiting, gastric lavage if vomiting is inefficacious, administration of activated charcoal, saline laxative drugs as well as the usual cardiorespiratory assistance. Stimulant should not be used. Vasopressors can be administered to treat hypotension.

## **Storage**

Dimestil oral drops should be stored at a temperature below 25 degrees C. Take it out of the sight and reach of children. Do not use after expiry date. Keep out of reach of children.

## **Presentation**

Bottle of 20 ml