

## HISTAMED-F® Tablets

**Dear patient,**

**Please read the following instructions carefully. They contain important information about the use of this medicine. If you have any further questions, please ask your doctor or pharmacist.**

### **Information about HISTAMED-F**

Each HISTAMED-F tablet contains:

Dexamethasone	0.25 mg
Dexchlorpheniramine maleate	2 mg
Fluphenazine hydrochloride	0.25 mg

Dexamethasone is a synthetic glucocorticoid having potent anti-inflammatory effects in disorders of many organ systems.

Dexchlorpheniramine is an H1-receptor antagonist. It is an alkylamine derivative. Dexchlorpheniramine antagonizes most of the pharmacological effects of histamine.

Fluphenazine is a piperazine phenothiazine derivative used for its tranquilizer effect.

HISTAMED-F is effective for the prevention and relief of many allergic manifestations.

HISTAMED-F is indicated for the treatment of allergic and inflammatory conditions:

- Perennial and seasonal allergic rhinitis: HISTAMED-F relieves sneezing, rhinorrhea, nasal itch and conjunctivitis
- Acute and chronic allergic and inflammatory processes involving the eye such as allergic conjunctivitis, keratitis, nongranulomatous iritis, and iridocyclitis
- Allergic skin disorders including mild, uncomplicated, acute urticaria and angioedema, pruritus, insect bites, some drug allergies, atopic dermatitis (eczema), and contact dermatitis
- Allergic and non-allergic pruritic symptoms
- Adjunctive therapy in anaphylactic reactions
- Severe chronic asthma and seasonal asthma

### **The way to take HISTAMED-F**

Take HISTAMED-F as directed by your physician. Do not discontinue the treatment without consulting your doctor.

Dosage is individualized on the basis of the condition under treatment and the response of the patient.

The recommended average initial dose for adults and children over 12 years is one tablet 4 times a day after meals and at bedtime.

In severe cases this dosage can be increased up to 6 tablets a day. However, as improvement takes place the dosage should be reduced to the minimum maintenance level.

### **Duration**

The duration of the treatment is determined according to the condition under treatment.

In ordinary self-limited conditions, e.g. poison ivy dermatitis, simple urticaria and certain cases of contact dermatitis, a short course of therapy will relieve symptoms and may in these cases be considered as a cure course.

In seasonal allergic disorders, such as hay fever, asthma and allergic conjunctivitis, therapy will not be required during times when the offending allergen is not present in the patient's environment.

Certain chronic disorders resistant to standard allergy treatment may require prolonged maintenance therapy (eczema, perennial rhinitis, chronic urticaria).

### **In case of overdose**

In case of intake of high doses of this medication, inform your doctor at once and seek emergency medical attention. General measures should be adopted.

### **In case of missed dose**

Take the missed dose as soon as you remember unless the next intake is near. Go on taking the next scheduled dose as directed. Do not take a double dose at once.

### **Contraindications**

This drug is contraindicated in the following cases:

- history of hypersensitivity to any of the components
- hypersensitivity or cross sensitivity with other drugs especially other phenothiazine derivatives
- greatly depressed states due to central nervous system depressants
- viral infections

### **Precautions**

- In case of pregnancy, consult your doctor about the use of this medicine. This drug should not be used during lactation.
- Caution must be used in case of liver or renal diseases.
- This drug may cause marked drowsiness or impair the mental and/or physical abilities required for the performance of potentially hazardous tasks, such as driving a vehicle or operating machinery.
- This drug must be used with caution in elderly patients and in patients with a predisposition to urinary retention, increased intraocular pressure, hyperthyroidism, diabetes, chronic constipation, cardiovascular disease, hypertension, osteoporosis, tuberculosis or gastroduodenal ulcer.
- Avoid prolonged exposure to sunlight during the treatment.

### **Associations with other medications**

Please inform your doctor if other medicines are being taken or have been taken recently.

Use with caution with alcohol, hypnotics, narcotic analgesics, oral anticoagulants, antidepressants, tranquilizers, anti-arrhythmic agents, atropine-like substances, digitalis glycosides, carbamazepine, phenobarbital, phenytoin, primidone, rifampicine, antidiabetics, isoniazide and bromocriptine.

Antacids containing aluminum, calcium or magnesium should not be taken within the two-hour period before or after taking this drug.

### **Adverse reactions**

This drug is usually well tolerated when used as directed.

Side effects related to the presence of the corticoid may appear during a prolonged use or at high doses.

Certain patients may, however, respond to antihistamine drugs by becoming drowsy, dizzy or nauseated. Other possible side effects include restlessness, dry mouth, anorexia, blurred vision, constipation and headache.

Inform your doctor if any side effect appears or becomes bothersome.

### **Storage**

Store at controlled room temperature (up to 25°C), protected from light and humidity, beyond the reach of children.

The expiry date is printed on the pack; don't use this medicine after this date.

### **Pack Presentation**

HISTAMED-F, pack of 30 tablets

**Revision date: 07/2006**

HIST/004