

## FLUDINIUM® Capsules

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 FLUDINIUM

Each FLUDINIUM capsule contains:

Trifluoperazine hydrochloride	1 mg
Clidinium bromide	2.5 mg

Trifluoperazine is a phenothiazine derivative having tranquilizing and antiemetic effects.

Clidinium bromide is an anticholinergic agent used for the symptomatic treatment of peptic ulcer and other gastrointestinal disorders.

FLUDINIUM provides rapid stabilization of functional gastrointestinal and genitourinary tracts disorders.

FLUDINIUM is used for the symptomatic treatment of duodenal ulcer and other functional gastrointestinal and genitourinary tracts disorders associated with anxiety and tension.

FLUDINIUM is indicated for the symptomatic treatment of:

- gastric and duodenal ulcer
- hypersecretion and hypermotility of the gastrointestinal tract
- gastroduodenitis
- neurogenic dyspepsia
- irritable or spastic colon
- colitis
- biliary dyskinesia
- irritable bladder
- dysmenorrhea

### The way to take FLUDINIUM

Take FLUDINIUM as directed by your physician. Do not discontinue the treatment without consulting your doctor.

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

The usual recommended dose for adults is one capsule 2 to 4 times a day, with a glass of water before meals and at bedtime.

In elderly and debilitated patients, the lowest effective dose should be given; 1 to 2 capsules a day to be increased gradually to the most effective well tolerated dose.

In dysmenorrhea, FLUDINIUM should be taken 3 to 5 days before menstruation.

### 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 patients with a history of hypersensitivity to any of the components. It is also contraindicated in greatly depressed states due to central nervous system depressants, bone-marrow depression, pre-existing liver damage and in case of hypersensitivity or cross sensitivity with other drugs especially other phenothiazine derivatives.

This drug is also contraindicated in case of glaucoma, prostatic hypertrophy and myasthenia gravis.

### Precautions

- In case of pregnancy, consult your doctor about the use of this medicine. This drug should not be used during lactation.

- Use with caution in case of liver or renal diseases, cardiac arrhythmia, angina pectoris, hyperthyroidism, epilepsy and chronic bronchitis.
- This drug may cause 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.
- Avoid prolonged exposure to sunlight and use with caution in hot weather.

**Association with other medications**

Please inform your doctor if other medicines are being taken or have been taken recently. Use with caution with alcohol, oral anticoagulants, propranolol, narcotic analgesics, thiazide diuretics, anticonvulsants, antidepressants, or levodopa.

**Adverse reactions**

Minor side effects such as drowsiness, dizziness, photosensitivity, rash, dry mouth, amenorrhea, fatigue, muscular weakness, anorexia, blurred vision, tachycardia, hypotension, constipation, agitation and neuromuscular reactions have been reported. Inform your doctor if any of these effects appears or becomes bothersome.

**Storage**

Store at controlled room temperature (up to 30°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**

Each FLUDINIUM capsule contains trifluoperazine hydrochloride 1mg and clidinium bromide 2.5 mg, pack of 30 capsules.

**Revision date: 01/2010**

FLUC/006