

SIBELIUM® 5 mg capsules

SCHEDULING STATUS

Schedule 2.

PROPRIETARY NAME

(and dosage form)

SIBELIUM® 5 mg capsules

COMPOSITION

Each capsule contains 5.9 mg **flunarizine** hydrochloride equivalent to 5 mg flunarizine base.

PHARMACOLOGICAL CLASSIFICATION

A 5.7.1 Drugs Affecting Autonomic Functions. Antihistamines.

PHARMACOLOGICAL ACTION

SIBELIUM is a selective calcium antagonist. It prevents cellular calcium overload by reducing excessive transmembrane calcium influxes. Flunarizine is well absorbed from the gut, reaching peak plasma levels within 2 - 4 hours and reaching steady state at 5 - 6 weeks. After extensive hepatic metabolism, flunarizine and its metabolites are excreted through the faeces via the bile. The mean terminal elimination half-life is about 18 days. Plasma protein binding is 99%.

INDICATIONS

SIBELIUM is indicated in:

- Prophylaxis of classic (with aura) or common (without aura) migraine.
- Symptomatic treatment of vestibular vertigo (due to a diagnosed functional disorder of the vestibular system).

CONTRA-INDICATIONS

Hypersensitivity to flunarizine. SIBELIUM is contra-indicated in patients with a history of depressive illness, or with pre-existing symptoms of Parkinson's disease or other extrapyramidal disorders.

Pregnancy

Safety in pregnancy and lactation has not been established.

WARNINGS

SIBELIUM may lead to drowsiness which is aggravated by the simultaneous intake of alcohol or other central nervous system depressants.

Patients should be cautioned against driving motor vehicles or performing other potentially hazardous tasks where a loss of mental alertness may lead to accidents.

SIBELIUM is not suited for aborting a migraine attack. The possible occurrence of an attack is therefore no reason to increase the dose of SIBELIUM.

This treatment may give rise to extrapyramidal and depressive symptoms and reveal Parkinsonism, especially in predisposed patients such as the elderly. SIBELIUM should therefore be used with caution in such patients.

DOSAGE AND DIRECTIONS FOR USE

Migraine Prophylaxis

Starting Dose:

Two 5 mg capsules (10 mg) SIBELIUM at night in patients less than 65 years of age and 5 mg daily in patients older

than 65 years. If, during this treatment depressive, extrapyramidal or other unacceptable symptoms occur, administration should be discontinued. If, after 2 months of this initial treatment, no significant improvement is observed, the patient should be considered a non-responder and administration should be discontinued.

Maintenance Treatment:

If a patient is responding satisfactorily and if a maintenance treatment is needed, the dose should be decreased to 5 days treatment at the same daily dose with two successive medicine free days every week.

Even if the prophylactic maintenance treatment is successful and well tolerated, it should be interrupted after 6 months and it should be re-initiated only if the patient relapses.

Vertigo

The same dosage should be used as for migraine, but the starting treatment should not be given longer than needed for symptom control, which generally takes less than two months.

After one month of treatment for chronic vertigo or after two months treatment for paroxysmal vertigo, no significant improvement is observed, the patient should be considered a non-responder and administration should be discontinued.

SIDE-EFFECTS AND SPECIAL PRECAUTIONS

Side-Effects

Drowsiness and/or fatigue, as well as weight gain and/or increased appetite may occur.

The following adverse experiences have been reported during chronic treatment with SIBELIUM: depression, of which female patients with a history of depressive illness may be particularly at risk; extrapyramidal symptoms (such as bradykinesia, rigidity, akathisia, orofacial dyskinesia, tremor), of which elderly patients seem particularly at risk.

Infrequently reported adverse reaction are: heartburn; nausea; gastralgia; insomnia; anxiety; galactorrhoea; dry mouth; muscle ache; skin rash.

Special Precautions

SIBELIUM should be used with care in patients with depression or those being prescribed other agents, such as phenothiazines, concurrently, which may cause extrapyramidal side-effects.

Fatigue may increase progressively during SIBELIUM therapy; in this event therapy should be discontinued.

The recommended dose should not be exceeded. Patients should be seen at regular intervals, especially during maintenance treatment, so that extrapyramidal or depressive symptoms may be detected early and if so, treatment discontinued. If during maintenance treatment the therapeutic effects subside, treatment should also be discontinued (for duration of treatment see "Dosage and Directions for Use").

Interactions

Galactorrhoea has been reported in few woman on oral contraceptives within the first two months of SIBELIUM treatment.

Hepatic enzyme inducers such as carbamazepine and phenytoin may interact with flunarizine by increasing its metabolism. An increase in dosage of flunarizine may be required.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT

Acute overdosage has been reported and the observed symptoms were sedation, agitation and tachycardia.

Treatment of acute overdosage consists of charcoal administration, induction of emesis or gastric lavage, and supportive measures. No specific antidote is known.

IDENTIFICATION

Capsule with red, opaque cap and dark grey, opaque body.

PRESENTATION

Carton containing one or more blister packs of 20 capsules each.

STORAGE INSTRUCTIONS

Store below 25°C. Protect from light and store in a dry place.
Keep out of reach of children.

REGISTRATION NUMBER

M/5.7.1/529

NAME AND BUSINESS ADDRESS OF APPLICANT

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