



**AGOG Pharma Ltd.**



(WHO - GMP CERTIFIED - GOVT RECOGNISED EXPORT HOUSE)

Regd. Office & Factory : Plot No. 33, Sector II, The Vasai Taluka Industrial Co-op. Estate Ltd. Gauripada, Vasai (E), Dist. Thane - 401 208, INDIA.  
Tel. : 95250 - 2455801 / 2452714 / 2453525 • Fax: 95250 - 2452074 (0091 - 250 - 2452074) • Email : agog@vsnl.net & agogpharma@rediffmail.com

### 1.5.3 Patient information leaflet (PIL)

caution in patients with a mixed seizure disorder that includes atypical absence seizures, since in these patients it has been associated with increased frequency of generalized convulsions. Shake the bottle well each time before use.

#### **SIDE EFFECTS AND ADVERSE REACTIONS**

Zepin syrup can cause serious side effects, including:

1. Serious skin rashes that may lead to death, hives, sores in mouth, blistering or peeling of the skin. These serious skin reactions are more likely to happen at the beginning within the first four months of treatment but may occur at later times.

2. Zepin syrup may cause rare but serious blood problems. Symptoms may include:

Fever, easy bruising, red or purple spots on your body, bleeding gums or nose bleeds, severe fatigue or weakness

3. Like other antiepileptic drugs, Zepin syrup may cause suicidal thoughts or actions in a very small number of people, about 1 in 500.

#### **OVERDOSAGE AND TREATMENT**

The first signs and symptoms appear after 1-3 hours. Neuromuscular disturbances are the most prominent. Cardiovascular disorders are generally milder, and severe cardiac complications occur only when very high doses (>60 g) have been ingested.

Respiration: Irregular breathing, respiratory depression.

Cardiovascular System: Tachycardia, hypotension or hypertension, shock, conduction disorders.

Nervous System and Muscles: Impairment of consciousness ranging in severity to deep coma. Convulsions, especially in small children.

Gastrointestinal Tract: Nausea, vomiting.

Kidneys and Bladder: Urinary retention.

#### **TREATMENT**

Treatment includes elimination of the drug by inducing vomiting, irrigating the stomach, and by taking appropriate steps to diminish absorption.

#### **CONTRAINDICATIONS**

Zepin syrup should not be used in patients with a history of previous bone marrow depression, hypersensitivity to the drug, or known sensitivity to any of the tricyclic compounds, such as Amitriptyline, desipramine, imipramine, protriptyline, nortriptyline, etc. Likewise, on theoretical grounds its use with monoamine oxidase inhibitors is not recommended. Before administration of Zepin syrup, MAO inhibitors should be discontinued for a minimum of 14 days, or longer if the clinical situation permits.

#### **DRUG INTERACTIONS**

Concomitant administration of carbamazepine and lithium may increase the risk of neurotoxic side effects.

Concomitant use of carbamazepine and isoniazid has been reported to increase isoniazid-induced hepatotoxicity. Concomitant medication with Zepin syrup and some diuretics (hydrochlorothiazide, furosemide) may lead to symptomatic hyponatremia.

Alterations of thyroid function have been reported in combination therapy with other anticonvulsant medications.

Concomitant use of Zepin syrup with hormonal contraceptive products (e.g., oral, and levonorgestrel subdermal implant contraceptives) may render the contraceptives less effective.

#### **PREGNANCY**

Carbamazepine can cause fetal harm when administered to a pregnant woman.

**STORAGE:** Store under normal storage conditions

(15°C to 30°C)

Protect from light.

Keep all medicines out of reach of children.

#### **PRESENTATION**

250 ml in amber coloured pet bottle.



Manufactured in India by:

**AGOG PHARMA LTD.**

Plot No. 33, Sector II, The Vasai Taluka Indl. Co-op. Estate Ltd., Vasai (E), Dist. Thane. INDIA.