

# Zinasen

(Flunarizine)



## QUALITATIVE AND QUANTITATIVE COMPOSITION OF ACTIVE SUBSTANCES

### Zinasen, tablets

Per tablet: Flunarizine (as dihydrochloride) 10mg

## PHARMACEUTICAL FORM AND PRESENTATION

**Zinasen, tablets** - each tablet contains 10mg of flunarizine (as dihydrochloride).

Packs of 20, 50 and 60 units.

Not all pack sizes may be marketed.

**Pharmacotherapeutic group:** Anti-vertiginous preparations

### Marketing Authorisation Holder

**LABORATÓRIOS ATRAL, S.A.**

Vala do Carregado

2600-726 Castanheira do Ribatejo - Portugal

## Description

**Zinasen** contains a vasoactive substance, which generic name is flunarizine (difluorinated derivative of cinnarizine), effective in migraine prophylaxis and in vascular disorders. Experimental studies in animals *in vitro* and *in vivo*, show that flunarizine is a potent anti-vasoconstrictor musculotropic, which antagonise the effects of noradrenaline, CLK and calcium. It has an elective action on arteries, affecting minimal myogenic activity of veins.

Flunarizine increases cerebral cortical blood flow and oxygen partial pressure in cerebral cortical tissue.

**Zinasen** is effective in vertiginous syndrome. In therapeutic doses, flunarizine improves the circulation in the affected areas without changing the general hemodynamic, cardiac inotropism and frequency, arterial pressure and venous circulation. Its effect is selective on arteries. In relation to its elective action, as well as the intensity and duration of effects, flunarizine displays superior to a large number of others vasoactive substances (cinnarizine, dihydroergotamine, cycandelate, papaverine, etc.).

**Zinasen** reduces the hyperviscosity provoked by ischemia, which could contribute to a better irrigation.

## THERAPEUTIC INDICATIONS

Migraine prophylaxis in patients with frequent and severe crisis and symptomatic treatment of vestibular vertigo.

## CONTRA-INDICATIONS

Cerebral vascular disorders in acute phase.

## UNDESIRABLE EFFECTS

**Zinasen** is usually well tolerated. However, in the beginning of treatment, adverse effects, such as gastrointestinal disorders, fatigue sensation and somnolence, can occur. Usually, these symptoms disappear in a few days; in some cases it's necessary to reduce the dose.

Treatment with flunarizine should be interrupted and restarted with lower doses in pre-disposed patients that exceptionally revealed extrapyramidal reactions or depression. Flunarizine is a long action drug; however, in recommended doses, accumulation signs are not usually observed.

## Effects on pregnant women, lactating infants, children, elderly and patients with special pathologies

Like others medicines, **Zinasen** should not be administered to pregnant women.

## Effects on the ability to drive and use machines

Especially in the beginning of treatment, **Zinasen** may provoke reduction of reflexes, so some precautions are recommended when driving vehicles and/or using certain kind of machines.

## LIST OF EXCIPIENTS

**Zinasen** tablets contains lactose.

## USUAL POSOLOGY

Recommended dose:

1 tablet (10mg) at bedtime

## METHOD OF ADMINISTRATION

**Zinasen** tablets for oral administration.

## ACTIONS IN CASE OF OVERDOSE AND/OR INTOXICATION

There are no known cases of intoxication with **Zinasen**.

In case of overdose hospital internment and the beginning of support treatment is recommended.

If you notice any undesirable effect not mentioned in this leaflet, please inform your doctor or pharmacist.

Please verify the shelf life which is stated on the label.

## SPECIAL PRECAUTIONS FOR STORAGE

Store below 25°C, in a dry place protected from light.

**Keep out of the reach and sight of children**

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