# VERTINEX<sup>®</sup> 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 VERTINEX

VERTINEX is available as 16 mg and 24 mg tablets for oral administration containing respectively 16 mg and 24 mg betahistine dihydrochloride

Other ingredients are: lactose monohydrate, microcrystalline cellulose, magnesium stearate, croscarmellose sodium.

Betahistine is an analogue of histamine. It improves the microcirculation of the labyrinth resulting in reduced endolymphatic pressure. Betahistine has weak H1 receptor agonistic and considerable H3 antagonistic properties in the central nervous system and autonomic nervous system.

VERTINEX is used to reduce the symptoms of vertigo, tinnitus, and hearing loss associated with Ménière's disease.

VERTINEX is effective for the symptomatic treatment of vestibular vertigo.

#### The way to take VERTINEX

Take VERTINEX as directed by your physician. Do not discontinue the treatment or change the dosage prescribed without consulting your doctor.

The usual daily dosage range is 24 to 48 mg taken preferably with meals in divided doses: half-tablet or 1 tablet of 16 mg 3 times daily or 1 tablet of 24 mg 2 times daily. The dosage should be individually adapted according to the response.

#### **Duration of treatment**

Improvement can sometimes only be observed after a couple of weeks of treatment. The usual recommended duration of treatment is 2 to 3 months that may eventually be renewed depending on the condition under treatment.

#### 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. An antihistaminic treatment may be administered.

## 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 conditions:

- Known hypersensitivity to any of the components
- Phaeochromocytoma
- Active peptic ulcer disease

#### Precautions

-This drug should not be given to patients with porphyria.

-This drug should be used with care in patients with asthma, or a history of peptic ulcer disease.

-Inform your doctor before using this medication in case of pregnancy or lactation. It is recommended to avoid using this medication in case of pregnancy and lactation.

## Associations with other medications

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

Concomitant use with H<sub>1</sub> receptor antagonists is not recommended.

## Adverse reactions

This drug is usually well tolerated. The most reported adverse reactions include gastric pain, nausea, vomiting, dry mouth, and diarrhea. Mild gastric pain can be easily managed by taking the dose during meals or by lowering the dose.

Rarely reported adverse reactions include headache, fatigue, somnolence, skin rashes, and pruritus.

Please 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

VERTINEX 16, betahistine dihydrochloride 16 mg, pack of 60 tablets and pack of 20 tablets VERTINEX 24, betahistine dihydrochloride 24 mg, pack of 30 tablets

# Revision date: 05/2011

VERT1/003