

INFORMATION FOR THE USER

VASOSERC FORT tablet

It is taken by oral route.

Active substance: Each tablet contains 16 mg betahistine dihydrochloride.
Excipients: Mannitol (E421), Microcrystalline cellulose, Talc, Aerosil 200.

Because it contains important information for you, read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- This medicine has been prescribed for you personally and you should not pass it onto others.
- Tell your doctor you are taking this medicine if you go to a doctor or to a hospital.
- Follow the instructions in this leaflet. Do not use higher or lower dose than the dose that is recommended for you.

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1. What is VASOSERC FORT and what is it used for?

VASOSERC FORT is presented in blister packages containing 60 tablets, each tablet contains 16 mg betahistine dihydrochloride as an active substance.

VASOSERC FORT is a "histamine analogue" medicine.

It is used for treatment of Ménière's disease. Symptoms of Ménière's disease include:

- Vertigo, nausea and vomiting,
- Tinnitus,
- Hearing loss or hearing difficulty.

Vertigo is due to improper work of some part of your inner ear that controls your balance (it is called as "vestibular vertigo").

VASOSERC FORT works by improving blood flow in the inner ear. This lowers the build-up of pressure.

2. Before you take VASOSERC FORT

VASOSERC FORT is used only in adults.

DO NOT TAKE VASOSERC FORT in the following conditions

- If you are allergic (hypersensitive) to betahistine or any of the other ingredients in the VASOSERC FORT
- If your doctor told you that you have adrenal gland tumor (pheochromocytoma).

If any of the above applies to you, do not take this medicine. If you are not sure, talk to your doctor or pharmacist before you take VASOSERC FORT.

TAKE VASOSERC FORT WITH CAUTION in the following conditions

Before taking this medicine, check with your doctor that the followings are valid for you:

- If you have ever had a stomach ulcer
- If you have asthma.

If these warnings are valid for you even if in the past, please consult your doctor.

Your doctor may want to monitor you more closely while you take VASOSERC FORT.

VASOSERC FORT use with food and fluids

You can take VASOSERC FORT with or without food. However, VASOSERC FORT can cause mild stomach problems (listed in Section 4). Taking VASOSERC FORT with food can help reduce stomach problems.

Pregnancy

Consult your doctor or pharmacist before taking this drug.

It is not known if VASOSERC FORT affects an unborn baby:

- Stop taking VASOSERC FORT and tell your doctor if you become pregnant or think you might be pregnant.
- Do not take VASOSERC FORT if you are pregnant unless your doctor has decided that it is necessary.

If you noticed you became pregnant during your treatment, immediately consult your doctor or pharmacist.

Breast - feeding

Consult your doctor or pharmacist before taking this drug.

It is not known if VASOSERC FORT passes into breast milk.

- Do not breast-feed while using VASOSERC FORT unless instructed by your doctor.

Effects on ability to drive and use machines

VASOSERC FORT is not likely to affect your ability to drive or use tools or machinery. However, remember that the disease for which you are being treated with VASOSERC FORT (Ménière's disease or Vertigo) can make you feel dizzy or sick, and can affect your ability to drive and use machines.

Important information on some excipients of VASOSERC FORT

VASOSERC FORT contains mannitol E421, however no warning is necessary because of its dose.

Combined use with other drugs

In particular, tell your doctor or pharmacist if you are taking any of the following medicines:

- Anti-histamines - In theory these medicines may decrease effect of VASOSERC FORT. Also, VASOSERC FORT may lower the effect of anti-histamines.
- Monoamine-oxidase inhibitors (MAOIs) - used to treat depression or Parkinson's disease. These may increase the effect of VASOSERC FORT.

If any of the above applies to you (or you are not sure), talk to your doctor or pharmacist before taking VASOSERC FORT.

If you are taking prescribed product or over-the-counter product or you took recently, please inform your doctor or pharmacist about this condition.

3. How to take VASOSERC FORT?

Directions on proper usage and dose/administration frequency:

Always take VASOSERC FORT exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

- Your doctor will adjust your dose, depending on your progress.
- Keep taking your medicine. The medicine can take a while to start to work.

The usual dose is one or two VASOSERC FORT 16 mg tablet 3 times in a day.

If you take more than one tablet each day, spread your tablets evenly over the day. For example, take one tablet in the morning and one in the evening.

Take the tablets at the same time of the day. This will provide constant amount of medicine in your body. It also helps you remember to take the medicine.

Administration route and method:

- Swallow the tablets with water.
- You can take VASOSERC FORT with or without food. However, VASOSERC FORT can cause mild stomach problems (listed in Section 4). Taking VASOSERC FORT with food can help reduce stomach problems.

Some age groups:

Use in children:

Because there is no adequate data on efficacy and safety, VASOSERC FORT use is not recommended in children under the age of 18 years old.

Geriatric population:

Although there are limited data from clinical studies in this patient group, extensive post marketing experience suggests that no dose adjustment is necessary in this patient population.

Special uses:

Renal / hepatic insufficiency:

There are no specific clinical trials available in these patient groups, but according to post-marketing experience no dose adjustment appears to be necessary.

If you have an impression that the effect of VASOSERC FORT is too strong or too weak, talk to your doctor or pharmacist.

If you take more VASOSERC FORT than you should:

If you took more VASOSERC FORT than you should, talk to a doctor or a pharmacist.

If you took more VASOSERC FORT than you should, you may feel nauseous, sleepy or have stomach pain. Talk to your doctor.

If you forget to take VASOSERC FORT

If you miss a dose, ignore the missed dose and take the next dose in due time.

Do not use double-dose to replace forgotten dose.

The effects that may occur if VASOSERC FORT treatment is stopped

Even when you start feeling better, do not stop VASOSERC FORT without consulting your doctor. If you have additional questions about the use of this medicine, consult your doctor or pharmacist.

4. What are the possible side effects?

As in all other drugs, side effects may occur in persons sensitive to any of the content of VASOSERC FORT.

In studies undesirable effects have been reported with the following frequencies: very common ($\geq 1/10$); common ($>1/100$, $<1/10$); uncommon ($>1/1,000$, $<1/100$); rare ($>1/10,000$, $<1/1,000$); very rare ($<1/10,000$), unknown (cannot be estimated from available data).

Stop taking VASOSERC FORT and see your doctor or go to a hospital STRAIGHT AWAY, if you notice any of the signs below.

Frequencies of the following side effects are unknown:

- Allergic reactions. The signs may include:
 - a red or lumpy skin rash or inflamed itchy skin
 - swelling of your face, lips, tongue or neck
 - a drop in your blood pressure
 - loss of consciousness
 - difficulty in breathing.

All of these are very serious side effects.

If you have any of the above, you are seriously allergic to VASOSERC FORT. You may need urgent medical intervention or hospitalization.

If you notice any of the followings, talk to your doctor:

Common (affects less than 1 in 10 people)

- nausea
- indigestion (dyspepsia)
- headache.

Frequency unknown:

- Mild stomach problems such as vomiting, stomach pain, abdominal distension.

Taking VASOSERC FORT with food can help to reduce stomach problems.

These are mild side effects of VASOSERC FORT.

If you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. How to store VASOSERC FORT

Keep VASOSERC FORT out of the reach and sight of children, and in its package.

Store in room temperature below 25°C and protect from moisture.

Use in concordance with its expiry date.

Do not use VASOSERC FORT after expiry date on the package.

Prescription drug.

Reg N° Lebanon 194310/05

Produced by **Pharmaline - Lebanon**
Licensed by **Tripharma - Turkey**

This leaflet was approved on 28.12.2013.