

1.3.2 PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S3

PROPRIETARY NAME AND DOSAGE FORM

MENIVERT 24 mg TABLETS

Read all of this leaflet carefully before you start MENIVERT 24 mg TABLETS

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- MENIVERT 24 mg TABLETS has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

WHAT MENIVERT 24 mg TABLETS CONTAINS

The active substance per tablet of MENIVERT 24 mg TABLETS is 24 mg betahistine dihydrochloride.

The other ingredients are citric acid anhydrous, crospovidone, hydrogenated vegetable oil, lactose monohydrate, maize starch, microcrystalline cellulose and povidone.

Contains sugar: Lactose monohydrate 150 mg

WHAT MENIVERT 24 mg TABLETS ARE USED FOR

Betahistine, the active substance of MENIVERT 24 mg TABLETS, is similar to histamine, a substance which is found naturally in the human body.

MENIVERT 24 mg TABLETS are used for the treatment of Ménière's syndrome, which is a disease affecting the inner ear characterised by ringing in the ears, nausea, dizziness and progressive hearing loss.

BEFORE YOU TAKE MENIVERT 24 mg TABLETS

Do not take MENIVERT 24 mg TABLETS

- If you are hypersensitive (allergic) to betahistine or any of the other ingredients of MENIVERT 24 mg TABLETS (see WHAT MENIVERT 24 mg TABLETS CONTAINS).
- If you suffer from a tumour of the adrenal gland (phaeochromocytoma).

Take special care with MENIVERT 24 mg TABLETS

- If you have ulcers of the stomach or intestine or have had them in the past.
- If you suffer from a chronic disease of the respiratory tract (bronchial asthma).
- If you suffer from hives, skin rashes, or allergic rhinitis - your symptoms may get worse when taking MENIVERT 24 mg TABLETS.
- If you have very low blood pressure.
- If you are taking at the same time other medicines used to treat allergies or colds - so called antihistamines.
- If you suffer from porphyria (an inherited disorder of blood pigment metabolism).

Taking MENIVERT 24 mg TABLETS with food and drink

This medicine sometimes causes stomach disorders. The likelihood of these happening may be reduced by taking MENIVERT 24 mg TABLETS with, or shortly after food.

Pregnancy and breastfeeding

The safety of MENIVERT 24 mg TABLETS during pregnancy and whilst breastfeeding has

not been established.

Always tell your healthcare provider if you are taking any other medicine. If you are pregnant or breastfeeding your baby, please consult your healthcare provider for advice before taking MENIVERT 24 mg TABLETS.

Driving and using machinery

Since adverse reactions such as drowsiness have been reported in patients taking MENIVERT 24 mg TABLETS, you should not drive, use machinery or perform any tasks that require concentration, until you are certain that MENIVERT 24 mg TABLETS does not adversely affect your ability to do so (see POSSIBLE SIDE EFFECTS).

Important information about some of the ingredients of MENIVERT 24 mg TABLETS

MENIVERT 24 mg TABLETS contains lactose which may have an effect on the control of your blood sugar if you have diabetes mellitus. Patients with the rare hereditary conditions of lactose or galactose intolerance should not take MENIVERT 24 mg TABLETS.

Taking other medicines with MENIVERT 24 mg TABLETS

Always tell your healthcare provider if you are taking any other medicines (this includes complementary or traditional medicines).

Tell your doctor if you are taking any of the following medicines:

- Monoamine-oxidase inhibitors (MAOIs) (e.g. moclobemide, selegiline): medicines used to treat depression.
- Certain medicines for the treatment of allergies or colds, which contain antihistamines (e.g. chlorpheniramine): medicine used to relieve the symptoms of allergic reactions such as itching, rash and sneezing. If MENIVERT 24 mg TABLETS and these medications are used at the same time, the effects of both medicines may be reduced. If

you are currently taking an antihistamine, the dose of this medicine must be slowly reduced over about 6 days before you can start using MENIVERT 24 mg TABLETS.

HOW TO TAKE MENIVERT 24 mg TABLETS

Do not share medicines prescribed for you with any other person.

Always take MENIVERT 24 mg TABLETS exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

The usual dose is 24 mg to 48 mg (one to two tablets) of MENIVERT 24 mg TABLETS daily, divided into 2 or 3 equal doses.

Your doctor will adjust your dose according to your response.

The tablets should be swallowed whole, with sufficient liquid, during or after meals.

Children and Adolescents: MENIVERT 24 mg TABLETS should not be used by children and adolescents below the age of 18 years.

If you take more MENIVERT 24 mg TABLETS than you should

If you use more tablets than you should, the following symptoms may occur due to overdose: headache, redness of the face, low blood pressure, faster heartbeat, breathing difficulties due to constriction of the lungs (bronchial asthma), and swelling of the surface of the upper airways due to water retention, angioedema.

In the event of overdosage, or if you experience these symptoms, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

Always take the medicine package with you when seeking help.

If you forget to take MENIVERT 24 mg TABLETS

Take your missed dose as soon as you remember, if within a few hours after missing a dose.

If you only remember about the missed dose the following day, do not take a double dose to make up for the forgotten dose. In this case just continue taking one tablet daily.

POSSIBLE SIDE EFFECTS

MENIVERT 24 mg TABLETS can have side effects.

Not all side effects reported for MENIVERT 24 mg TABLETS are included in this leaflet.

Should your general health worsen or if you experience any untoward effects while taking MENIVERT 24 mg TABLETS, please consult your healthcare provider for advice.

If any of the following happens, stop taking MENIVERT 24 mg TABLETS and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Hypersensitivity reactions, such as breathing difficulty;
- swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing.

These are very serious side effects. If you have this, you may have had a serious allergic reaction to MENIVERT 24 mg TABLETS. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

The following side effects have been frequently reported:

- Headache;

- nausea, indigestion.

The following side effects have been reported less frequently:

- Head pressure;
- feeling your heartbeat, tightness of the chest;
- existing bronchial asthma is worsened;
- retching, heartburn, stomach discomfort and pain, flatulence.

The following side effects have been reported with an unknown frequency:

- Occasional drowsiness;
- skin rashes and itching.

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

STORING AND DISPOSING OF MENIVERT 24 mg TABLETS

Store at or below 25 °C.

Keep in original packaging until required for use.

Do not store in a bathroom.

Do not use after the expiry date stated on the label.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

PRESENTATION OF MENIVERT 24 mg TABLETS

20 tablets are packed in a polyvinylchloride, polyethylene, polyvinylidene chloride film sealed with aluminium foil backing. There are 10 tablets per blister strip and two blister strips are

packed into an outer cardboard carton.

IDENTIFICATION OF MENIVERT 24 mg TABLETS

MENIVERT 24 mg TABLETS are white, round, flat tablets with bevelled edges, breakline on one side. The tablets can be divided into equal halves.

REGISTRATION NUMBER

46/5.6/0960

NAME, BUSINESS ADDRESS AND TELEPHONE NUMBER OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION

PHARMACARE LIMITED

Healthcare Park

Woodlands Drive

Woodmead 2191

Hotline: 0800 122 912 (South Africa)

DATE OF PUBLICATION

Date of registration: 02 June 2017

Date of the most recent amendment to the patient information leaflet as approved by the

Authority: 02 June 2017

ZA_MENITAB_1706_01