PACKAGE LEAFLET: INFORMATION FOR THE USER

BRINAVESS® 20 mg/ml concentrate for solution for infusion

vernakalant hydrochloride

Read all of this leaflet carefully before you are given this medicine.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor.

The full name of your medicine is BRINAVESS 20 mg/ml concentrate for solution for infusion. In this leaflet the shorter name BRINAVESS is used.

In this leaflet:

1. WHAT BRINAVESS IS AND WHAT IT IS USED FOR

BRINAVESS contains the active substance vernakalant hydrochloride. BRINAVESS works by changing your irregular or fast heart beat to a normal heart beat.

In adults it is used if you have a fast, irregular heart beat called atrial fibrillation which has started recently (≤ 7 days) for non-surgery patients and ≤ 3 days for post-cardiac surgery patients. Your doctor will decide whether you should be treated with BRINAVESS.

2. BEFORE YOU ARE GIVEN BRINAVESS

You should not be given BRINAVESS if:
- you are allergic (hypersensitive) to vernakalant hydrochloride or any of the other ingredients of BRINAVESS (see section 6)
- you have had new or worsening chest pain (angina) diagnosed by your doctor as an acute coronary syndrome in the last 30 days or you have had a heart attack in the last 30 days
- you have a very narrow heart valve, systolic blood pressure <100 mm Hg or advanced heart failure with symptoms at minimal exertion or at rest
- you have an abnormally slow heart rate or skipped heart beats and do not have a pacemaker, or you have conduction disturbance called QT prolongation - which can be seen on an ECG by your doctor
- you have been given certain other intravenous medicines (anti-arrhythmics Class I and III) used to normalize an abnormal heart rhythm, 4 hours before BRINAVESS is to be given

You should not be given BRINAVESS if any of the above apply to you. If you are not sure, talk to your doctor before you are given this medicine.

Take special care with BRINAVESS
Check with your doctor before you are given BRINAVESS if:
- you have any of the following problems:
  - heart failure
  - certain heart diseases involving the heart muscle, lining that surrounds the heart and a severe narrowing of the heart valves
  - a disease of the heart valves
  - liver problems
  - you are taking other rhythm control medicines

If you have very low blood pressure or slow heart rate or certain changes in your ECG while using this medicine, your doctor may stop your treatment.
Your doctor will consider if you need additional rhythm control medicine 4 hours after BRINAVESS.
BRINAVESS may not work in treating some other kinds of abnormal heart rhythms, however your doctor will be familiar with these.

Tell your doctor if you have a pacemaker.

If any of the above apply to you (or you are not sure), talk to your doctor.

Blood tests
Before giving you this medicine, your doctor will decide whether to test your blood to see how well it clots and also to see your potassium level.

Use in Children

There is no experience on the use of BRINAVESS in children and adolescents less than 18 years of age; therefore its use is not recommended.

Using other medicines
Please tell your doctor if you are taking or have recently taken any other medicines, including medicines obtained without a prescription or herbal medicines and natural products.

Pregnancy and breast-feeding
- Talk to your doctor before having this medicine if you are pregnant or might become pregnant. This is because it is preferable to avoid the use of BRINAVESS during pregnancy.
- If you are breast-feeding or planning to breast-feed you should talk to your doctor before you are given BRINAVESS. This is because it should be used with care as it is not known whether BRINAVESS passes into the breast milk.

Ask your doctor for advice before taking any medicine, if you are pregnant or breast-feeding.

Driving and using machines
It should be taken into account that some people may get dizzy after receiving BRINAVESS, usually within the first two hours (see POSSIBLE SIDE EFFECTS). If you get dizzy, you should avoid driving or operating machinery after receiving BRINAVESS.

Important information about some of the ingredients of BRINAVESS
This medicinal product contains approximately 1.4 mmol (32 mg) sodium in each 200 mg vial. Each vial of 500 mg contains approximately 3.5 mmol (80 mg) of sodium.
Take into consideration if you are on a controlled sodium diet.

3. HOW BRINAVESS IS GIVEN

- BRINAVESS will be given to you by a health care professional.
- It will be given to you into your vein over 10 minutes.
- The amount of BRINAVESS you may be given will depend on your weight. The recommended initial dose is 3 mg/kg. While you are being given BRINAVESS, your breathing, heart beat, blood pressure and the electrical activity of your heart will be checked.
- If your heart beat has not returned to normal 15 minutes after the end of your first dose, you may be given a second dose. This will be a slightly lower dose of 2 mg/kg. Total doses of greater than 5 mg/kg should not be administered within 24 hours.

If you are given more BRINAVESS than you should
If you think that you may have been given too much BRINAVESS, tell your doctor straight away.

If you have any further questions on the use of this medicine, ask your doctor.

4. POSSIBLE SIDE EFFECTS

The following terms are used to describe how often side effects have been reported.
very common: affects more than 1 user in 10
common: affects 1 to 10 users in 100
uncommon: affects 1 to 10 users in 1,000

Like all medicines, BRINAVESS can cause side effects, although not everybody gets them.
Your doctor may decide to stop the infusion if your doctor observes any abnormal changes of:
- your heart beat
- your blood pressure
- the electrical activity of your heart

Very common side effects seen within 24 hours of being given BRINAVESS include:
- taste disturbances
- sneezing

These effects should pass quickly.

Other side effects include:
Common:
- numbness or pain at the infusion site, numbness or decreased skin sensation, tingling feelings or numbness
- nausea and vomiting
- feeling hot and tired
- low blood pressure, slow, fast or irregular heart beat, feeling dizzy
- headache
- coughing, dry mouth, sore nose
- sweating, itching

Uncommon:
- certain kinds of heart beat problems (such as a short pause in the normal activity of your heart or a missed beat; awareness of your heart beating (palpitations))
- eye irritation or watery eyes or changes in your vision; a change in your sense of smell; pain in your fingers and toes; a burning feeling; cold sweats; hot flush; itching
- urgency to have a bowel movement; diarrhoea
- shortness of breath or a tight chest
- irritation at the infusion site
- feeling light-headed or fainting; generally feeling unwell; feeling drowsy or sleepy
- runny nose; sore throat
- pale skin
- a serious heart condition caused by very low blood pressure

If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor.

5. HOW TO STORE BRINAVESS

Keep out of the reach and sight of children.

Do not use BRINAVESS after the expiry date which is stated on the carton and vial after EXP. The expiry date refers to the last day of that month.

Store BRINAVESS below 30°C
BRINAVESS must be diluted before it is used. The diluted sterile concentrate is chemically and physically stable for 12 hours at store below 25°C.

From a microbiological point of view, the product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at 2-8 °C, unless dilution has taken place in controlled and validated aseptic conditions.

Do not administer BRINAVESS if you notice particulate matter or discolouration.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What BRINAVESS contains

- The active substance is vernakalant hydrochloride. Each ml of concentrate contains 20 mg vernakalant hydrochloride equivalent to 18.1 mg vernakalant free base.
  Each vial of 200 mg vernakalant hydrochloride is equivalent to 181 mg vernakalant free base.
  Each vial of 500 mg of vernakalant hydrochloride is equivalent to 452.5 mg of vernakalant free base.
- The other ingredients are citric acid, sodium chloride, sodium hydroxide and water for injection.

What BRINAVESS looks like and contents of the pack

BRINAVESS is a concentrate for solution for infusion (sterile concentrate) which is clear and colourless to pale yellow.

Pack size of 1 vial Manufactured by:
Hameln Pharmaceuticals GmbH
Langes Feld 13,
31789 Hameln
Germany

Released by
Merck Sharp & Dohme B.V
Waarderweg 39, Haarlem,
2031 BN, 2003 PC Holland,
THE NETHERLANDS

For
Merck Sharp & Dohme Ltd.
Hertford Road, Hoddesdon
Hertforshire EN11 8BU
United Kingdom

This leaflet was last approved in 04/2011

MSD

(THIS IS A MEDICAMENT)

- Medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use, and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are experts in medicine, its benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.

Keep medicament out of reach of children

Council of Arab Health Ministers
Union of Arab Pharmacists

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