TACHYBEN
25 mg solution for injection

Read all of this leaflet carefully before you start using this medicine because it contains inportant information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor.
- If you get side effects talk to your doctor. This includes any possible side effects not listed in this leaflet.

What is in this leaflet

1. WHAT TACHYBEN IS AND WHAT IT IS USED FOR

TACHYBEN contains the active substance Urapidil.
TACHYBEN belongs to a group of medicines called alpha blockers. The action of this medicine is located in the blood vessels (i.e. arteries and veins). It reduces the blood pressure by relaxing the blood vessels wall.

TACHYBEN is used to treat severe high blood pressure:
- in case of high blood pressure emergency with short term life threatening organ injury;
- during and/or after surgery.

2. WHAT YOU NEED TO KNOW BEFORE YOU ARE GIVEN TACHYBEN

Do not use TACHYBEN:
- if you are allergic to urapidil or any of the other ingredients of this medicine (listed in section 6).
- if you have a cardiac abnormality called aortic stenosis or a blood vessels abnormality called cardiac shunt (except the cardiac shunt in people on dialysis).

Warning and precautions:
Before using TACHYBEN, your doctor should check:
- if you have had diarrhoea or vomiting (or any other causes of reduction of the liquids in your body);
- if your blood sodium is decreased.

Other medicines and TACHYBEN
Tell your doctor if you are taking or have recently taken any other medicines.

Tell your doctor before using this medicine if you are taking any of the following medicines as they may interact with TACHYBEN and this could alter their effectiveness or make side effects more likely:
- Alphablocking drugs used for urinary problems caused by prostate disease
- Any medicines to reduce your blood pressure
- Baclofen (used to treat muscle spasms)
- Cimetidine (used to inhibit the production of acid in the stomach).
- Imipramine and neuroleptics (used to treat depressions).
- Corticoids (anti-inflammatory agents, sometimes called 'steroids').

Using TACHYBEN with alcohol
You should be cautious while drinking alcohol during treatment with TACHYBEN. It might increase the effect of Urapidil.

Pregnancy and breast-feeding
The use of TACHYBEN during pregnancy is not recommended. There is no adequate data to judge the safety of the use of urapidil in pregnant women.

If a high blood pressure occurs during a pregnancy and needs to be treated with this medicine, the reduction of blood pressure should be gradual and always monitored by a doctor.

There is no data on the passage of urapidil in mother's milk. For safety reasons, breast-feeding is not advised during treatment with TACHYBEN.

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

Driving and using machines
The use of TACHYBEN can affect your ability to drive a car or operate machinery, most particularly:
- at the beginning of the treatment or in case of changes to the treatment;
- in the event of concomitant intake of alcoholised drinks.

If you feel sick, it is not advised to drive or to use any machines until symptoms disappear.

TACHYBEN contains propylene glycol. This ingredient may cause alcohol-like symptoms.
TACHYBEN contains less than 23 mg sodium per ampoule, i.e. essentially 'sodium-free'. It means you can use it if you follow a low-salt diet.

3. HOW TACHYBEN IS GIVEN

TACHYBEN is to be prescribed and administrated by a healthcare professional.

Dosage
The doctor will decide the appropriate dosage depending on your health status.

Particular groups of patients
- Use in children under 18 years old is not recommended due to lack of safety and efficacy data
- For elderly people (over 65 years old), a reduction of the intake might be necessary.
- If you suffer from liver disease (severe liver failure), the dosage should be reduced.
- If you suffer from kidneys disease (renal failure), some tests might be necessary to check your blood circulation.
- If you suffer from cardiac insufficiency caused by mechanical function impairment special precautions would be taken.

Route of administration
TACHYBEN is administrated into a vein.

Duration of treatment
The duration of treatment of TACHYBEN should not exceed 7 days.

If you are given more TACHYBEN than you should
The main event in case of overdose is a sudden fall in blood pressure on standing up which causes dizziness, light headedness or fainting (orthostatic hypotension). In that case, lay the patient on the back with the legs raised. If the symptoms remain, contact your doctor immediately.

If you have any further questions about this product, ask your doctor.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this can cause side effects, although not everybody gets them.

The following adverse effects may occur during the treatment. You should tell your doctor who will decide to stop or to continue your treatment.

Common: may affect up to 1 in 10 people: Nausea, dizziness and headaches

Uncommon: may affect up to 1 in 100 people: Palpitations, increase or decrease of the cardiac rhythm, feelings of tightness in the chest and breathing difficulties, vomiting, fatigue and sweating.

Rare: may affect up to 1 in 1,000 people: prolonged and painful erection, nasal congestion, skin allergic reactions (itching, unusual redness of the skin, rash).

Very rare: may affect up to 1 in 10,000 people: Reduction of the number of platelets (blood cells in coagulation); weakness, restlessness,.
If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor.
If you get any side effects talk to your doctor. This includes any possible side effects not listed in this leaflet.

5. HOW TO STORE TACHYBEN

Keep this medicine out of the sight and reach of children.

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

Do not store above 30°C.

After first opening/dilution:
Chemical and physical in use stability has been demonstrated for 50 hours at 15-25 °C.
From the 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 to 8° C, unless reconstitution/dilution has been taken place in controlled and validated conditions.

For single use only.

Use immediately after first opening the ampoule.
Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What TACHYBEN contains
The active substance is Urapidil.

One ampoule of 5 ml contains 25 mg of urapidil.

The other ingredients are:
propylene glycol (refer to section 2),
sodium dihydrogen phosphate dihydrate,
hydrochloric acid (37 % w/w),
disodium phosphate dihydrate,
hydrochloric acid (3.7 % w/w),
sodium hydroxide (4 % w/w),
water for injection.

What TACHYBEN looks like and contents of the pack
TACHYBEN 25 mg is a solution for injection in ampoule.
A carton contains 5 ampoules.

Marketing Authorisation Holder:
EVER Neuro Pharma GmbH
A-4866 Unterach
AUSTRIA

Manufacturer:
EVER Neuro Pharma GmbH
A-4866 Unterach
AUSTRIA

This leaflet was last revised in 11/2011.

The following information is intended for medical or healthcare professionals only:

Incompatibilities
This medicinal product must not be mixed with other medicinal products except compatible solvents listed above.
The following active substance(s) [or solution for reconstitution/dilution] should not be administered simultaneously:
alkaline injection and infusion solutions
This may cause turbidity or flocculation.

Special precautions for disposal
The 100 mg ampoule can only be used for stabilisation of blood pressure by infusion.
For the initial treatment ampoules containing 25 mg and 50 mg urapidil are available. These dosage strengths can also be used for intravenous infusion after dilution.

The dilution is made under aseptic conditions.

The solution should be expected visually for particulate matter and discoloration prior to administration. Only clear and colourless solution should be used.

Preparation of diluted solution:
- Intravenous infusion:

Add 250 mg urapidil (2 ampoules of 100 mg urapidil + 1 ampoule of 50 mg urapidil) to 500 ml of one of the compatible solvents.

- Syringe pump:

100 mg urapidil is drawn up into a syringe pump and diluted to a volume of 50 ml with one of the compatible solvents.

Compatible solvents for dilution:
- Sodium chloride 9 mg/ml (0.9%) solution for infusion
- Glucose 50 mg/ml (5%)
- Glucose 100 mg/ml (10%)

For single use only.
Any unused solution and the "bags/sachets" should be adequately disposed of, in accordance with local requirements".

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