Anti-arrhythmic drugs known as Class IA (quinidine, procainamide, disopyramide) and Class III (amiodarone) as well as tricyclic antidepressants, may also alter cardiac electrophysiology.

Terlipressin Acetate 1mg solution for injection should be used only under supervision of a doctor if it is vital to treat the patient. It is not known if Terlipressin Acetate 1mg solution for injection alters the course of the disease.

If you are affected by any of the following side effects,

- Severe or life threatening bleeding in your food pipe (called bleeding varices)
- Severe and persistent irregular heart beats
- Severe difficulty with or stopping breathing
- Severe shortness of breath due to an asthma attack
- Numbness or weakness of the limbs
- Convulsions (seizure)
- Swelling of the face, lips, tongue or throat
- diameter of objects or difficulty in understanding speech

Possible side effects

If you are affected by any of the following side effects,

- Nausea
- Vomiting
- Flatulence
- Headache
- Dizziness
- Urinary retention
- Drowsiness
- Fatigue
- Anorexia (loss of appetite)
- Elevated liver enzymes
- Itching
- Rash
- Acne

The use of this medicine is limited to -2 to 3 days, depending on the condition.

If you use more terlipressin acetate than recommended for your condition, for example, by the occurrence of adverse reactions.

The maximum dose you can receive each day is approximately 120 microgrammes/kg body weight.

If you forget to use Terlipressin Acetate 1mg solution for injection

- Do not use Terlipressin Acetate 1mg solution for injection if it is cloudy or it contains particles.

Precautions

- Store in a refrigerator at 2-8˚C.

- Keep the vial in the outer carton to protect from light.

This medicinal product contains 30.6mg (1.33mmol) solution for injection contains sodium per ampoule. To be taken into consideration by patients on a controlled sodium diet.

Side effects

- Convulsions (seizure)
- Swelling of the face, lips, tongue or throat
- Dizziness
- Urinary retention
- Itching
- Rash
- Acne

- Do not use Terlipressin Acetate 1mg solution for injection if you notice:

- That the solution discolors.

- This medicine is not to be used by yourself but will always be administered to you by your doctor. Please ask your doctor for further information regarding its use.

- After the initial injection, your dose may be reduced to 1mg every 4 to 6 hours.

- The use of this medicine is limited to -2 to 3 days, depending on the condition.

- If you use more terlipressin acetate than recommended for your condition, for example, by the occurrence of adverse reactions.

- If you are affected by any of the following side effects, please contact your doctor:

- Severe or life threatening bleeding in your food pipe (called bleeding varices)
- Severe and persistent irregular heart beats
- Severe difficulty with or stopping breathing
- Severe shortness of breath due to an asthma attack
- Numbness or weakness of the limbs
- Convulsions (seizure)
- Swelling of the face, lips, tongue or throat
- Diameter of objects or difficulty in understanding speech

- It is not known if Terlipressin Acetate 1mg solution for injection alters the course of the disease.

- Terlipressin Acetate 1mg solution for injection contains inactive ingredients.

- This medicinal product contains 30.6mg (1.33mmol) solution for injection contains sodium per ampoule. To be taken into consideration by patients on a controlled sodium diet.

- If you forget to use Terlipressin Acetate 1mg solution for injection

- Do not use Terlipressin Acetate 1mg solution for injection if it is cloudy or it contains particles.

- This medicine is not to be used by yourself but will always be administered to you by your doctor. Please ask your doctor for further information regarding its use.
Frequency of possible side effects:

Common (affects less than 1 in 10 people):
- Heart and circulation
  - very slow heart rate
  - signs of insufficient blood circulation in the heart vessels in the ECG
  - high or low blood pressure
  - insufficient blood circulation in arms, legs and skin
  - paleness of face
  - pale skin
- General
  - headache
- Stomach and gut
  - temporary abdominal cramps
  - temporary diarrhoea
  - abdominal cramps (in women)

Uncommon (affects less than 1 in 100 people):
- Mind and nervous system
  - triggering of a fit
- Heart and circulation
  - chest pain
  - rapid increase in blood pressure
  - heart attack
  - irregular heart rate
  - too fast heart rate (palpitations)
  - bluish colouration of the skin or lips
  - hot flushes
  - heart failure (Torsade de Pointes)
- Lungs and breathing
  - excess fluid on the lungs
  - shortness of breath due to spasm in the bronchial muscles
  - severe difficulty with or stopping breathing
- Stomach and gut
  - temporary nausea
  - temporary vomiting
- General
  - inflammation of the lymph vessels
  - reduced blood supply to the intestinal system
  - uterine cramps
  - decreased blood flow to the uterus
  - dead skin (necrosis) not related to the injection site
  - decreased blood flow to the uterus
  - dead skin (necrosis) not related to the injection site
  - dead skin (necrosis) not related to the injection site
  - dead skin (necrosis) not related to the injection site

Results of blood tests
- too little sodium in the blood (hyponatraemia)
- too much sugar in the blood (hyperglycaemia)

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the United Kingdom Yellow Card Scheme.

Website: www.mhra.gov.uk/yellowcard

By reporting side effects you can help provide more information on the safety of this medicine.

5 How to store Terlipressin Acetate 1mg solution for injection
Keep the medicine out of the sight and reach of children.

Store in a refrigerator at 2-8˚C. Keep in the original package in order to protect from light.

The reconstituted Terlipressin Acetate 1mg solution for injection -solution has to be used immediately.
Do not use this medicine after the expiry date which is stated on the pack after EXP. The expiry date refers to the last day of that month.

Do not use Terlipressin Acetate 1mg solution for injection if you notice
- that the solution discours.

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 Terlipressin Acetate 1mg solution for injection contains
- The active substance is terlipressin-acetate.
  - Each ampoule contains 1 mg of terlipressin-acetate in 8.5 ml solution for injection, corresponding to 0.85 mg terlipressin.
  - 1 ml of solution contains 0.12 mg/ml of terlipressin-acetate, equivalent to 0.1 mg terlipressin.
  - The other ingredients are:
    - sodium chloride, glacial acetic acid, sodium acetate and water for injection.

What Terlipressin Acetate 1mg solution for injection looks like and contents of the pack
This medicine is presented as a solution for injection. It is supplied in clear Type I glass ampoules containing solution for injection.
Each ampoule contains 0.5 ml of solution.

Terlipressin Acetate 1mg solution for injection is a clear, colourless solution for injection. This medicine is available in pack sizes of:
- One carton with 5 ampoules with 8.5 ml of solution.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder
Inresa Arzneimittel GmbH
Obere Hardtstraße 18
79114 Freiburg
Germany

Manufacturer
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45910 Cañadillas del Monte (Toledo)
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and
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This medicinal product is authorised in the Member States of the EEA under the following names:

DE: TERLIPRESSIN 1mg SOLUTION FOR INJECTION
UK: TERLIPRESSIN ACETATE 1mg SOLUTION FOR INJECTION

This leaflet was last revised in October 2016