

Package leaflet: information for the user

Terlipressin Acetate 1 mg solution for injection

(Terlipressin acetate)

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

- 1. What Terlipressin Acetate 1 mg solution for injection is and what it is used for**
- 2. What you need to know before you use Terlipressin Acetate 1 mg solution for injection**
- 3. How to use Terlipressin Acetate 1 mg solution for injection**
- 4. Possible side effects**
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1 What Terlipressin Acetate 1 mg solution for injection is and what it is used for

Terlipressin Acetate 1 mg solution for injection is a synthetic pituitary hormone

Terlipressin Acetate 1 mg solution for injection is used for the treatment of:

- bleeding from dilated (widening) veins in the food pipe leading to your stomach (called bleeding oesophageal varices).

2 What you need to know before you start using Terlipressin Acetate 1 mg solution for injection

Do not use Terlipressin Acetate 1 mg solution for injection

- if you are allergic to terlipressin or any of the other ingredients of Terlipressin Acetate 1 mg solution for injection (see section 6).

Warnings and precautions

Talk to your doctor, pharmacist or nurse before you start using Terlipressin Acetate 1 mg solution for injection

This medicine will be given to you if you have:

- Severe or life threatening bleeding in your food pipe (oesophagus).

It is given under continuous monitoring of your heart and blood circulation.

If you are able, please tell the doctor if you have any of the conditions shown below:

- if you are suffering from a severe infection known as septic shock
- if you suffer from bronchial asthma or other conditions that affect your breathing
- if you suffer from uncontrolled high blood pressure, insufficient blood circulation in the heart vessels (e.g. angina), have previously had a heart attack (myocardial infarction), or you have hardening of the arteries (arteriosclerosis)
- if you suffer from irregular heartbeats (cardiac arrhythmias)
- if you have poor blood circulation to your brain (e.g. you have had a stroke) or to your limbs (peripheral vascular disease)
- if you suffer from impaired kidney function (renal insufficiency)
- if you suffer from disturbances in the level of salt (electrolytes) in your blood
- if you are suffering from reduced amount of fluid in your circulation or have already lost a large amount of blood
- if you are pregnant
- if you are over the age of 70 years

Other medicines and Terlipressin Acetate 1 mg solution for injection

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

Please inform your doctor immediately if you take any of the following medicines:

- drugs that have an effect on your heart rate (e.g. beta-blockers, sufentanil or propofol)
- drugs that can trigger irregular beating of the heart (arrhythmia) such as the following:
 - anti-arrhythmic drugs known as Class IA (quinidine, procainamide, disopyramide) and Class III (amiodarone, sotalol, ibutilide, dofetilide)
 - an antibiotic called erythromycin
 - antihistamines (mainly used to treat allergies but also found in certain cough and cold remedies)
 - a type of medicine used to treat depression called tricyclic antidepressants
 - medicines that may alter the level of salt or electrolytes in your blood, particularly diuretics (used to treat high blood pressure and heart failure)

The following information is intended for medicinal or healthcare professionals only

Posology

Initially 1-2 mg terlipressin acetate (equivalent to 1-2 ampoules of Terlipressin Acetate 1mg solution for injection) are administered.

Depending on the patient's body weight the dose can be adjusted as follows:

- weight less than 50 kg: 1 mg (1 ampoule of 8.5 ml)
- weight 50 kg to 70 kg: 1.5 mg (1.5 ampoules of 8.5 ml)
- weight exceeding 70kg: 2mg (2 ampoules of 8.5ml).

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

The approximate value for the maximum daily dose of Terlipressin Acetate 1 mg solution for injection is 120 micrograms/kg body weight.

The therapy is to be limited to 2 – 3 days in adaptation to the course of the disease.

Terlipressin Acetate 1 mg solution for injection is injected intravenously and should be given over a period of one minute.

Terlipressin Acetate 1 mg solution for injection with food and drink

There are no limitations.

Pregnancy and breast-feeding and fertility

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

Ask your doctor or pharmacist for advice before taking any medicine.

Terlipressin Acetate 1 mg solution for injection should only be used during pregnancy if it is vital to treat your condition.

It is not known if Terlipressin Acetate 1 mg solution for injection is present in breast milk, therefore it is not known if there may be an effect on your baby. You should discuss the potential risk to your baby with your doctor.

Driving and using machines

No studies on the effects on the ability to drive and use machines have been performed.

Terlipressin Acetate 1 mg solution for injection contains sodium

This medicine contains 30.6 mg sodium (main component of cooking/table salt) in each ampoule. This is equivalent to 1.53% of the recommended maximum daily dietary intake of sodium for an adult.

3 How to use Terlipressin Acetate 1 mg solution for injection

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.

Adults

The dose will be determined by the doctor depending on patient's weight.

Initially 1-2 mg terlipressin acetate equivalent to 1-2 ampoules of Terlipressin Acetate 1mg solution for injection are administered. Your dose will depend on your body weight.

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

Treatment should be maintained for 24 consecutive hours until bleeding is under control or for a maximum period of 48 hours. After the initial injection, the following doses can be reduced to 1 milligram (1 ampoule) of Terlipressin Acetate 1 mg solution for injection if necessary as, for example, by the occurrence of adverse reactions.

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

Elderly

If you are over 70 years of age speak with your doctor before you receive Terlipressin Acetate 1mg solution for injection

Use in children and adolescents

Terlipressin Acetate 1 mg solution for injection is not recommended for use in children and adolescents due to insufficient experience.

Method and route of administration

After opening the ampoule, remove the solution with a syringe and inject it slowly intravenously.

Duration of treatment

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

If you use more Terlipressin Acetate 1 mg solution for injection than you should

You must not use more Terlipressin Acetate 1 mg solution for injection than the recommended dose.

If you are given too much then you may have a rapid increase in your blood pressure, especially if you already suffer with high blood pressure. If this happens then you need another medicine called an alpha blocker (e.g. clonidine) to control your blood pressure.

You may also experience a low heart rate. This can be treated with a medicine called atropine.

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

You will be given Terlipressin Acetate 1 mg solution for injection in hospital under the supervision of a doctor.

If you stop using Terlipressin Acetate 1 mg solution for injection

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

4 Possible side effects

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

Important side effects which need immediate attention:

In very rare cases, there may be severe side effects when you are given Terlipressin Acetate 1 mg solution for injection.

If you are affected by any of the following side effects, **please tell your doctor immediately** if you are able to. Your doctor should not give you any more Terlipressin Acetate 1 mg solution for injection to you.

- severe shortness of breath due to an asthma attack
- severe difficulty with or stopping breathing
- severe pain in the chest (angina)
- severe and persistent irregular heart beats
- locally dead skin (necrosis)
- convulsions (seizure)
- kidney failure.

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

Results of blood tests

- too little sodium in the blood (hyponatraemia) if not monitored

Rare (affects less than 1 in 1000 people):**Lungs and breathing**

- shortness of breath

Very rare (affects less than 1 in 10,000 people):**Heart and circulation**

- stroke
- severe angina

Results of blood tests

- 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 1 mg solution for injection

Keep this 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.

Once opened the medicine should 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 this medicine if you notice

- that the solution discolours.

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 1 mg solution for injection contains**

- The **active** substance is terlipressin acetate.

Each ampoule contains: 1mg of terlipressin acetate in 8.5 ml solution for injection, corresponding to 0.85 mg terlipressin.

1 ml of solution for injection 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 1 mg 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 8.5 ml of solution for injection.

Terlipressin Acetate 1 mg 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**

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This medicinal product is authorised in the Member States of the EEA under the following names:**Germany:** Terlipressin Inresa 1 mg Injektionslösung**UK:** Terlipressin Acetate 1 mg solution for injection

This leaflet was last revised in May 2022



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Artwork for:	Flynn Pharma Limited
Product name:	Terlipressin (Flynn version)
PL/PA no:	PL 13621/0075
Type:	Leaflet
Artwork dimensions:	540mm x 175mm
Profile supplied:	Yes
Date of first artwork:	19 October 2016
Reason for request:	MAH address changes: text addition
Version no:	10FP
Date of revision:	10 May 2022
Colours:	As swatch(es)
Font(s):	9pt FF Zwo
Artwork software:	InDesign CS6
Proof software:	PDF
BAC ref:	Z459 (formerly V259)

