PATIENT INFORMATION LEAFLET

TERLIPRESS® (TERLIPRESSIN INJECTION 1mg)

Read all of this leaflet carefully before you start taking 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 or pharmacist.

• 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 or pharmacist. This includes any possible side effects not listed in this leaflet.

IN THIS LEAFLET

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1. What TERLIPRESS is and what it is used for

TERLIPRESS contains the active ingredient terlipressin which is a synthetic pituitary hormone (this hormone is usually produced by the pituitary gland found in the brain).

It will be given to you by injection into a vein.

TERLIPRESS is used for the treatment of:

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

2. Before you use TERLIPRESS

You should NOT be given TERLIPRESS if you:

- are hypersensitive (allergic) to terlipressin or any of the other ingredients of TERLIPRESS

Warnings and precautions

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 below:

- a severe infection known as septic shock
- bronchial asthma or other conditions that affect your breathing
- 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)
- irregular heartbeats (cardiac arrythmias) or a history of QT interval prolongation (disturbance of heart rhythm)
- poor blood circulation to your brain (e.g. you have had a stroke) or to your limbs (peripheral vascular disease)
- impaired kidney function (renal insufficiency)
- disturbances in the level of salt (electrolytes) in your blood
- reduced amount of fluid in your circulation or have already lost a large amount of blood
- are over the age of 70 years
- are pregnant

Other medicines and TERLIPRESS

Please tell your doctor or pharmacist if you are taking or have recently taken

any other medicines, including medicines obtained without prescriptions.
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-arryhthmic drugs known as Class IA (quinidine, procainamide, disopyramide) and Class III (amiodarone, sotalol, ibutilide, dofetilide)
• erythromycin (an antibiotic)
• antihistamines (mainly used to treat allergies but also found in certain cough and cold remedies)
• tricyclic antidepressants used to treat depression
• medicines that may alter the level of salt or electrolytes in your blood, particularly diuretics (water tablets used to treat high blood pressure and heart failure)

Pregnancy and breast-feeding
TERLIPRESS should only be used during pregnancy if it is vital to treat your condition. 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.
It is not known if TERLIPRESS is present in breast milk, therefore the possible effects on your baby are unknown. You should discuss the potential risk to your baby with your doctor.
Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines
No studies on the effects on the ability to drive and use machines have been performed. However, if you feel unwell after receiving the injection, do not drive or operate machinery.

3. HOW TO USE TERLIPRESS
This medicine will always be given to you by a doctor into your vein. The doctor will decide the most appropriate dose for you and your heart and blood circulation will be continuously monitored during the injection. Please ask your doctor for further information regarding its use.
Use in adults
Initially 1-2 mg terlipressin acetate (5-10 ml of TERLIPRESS) is given by injection into your vein. Your dose will depend on your body weight.
After the initial injection, your dose may be reduced to 1 mg terlipressin acetate (5 ml) every 4 to 6 hours.
Use in the elderly
If you are over 70 years of age speak with your doctor before you receive TERLIPRESS.
Use in patients with kidney problems
TERLIPRESS should be used with caution in patients with long standing kidney failure.
Use in patients with liver problems
No dose adjustment is required in patients with liver failure.

Use in children and adolescents
TERLIPRESS is not recommended for use in children and adolescents due to insufficient experience.
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 TERLIPRESS than you should

As this medicine is given by a healthcare professional, then it is unlikely you will be given more than the recommended dose. If you are given too much then you may have a rapid increase in your blood pressure (this will be noticed during the continuous monitoring), especially if you already suffer with high blood pressure. If this happens then you will be given another medicine called an alpha blocker (e.g. clonidine) to control your blood pressure.

If you experience lightheadedness, dizziness, or feeling faint, tell your doctor because these could be signs of a low heart rate. This can be treated with another medicine called atropine.

If you forget to use TERLIPRESS

You will be given TERLIPRESS in hospital under the supervision of a doctor.

If you stop using TERLIPRESS

Your doctor will advise when it is time to stop receiving this medicine.

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

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 TERLIPRESS.

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 TERLIPRESS.

• 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
• dead skin around the injection site (necrosis)
• convulsions (seizure)
• kidney failure.

Other possible side effects:

Common

• 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
• headache
• temporary abdominal cramps
• temporary diarrhoea
• abdominal cramps (in women)

Uncommon

• chest pain
• rapid increase in blood pressure
• heart attack
• too fast heart rate (palpitations)
• swelling of the tissues in the body or fluid on the lungs
• bluish colouration of the skin or lips
• hot flushes
• excess fluid on the lungs
• temporary nausea
• temporary vomiting
• reduced blood supply to the intestinal system
• inflammation of the lymph vessels – seen as fine red streaks under your skin extending from the affected area to the armpit or groin and by fever, chills, headache, and muscle pain

• too little sodium in the blood (hyponatraemia)

Rare
• shortness of breath

Very rare
• stroke
• results of blood tests o too much sugar in the blood (hyperglycaemia)

The frequency of the following side effects is not known:
• heart failure (Torsade de Pointes)
• dead skin (necrosis) in areas other than at the injection site
• decreased blood flow to the uterus
• uterine cramps (cramps in the womb)

If you get any side effects, talk to your doctor or nurse. This includes any side effects not listed in this leaflet.

5. HOW TO STORE TERLIPRESS
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 vial after 'EXP' .The expiry date refers to the last day of that month.
Store in a refrigerator (2˚C-8°C)
Keep the vial in the outer carton in order to protect from light. The solution should be inspected visually for particles and discolouration prior to administration. Do not use this medicine if you notice discoloration.
Medicines should not be disposed via wastewater or household waste. The doctor will dispose of this medicine. These measures will help protect the environment.

6. FURTHER INFORMATION
What TERLIPRESS contains
- the **active** substance is terlipressin acetate.
Each vial contains 1 mg terlipressin acetate in 5 ml solution, corresponding to 0.85 mg terlipressin. This is equivalent to 0.2 mg terlipressin acetate per ml, corresponding to 0.17 mg terlipessin per ml.

- the **other ingredients** are: acetic acid, sodium acetate and water for injections (see also end of section 2 for further information on sodium).

What TERLIPRESS looks like and contents of the pack
This medicine is supplied in a clear glass vial containing 5 ml of a clear, colourless solution.
This medicine is available in pack sizes of: 5 x 5ml

Manufactured By:

TAJ PHARMACEUTICALS Ltd.
Mumbai, INDIA

Marketed By:

TAJ PHARMA INDIA LTD.
CRESCENT, SAHAR AIRPORT ROAD,
MUMBAI, MAHARASHTRA 400059
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