

**GLYPRESSIN 0.12MG/ML SOLUTION FOR INJECTION
PL 03194/0101**

UKPAR

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GLYPRESSIN 0.12MG/ML SOLUTION FOR INJECTION
PL 03194/0101

LAY SUMMARY

On 11th May 2009, the MHRA granted Ferring Pharmaceuticals Limited a Marketing Authorisation (licence) for Glypressin 0.12mg/ml Solution for Injection (PL 03194/0101). This medicine is a ready-to-use solution for injection and contains the active ingredient terlipressin acetate.

This medicine is used to treat 'bleeding oesophageal varices', which are veins in your food pipe (oesophagus) that are enlarged because they have an increased blood flow. This is caused by liver problems. The increased blood flow can cause them to burst and bleed. When the medicine is injected into your bloodstream, the active ingredient (terlipressin acetate) is broken down to release a substance called "lysine vasopressin". This substance acts on the walls of your blood vessels, causing them to narrow and decrease the blood flow to your affected veins, which helps to stop or slow the bleeding.

No new or unexpected safety concerns arose from this application and it was, therefore, judged that the benefits of taking Glypressin 0.12mg/ml Solution for Injection outweigh the risks; hence Marketing Authorisations have been granted.

GLYPRESSIN 0.12MG/ML SOLUTION FOR INJECTION
PL 03194/0101

SCIENTIFIC DISCUSSION

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INTRODUCTION

Based on the review of the data on quality, safety and efficacy, the UK granted a marketing authorisation for the medicinal product Glypressin 0.12mg/ml (terlipressin acetate) Solution for Injection (PL 03194/0101) to Ferring Pharmaceuticals Limited on 11th May 2009. This product is a restricted prescription only medicine and is indicated in the treatment of bleeding oesophageal varices. Administration is by intravenous bolus injection.

This application for Glypressin 0.12mg/ml Solution for Injection is submitted as an abridged application according to Article 8.3 of Directive 2001/83/EC, of a known active substance. The application is for a line extension to an existing marketing authorisation for Glypressin 1mg Powder and Solvent for Solution for Injection (first authorised in October 1983).

The product contains the active substance terlipressin acetate.

Glypressin may be regarded as a circulating depot of lysine vasopressin. Following intravenous injection, three glycyl moieties are enzymatically cleaved from the N-terminus to release lysine vasopressin. The slowly released vasopressin reduces blood flow in the splanchnic circulation in a prolonged manner, thereby helping to control bleeding from ruptured oesophageal varices.

PHARMACEUTICAL ASSESSMENT**Legal Basis**

This line extension application is submitted in accordance with Directive 2001/83/EC as amended, Article 8.3. It is filed as a National Standard Abridged application.

Use : Posterior pituitary lobe hormones

The product is currently an updated version of the currently licensed product Glypressin 1mg Powder and Solvent for Solution for Injection (PL 03194/0018). Both products are considered clinically equivalent.

Glypressin is indicated in the treatment of bleeding oesophageal varices. In acute variceal bleeding, 2mg Glypressin should be administered by intravenous bolus, followed by 1 – 2 mg every 4 – 6 hours until bleeding is controlled, up to a maximum of 72 hours.

Legal status

Subject to Restricted Medical Prescription

DRUG SUBSTANCE: Terlipressin acetate**General information**

Terlipressin is a 12 amino acid peptide (*N*- α -triglycyl-8-*L*-lysinevasopressin) present as an acetate salt. Terlipressin acetate is a white fluffy powder, freely soluble in water, 0.1 M NaOH, and acetic acid but not acetone or ethanol. Terlipressin acetate is the subject to in-house specifications.

Nomenclature

INN/Ph.Eur name: Terlipressin acetate

ATC-code: H 01 BA 04 Posterior lobe hormones

Structure

Satisfactory information on the structure of terlipressin acetate has been provided.

An Active Substance Master File (ASMF) has been provided covering the manufacture and control of the active substance terlipressin acetate.

Manufacture**Manufacturers**

The manufacturing sites involved in the production of sealer protein have been satisfactorily identified.

Description of Manufacturing Process and Process Controls

Synthesis of the drug substance from the designated starting materials has been adequately described, and appropriate in-process controls and intermediate specifications are applied. Satisfactory specification tests are in place for all starting materials and reagents, and these are supported by relevant certificates of analysis.

Control of drug substance

All potential known impurities have been identified and characterised. Appropriate proof of structure data has been supplied for the active pharmaceutical ingredient.

Appropriate specifications have been provided for the active substance terlipressin acetate. Analytical methods have been appropriately validated and are satisfactory for ensuring compliance with the relevant specifications. Batch analysis data are provided and comply with the proposed specification.

Satisfactory certificates of analysis have been provided for working standards used by the active substance manufacturer and finished product manufacturer.

The specifications and typical analytical test reports are provided and are satisfactory.

Process Validation and/or Evaluation

Three consecutive batches of terlipressin acetate were produced according to the approved validation protocol with the established acceptance criteria. All results are within the specified limits.

Container closure system

Satisfactory specifications and certificates of analysis have been provided all aspects of the container-closure system. Compatibility of the container closure system with the drug substance terlipressin acetate has been demonstrated by stability studies, which have confirmed the suitability of the container closure system for terlipressin acetate.

Stability**Stability Summary and Conclusions**

The data provided generally support the physicochemical and biological stability of the drug substance under the storage and handling conditions described. An appropriate retest period has been proposed based on stability data submitted for the active substance terlipressin acetate.

Stability Data

Stability studies have been conducted with six batches of terlipressin acetate. Results did not show any significant changes during the whole period of observation, and therefore support the shelf life proposed and confirm the suitability of the container.

DRUG PRODUCT: GLYPRESSIN 0.12MG/ML SOLUTION FOR INJECTION**Composition of the drug product**

Terlipressin acetate is one of the components of Glypressin 0.12mg/ml Solution for Injection.

Other ingredients consist of pharmaceutical excipients sodium chloride, acetic acid, sodium acetate and water for injections. All the ingredients comply with their relevant European Pharmacopoeia monographs.

None of the excipients used contain material of animal or human origin.

Pharmaceutical development

The development pharmaceuticals were satisfactorily presented and the issues addressed include the rationale for the formulation and its subsequent evolution, and the manufacturing process development. Development studies on packaging materials were provided. Chemical and physical compatibility were demonstrated in the course of the finished product stability studies.

Manufacture**Batch Formula**

A batch formula has been provided for an average batch size.

Description of Manufacturing Process and Process Controls

A description and flow-chart of the manufacturing method has been provided. The In-process controls applied are appropriate and meet the required acceptance criteria.

Control of Critical Steps and Intermediates

The critical steps have been described.

Process Validation

Four batches of the drug product were manufactured to demonstrate process consistency. In-process controls are satisfactory based on process validation data and controls on the finished product.

The process was appropriately validated and is considered capable of producing a drug product of adequate quality, conforming to predetermined parameters and acceptance criteria.

Sterile Filtering, filling and sealing were satisfactorily validated. The validation results demonstrated that the in-process parameters and controls are within the established limits.

The drug product was tested for microbiological quality and all batches met the release criteria.

Overall, the data demonstrates that the process is capable of producing the drug product in bulk and filled containers which are homogeneous and of acceptable and consistent quality.

Control of Excipients**Specifications**

All excipients used in the pharmaceutical production of Glypressin 0.12mg/ml Solution for Injection, i.e. sodium chloride, acetic acid, sodium acetate and Water for Injections, comply with the current edition of the European Pharmacopoeia. Analytical procedures for the tests regarding the excipients are performed according to the requirements of the current European Pharmacopoeia monographs, and the specifications of the excipients are set to comply with the current edition of the European Pharmacopoeia.

Control of Drug product**Finished Product Specification**

The finished product specification has been provided and is compliant with in-house specifications.

Analytical Procedures

Details of the analytical procedures have been provided. Most are compendial methods and are considered appropriate.

Validation of Analytical Procedures

Validation reports for the pharmacopoeial methods are not presented and are not required on the basis that these methods are the same as those used for the drug substance and have therefore already been validated.

Batch Analyses

Batch data was provided for two full scale batches of the drug product representing the intended fill volume size. Both batches met the release specification. All results were well within the specifications and demonstrate the consistent manufacture of Glypressin 0.12mg/ml Solution for Injection.

Characterisation of Impurities

Details of the test for impurities are provided. Reference standards of terlipressin and each impurity are used. The results for the total number of impurities and unknown individual impurities were found to be within the set limits and are satisfactory.

Justification of Specification(s)

The specification for Glypressin 0.12mg/ml Solution for Injection is justified based on a combination of compendial limits, existing manufacturing and process development data, years of experience with the peptide drug product, process capabilities, analytical method validation data and product stability data. Test methods have been described and have been adequately validated, as appropriate. Batch data have been provided and comply with the release specification. Certificates of analysis for all working standards used have been provided and are satisfactory.

Reference Standards or Materials

No primary reference standards are used in the manufacture and quality control of Glypressin 0.12mg/ml Solution for Injection.

Container Closure System

The primary packaging for Glypressin 0.12mg/ml Solution for Injection, is in 10ml Type I clear glass ampoules, with a fill volume of 8.5ml. The ampoules are packed in cardboard boxes which protect from light. The product is packaged in sizes of 5 x 8.5ml.

Specifications and certificates of analysis for the packaging types used have been provided. All primary product packaging complies with European Pharmacopoeia Type I.

Stability**Stability Summary and Conclusion**

Stability data was provided for four batches of the drug product. Data was submitted for long term studies covering a storage period of 24 months at 2°C to 8°C and in accelerated conditions, for 6 months. All results remained within the range of specification during both storage periods. The finished product stability studies have been conducted in accordance with current guidelines. Based on the results, a shelf-life of 2 years has been set, which is satisfactory.

Storage conditions are 'Store in a refrigerator (2-8°C)' and 'Keep the ampoules in the outer carton in order to protect from light'.

Special precautions for disposal are 'Unused drug and waste should be destroyed in accordance with local requirements.'

Post-approval Stability Protocol and Stability Commitment

The ongoing stability studies examining the stability of Glypressin 0.12mg/ml Solution for Injection shall be continued post-approval as per the testing protocols provided.

APPENDICES**Facilities and Equipment**

Details of product manufacturing facilities are satisfactory.

Adventitious Agents Safety Evaluation

None have been provided and none are required as the product is chemically synthesized.

NON-CLINICAL ASSESSMENT

The Ferring substance terlipressin has had a new formulation developed, Glypressin solution for injection. Because the excipient profile of Glypressin solution for injection differs from the earlier formulation of terlipressin (Glypressin powder and solvent for solution for injection), a local tolerance study has been performed to determine whether there is any intolerance associated with the new formulation.

The local tolerance study was performed in accordance with the CPMP Note for Guidance on Non-Clinical Local Tolerance Testing of Medicinal Products (CPMP/SWP/2145/00; March 2001). The intended route of human administration is intravenous, and this was investigated by daily injections for 14 days into the ears of rabbits. The potential accidental routes of administration, intra-arterial and perivenous were investigated by single doses. The excipient vehicle alone and physiological saline were also tested as comparators. The dose injected by all three routes was 40 µg/kg terlipressin free base, with a dose volume of 0.4 mL/kg. The dose was selected to approximate to the highest bolus dose administered to human patients (1.7 mg in 17 mL, equivalent to 34 µg/kg in a 50 kg patient).

Daily intravenous injections of terlipressin formulated in excipient vehicle (Glypressin solution for injection), excipient vehicle alone, or physiological saline for 14 days in rabbits were well tolerated, and there were no differences between the three test items. In rabbits that received single intra-arterial injections, there were no marked macro- or microscopic differences between the animals, except for one animal that received Glypressin solution for injection that showed marked haemorrhaging, most likely due to needle-damage.

The group that received single doses perivenously showed similar scores for erythema, whereas moderate to marked haemorrhage and swelling were present at the excipient vehicle treatment site. In two of these animals there was also slight subcutaneous necrosis at the injection site. These findings were not seen at the saline injection sites, or at the Glypressin solution for injection sites despite the presence of excipient vehicle in the formulation.

NON CLINICAL OVERVIEW

The non-clinical overview has been written by a suitably qualified expert.

SmPC

This is acceptable.

CONCLUSION

There are no preclinical objections to the grant of this application.

CLINICAL ASSESSMENT

This is an abridged standard national application for Glypressin 0.12mg/ml Solution for Injection, which is a new formulation of the applicant's substance, terlipressin acetate. This application is considered a line extension of existing licence Glypressin 1mg Powder and Solvent for Solution for Injection (PL 03194/0018), which was first authorised to the applicant in October 1983.

CLINICAL PHARMACOLOGY

No studies have been performed and none are required for applications of this type.

EFFICACY

No new data has been provided.

SAFETY

No new data has been provided.

EXPERT REPORTS

The clinical expert report has been written by a suitably qualified person and is satisfactory.

PATIENT INFORMATION LEAFLET (PIL)

This is consistent with that for the reference product and is satisfactory.

LABELLING

These are satisfactory.

APPLICATION FORM (MAA)

This is satisfactory.

SUMMARY OF PRODUCT CHARACTERISTICS (SPC)

This is satisfactory.

DISCUSSION

New clinical data was not submitted for this application and are not required for applications of this type.

MEDICAL CONCLUSION

The grant of marketing authorisations is recommended for this application.

OVERALL CONCLUSION AND RISK BENEFIT ASSESSMENT

QUALITY

The important quality characteristics of Glypressin 0.12mg/ml Solution for Injection are well-defined and controlled. The specifications and batch analytical results indicate consistency from batch to batch. There are no outstanding quality issues that would have a negative impact on the benefit/risk balance.

PRECLINICAL

Preclinical studies were carried out in accordance with Good Laboratory Practice (GLP), and in accordance with recognised guidelines. No toxicity was demonstrated, and no new toxicological problems for these products were found.

EFFICACY

New clinical data was not submitted for this application and are not required for applications of this type.

No new or unexpected safety concerns arise from this application.

The SPC, PIL and labelling are satisfactory.

RISK BENEFIT ASSESSMENT

The quality of the product is acceptable and no new preclinical or clinical safety concerns have been identified, and some benefit has been shown to be associated with Glypressin 0.12mg/ml Solution for Injection. The benefit/risk is, therefore, considered to be positive.

GLYPRESSIN 0.12MG/ML SOLUTION FOR INJECTION
PL 03194/0101

STEPS TAKEN FOR ASSESMENT

1	The MHRA received the marketing authorisation applications on 17 th July 2007.
2	Following standard checks and communication with the applicant the MHRA considered the applications valid on 17 th October 2007.
3	Following assessment of the applications, the MHRA requested further information relating to the dossier on 23 rd January 2008 and 23 rd June 2008,
4	The applicant responded to the MHRA's requests, providing further information on 18 th June 2008 and 28 th August 2008 for the dossier.
5	The applications were determined on 11 th May 2009.

GLYPRESSIN 0.12MG/ML SOLUTION FOR INJECTION
PL 03194/0101

STEPS TAKEN AFTER AUTHORISATION - SUMMARY

Date submitted	Application type	Scope	Outcome

SUMMARY OF PRODUCT CHARACTERISTICS**1 NAME OF THE MEDICINAL PRODUCT**

Glypressin 0.12 mg/ml solution for injection

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

One ampoule contains 1mg terlipressin acetate in 8.5ml solution for injection.

For excipients, see section 6.1

3 PHARMACEUTICAL FORM

Solution for injection.

Clear, colourless liquid.

4 CLINICAL PARTICULARS**4.1 THERAPEUTIC INDICATIONS**

Glypressin is indicated in the treatment of bleeding oesophageal varices.

4.2 POSOLOGY AND METHOD OF ADMINISTRATION

In acute variceal bleeding, 2mg Glypressin should be administered by intravenous bolus, followed by 1 – 2 mg every 4 – 6 hours until bleeding is controlled, up to a maximum of 72 hours.

Administration is by intravenous injection.

4.3 CONTRAINDICATIONS

Contraindicated in pregnancy.

Hypersensitivity to terlipressin or any other excipients of the product.

4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE

Since Glypressin has antidiuretic and pressor activity it should be used with great caution in patients with hypertension, atherosclerosis, cardiac dysrhythmias or coronary insufficiency.

Constant monitoring of blood pressure, serum sodium and potassium and fluid balance is essential.

4.5 INTERACTION WITH OTHER MEDICINAL PRODUCTS AND OTHER FORMS OF INTERACTION

None known

4.6 PREGNANCY AND LACTATION

Glypressin® may stimulate contraction of smooth muscle and is therefore contraindicated in pregnancy. There is no data concerning its use in lactation.

4.7 EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

Not applicable

4.8 UNDESIRABLE EFFECTS

Glypressin® is only recommended for the short-term treatment of bleeding oesophageal varices, so few side effects have been reported. Those noted have included abdominal cramps, headache, transient blanching and increased arterial blood pressure.

4.9 OVERDOSE

The recommended dose (2mg/4 hours) should not be exceeded as the risk of severe circulatory adverse effects is dose-dependent.

5 PHARMACOLOGICAL PROPERTIES**5.1 PHARMACODYNAMIC PROPERTIES**

Pharmacotherapeutic group: Posterior pituitary lobe hormones (vasopressin and analogues) (H 01 BA 04)

Glypressin® may be regarded as a circulating depot of lysine vasopressin. Following intravenous injection, three glycyl moieties are enzymatically cleaved from the N-terminus to release lysine vasopressin.

The slowly released vasopressin reduces blood flow in the splanchnic circulation in a prolonged manner, thereby helping to control bleeding from ruptured oesophageal varices.

5.2 PHARMACOKINETIC PROPERTIES

Glypressin® is administered by bolus intravenous injection. It shows a biphasic plasma level curve which indicates that a two compartment model can be applied.

The half-life of distribution ($T_{1/2\alpha}$) is about 8 -10 minutes.

The half-life of elimination ($T_{1/2\beta}$) is about 50 -70 minutes.

Lysine vasopressin reaches maximum plasma levels about 1 - 2 hours following intravenous administration and has a duration of activity of 4 - 6 hours.

5.3 PRECLINICAL SAFETY DATA

There are no pre-clinical data of relevance to the prescriber which are additional to that already included in other sections of the SPC.

6 PHARMACEUTICAL PARTICULARS

6.1 LIST OF EXCIPIENTS

Sodium chloride

Acetic acid

Sodium acetate

Water for injections

6.2 INCOMPATIBILITIES

In the absence of compatibility studies, this medicinal product must not be mixed with other medicinal products.

6.3 SHELF LIFE

2 years

6.4 SPECIAL PRECAUTIONS FOR STORAGE

Store in a refrigerator (2-8 °C). Keep the ampoules in the outer carton in order to protect from light.

6.5 NATURE AND CONTENTS OF CONTAINER

Type I clear glass ampoules.

Pack size: 5 x 8.5ml

6.6 SPECIAL PRECAUTIONS FOR DISPOSAL

Unused drug and waste should be destroyed in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

Ferring Pharmaceuticals Ltd.,

The Courtyard

Waterside Drive

Langley, Berkshire

SL3 6EZ

UK

8 MARKETING AUTHORISATION NUMBER(S)

PL 03194/0101

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

11/05/2009

10 DATE OF REVISION OF THE TEXT
11/05/2009

PACKAGE LEAFLET: INFORMATION FOR THE USER

GLYPRESSIN[®] 0.12 mg/ml solution for injection
Terlipressin acetate

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 or nurse.
- If any of the side effects become serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or nurse.
- The full name of your medicine is GLYPRESSIN solution for injection. In this leaflet from here onwards it is called GLYPRESSIN.

In this leaflet:

1. What GLYPRESSIN is and what it is used for
2. Before you are given GLYPRESSIN
3. How you will be given GLYPRESSIN
4. Possible side effects
5. How GLYPRESSIN is stored
6. Further information

1. WHAT GLYPRESSIN IS AND WHAT IT IS USED FOR

GLYPRESSIN is a ready-to-use solution for injection containing the active substance, terlipressin acetate.

What GLYPRESSIN is used for

GLYPRESSIN is used to treat 'bleeding oesophageal varices'.

- 'Oesophageal varices' are veins in your food pipe (oesophagus) that are enlarged because they have an increased blood flow. This is caused by liver problems.
- The increased blood flow can cause them to burst and bleed.

This is a serious and life-threatening problem.

How GLYPRESSIN works

When the medicine is injected into your bloodstream:

- The active ingredient (terlipressin acetate) is broken down to release a substance called "lysine vasopressin".
- This substance acts on the walls of your blood vessels, causing them to narrow and decrease the blood flow to your affected veins.
- This helps to stop or slow the bleeding.

2. BEFORE YOU ARE GIVEN GLYPRESSIN**You must not be given GLYPRESSIN if:**

- You are **allergic (hypersensitive)** to terlipressin acetate or any of the other ingredients of GLYPRESSIN, (listed in Section 6).
- You are **pregnant**.
You must not be given GLYPRESSIN if any of the above apply to you. If you are not sure, talk to your doctor or nurse before you are given GLYPRESSIN.

Take special care with Glypressin

Please check with your doctor before GLYPRESSIN is given to you if:

- You have **high blood pressure (hypertension)**
- You have a **heart problem** such as an irregular heart beat
- You have **heart disease** such as where your heart's arteries have become hardened, narrow or blocked. This means that your heart's muscle is not getting enough blood supply (**coronary insufficiency**)
- You have a **circulation problem (atherosclerosis)**. This is where fatty plaques have developed on the inner lining of your arteries and are stopping your blood from flowing normally.

If any of the above apply to you (or you are not sure) talk to your doctor or nurse before you are given GLYPRESSIN.

Using other medicines

Please tell your doctor or nurse if you are taking or have recently taken any other medicines. This includes medicines obtained without a prescription, including herbal medicines. This is because GLYPRESSIN can affect the way some other medicines work. Also some other medicines can affect the way GLYPRESSIN works.

Pregnancy and breast-feeding

- You **must not** be given GLYPRESSIN if you are **pregnant**.
- You **must not** be given GLYPRESSIN if you are **breast-feeding**. It is not known if GLYPRESSIN passes into the mother's milk.

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

3. HOW YOU WILL BE GIVEN GLYPRESSIN

GLYPRESSIN is used in hospitals and will be given to you by a doctor or nurse.

GLYPRESSIN will be given to you as an injection into a vein.

- The usual starting dose is 2 milligrams (mg).
- Your doctor may then give you 1 to 2 mg every 4 to 6 hours until the bleeding has been controlled.
- Your treatment could last up to a maximum of 72 hours.
- During treatment, your blood pressure, serum sodium and potassium and fluid balance will be monitored closely.

4. POSSIBLE SIDE EFFECTS

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

Commonly reported side effects (affect less than 1 in 10 people):

- Headache.
- Raised blood pressure.
- Stomach pains or cramps.
- Skin becoming white which usually goes away after a short time (transient blanching).

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

5. HOW GLYPRESSIN IS STORED

Keep out of the reach and sight of children.

Do not use GLYPRESSIN after the expiry date which is stated on the pack. The expiry date refers to the last day of that month.

Store in a refrigerator at 2-8°C. Keep the ampoules in the outer carton in order to protect from light.

6. FURTHER INFORMATION**What GLYPRESSIN contains**

- The active substance is terlipressin acetate. Each ampoule contains 1 mg of terlipressin acetate in 8.5 ml solution for injection. This is equivalent to 0.12 mg terlipressin acetate per ml.
- The other ingredients are sodium chloride, acetic acid, sodium acetate and water for injection.

What GLYPRESSIN looks like and contents of the pack

GLYPRESSIN is a clear, colourless solution for injection. It is available in one pack size of 5 ampoules with 8.5 ml of solution in each ampoule.

Marketing Authorisation Holder

Ferring Pharmaceuticals Ltd.
The Courtyard
Waterside Drive
Langley, Berkshire
SL3 6EZ, UK.
tel 01753 214800
fax 01753 214801
e-mail contact@ferring.co.uk

Manufacturer

Ferring-Léciva a.s.
K Rybníku 475
252 42 Jesenice near Prague
Czech Republic

GLYPRESSIN[®] Solution for
Injection – PL 03194/0101

Glypressin[®]

FERRING
PHARMACEUTICALS

0.12mg/ml solution for injection.
1mg Terlipressin acetate per 8.5ml
dose. I.V. use only. PL 03194/0101
Batch No./Exp. Date:

POM

Glypressin[®]

0.12mg/ml solution for injection
Terlipressin Acetate

POM

1mg of Terlipressin Acetate in 8.5ml solution for injection

FOR INTRAVENOUS USE ONLY

This carton contains:
5 x 8.5ml ampoule of solution

FERRING
PHARMACEUTICALS

Glypressin[®]
0.12mg/ml solution for injection
Terlipressin Acetate



Active Ingredient:

Each ampoule contains 1mg of Terlipressin acetate in 8.5ml solution for injection.

Other Ingredients:

Sodium chloride
Acetic acid
Sodium acetate (trihydrate)
Water for injection to 8.5ml

This medicine will be administered by a doctor or a nurse, not for self-administration by the patient.

Please read the enclosed Patient Information Leaflet before using this medicine.

Store in a refrigerator (2°C - 8°C).

Keep the ampoules in the outer carton in order to protect from light.

Product Licence Holder:

Ferring Pharmaceuticals Ltd., The Courtyard, Waterside Drive
Langley, Berkshire, SL3 6EZ (UK)
PL03194/0101

**KEEP OUT OF THE REACH
AND SIGHT OF CHILDREN**

FERRING
PHARMACEUTICALS

Glypressin[®]
0.12mg/ml solution for injection
Terlipressin Acetate

Batch No:

Exp. Date: