

**PARTICULARS TO APPEAR ON THE OUTER PACKAGING**

**Carton box**

**1. NAME OF THE MEDICINAL PRODUCTS**

Ofost 10 IU/ml concentrate for solution for infusion or solution for intramuscular injection  
oxytocin

**2. STATEMENT OF ACTIVE SUBSTANCE(S)**

1 ml of solution contains 16.7 microgram of oxytocin (10 IU).

**3. LIST OF EXCIPIENTS**

Excipients: sodium acetate trihydrate, acetic acid glacial, sodium chloride, sodium hydroxide,  
water for injections.

**4. PHARMACEUTICAL FORM AND CONTENTS**

Solution for injection/infusion

5 ampoules of 1 ml

10 ampoules of 1 ml

100 ampoules of 1 ml

**5. METHOD AND ROUTE(S) OF ADMINISTRATION**

Intramuscular injection and intravenous infusion.  
Read the package leaflet before use.

**6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE  
STORED OUT OF THE SIGHT AND REACH OF CHILDREN**

Keep out of the sight and reach of children.

**7. OTHER SPECIAL WARNING(S), IF NECESSARY**

**8. EXPIRY DATE**

EXP

**9. SPECIAL STORAGE CONDITIONS**

Store in a refrigerator (2 °C – 8 °C). Do not freeze.

**10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL  
PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL  
PRODUCTS, IF APPROPRIATE**

**11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER**

AS Grindeks,  
Krustpils iela 53,  
Rīga, LV-1057,  
Latvia

<MAH Logo>

**12. MARKETING AUTHORISATION NUMBER(S)**

PA22992/001/002

**13. BATCH NUMBER**

Lot

**14. GENERAL CLASSIFICATION FOR SUPPLY**

POM

**15. INSTRUCTIONS ON USE**

**16. INFORMATION IN BRAILLE**

Justification for not including Braille is accepted.

**17. UNIQUE IDENTIFIER – 2D BARCODE**

2D barcode carrying the unique identifier included.

**18. UNIQUE IDENTIFIER – HUMAN READABLE DATA**

PC: {number}

SN: {number}

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS**

**Label for ampoule**

**1. NAME OF THE MEDICINAL PRODUCT AND ROUTE(S) OF ADMINISTRATION**

Ofostr 10 IU/ml concentrate for solution for infusion or solution for intramuscular injection  
oxytocin

**2. METHOD OF ADMINISTRATION**

IV, IM

**3. EXPIRY DATE**

EXP

**4. BATCH NUMBER**

Lot

**5. CONTENTS BY WEIGHT, BY VOLUME OR BY UNIT**

1 ml

**6. OTHER**

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