LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

CARTON 250 ml and 500 ml

1. NAME OF THE MEDICINAL PRODUCT

Human Albumin 50 g/l [Baxter/Baxalta]
Solution for Infusion

Active substance: Human Albumin

2. STATEMENT OF ACTIVE SUBSTANCE(S)

The product contains 50 g/l protein (at least 95% albumin) produced from human plasma.
A vial of 250 ml contains 12.5 g of human albumin.
A vial of 500 ml contains 25 g of human albumin.

3. LIST OF EXCIPIENTS

Excipients:
Sodium caprylate: 4 mmol/l (0.7 g/l)
Sodium acetyltryptophanate: 4 mmol/l (1.1 g/l)
Sodium chloride: q.s.
Water for injection: to 1 L

Total sodium content: 130 – 160 mmol/l

4. PHARMACEUTICAL FORM AND CONTENTS

Solution for Infusion
250 ml
500 ml

5. METHOD AND ROUTE(S) OF ADMINISTRATION

For intravenous use only.
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

Do not use if the solution is cloudy or contains a deposit.

Once the container has been opened the contents must be used immediately.
Contains sodium, see leaflet for further information.

8. EXPIRY DATE

Exp. Date:

9. SPECIAL STORAGE CONDITIONS

Do not store above 25°C.
Do not freeze.
Store in the original package to protect from light.

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

Baxalta Innovations GmbH
Industriestrasse 67
A-1221 Vienna
Austria

12. MARKETING AUTHORISATION NUMBER(S)

PA 2004/4/1

13. BATCH NUMBER

Lot No.:

14. GENERAL CLASSIFICATION FOR SUPPLY

Subject to medical prescription.

P.O.M

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

17. Unique Identifier – 2D BARCODE

2 D barcode carrying the unique identifier included

18. UNIQUE IDENTIFIER – HUMAN READABLE DATA

< PC: {number} [product code]
SN: {number} [serial number]
NN: {number} [national reimbursement number or other national number identifying the medicinal product]>

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING

VIAL 250 ml and 500 ml

1. NAME OF THE MEDICINAL PRODUCT

Human Albumin 50 g/l [Baxter/Baxalta]
Solution for Infusion

Active substance: Human Albumin

2. STATEMENT OF ACTIVE SUBSTANCE(S)

The product contains 50 g/l protein (at least 95% albumin) produced from human plasma.
A vial of 250 ml contains 12.5 g of human albumin.
A vial of 500 ml contains 25 g of human albumin.

3. LIST OF EXCIPIENTS

Excipients:
Sodium caprylate: 4 mmol/l (0.7 g/l)
Sodium acetyltryptophanate: 4 mmol/l (1.1 g/l)
Sodium chloride: q.s.
Water for injection: to 1 L

Total sodium content: 130 – 160 mmol/l

4. PHARMACEUTICAL FORM AND CONTENTS

Solution for Infusion
250 ml
500 ml

5. METHOD AND ROUTE(S) OF ADMINISTRATION

For intravenous use only.
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

Once the container has been opened the contents must be used immediately.
Do not use if the solution is cloudy or contains a deposit.

8. EXPIRY DATE

Exp. Date:

9. SPECIAL STORAGE CONDITIONS

Do not store above 25°C.
Do not freeze.
Protect from light.

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

Baxalta Innovations GmbH
Industriestrasse 67
A-1221 Vienna
Austria

12. MARKETING AUTHORISATION NUMBER(S)

PA 2004/4/1

13. BATCH NUMBER

Lot No.:

14. GENERAL CLASSIFICATION FOR SUPPLY

Subject to medical prescription.

P.O.M

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE