**ESTONIAN STATE AGENCY OF MEDICINES**
**LATVIAN STATE AGENCY OF MEDICINES**
**LITHUANIAN STATE MEDICINES CONTROL AGENCY**

# COMMON BALTIC PACKAGE GUIDANCE

**PARTICULARS TO APPEAR ON THE OUTER PACKAGING OR, WHERE THERE IS NO OUTER PACKAGING, ON THE IMMEDIATE PACKAGING**

**{NATURE/TYPE}**

## 1. NAME OF THE MEDICINAL PRODUCT

*{(Invented) name, strength and pharmaceutical form}*
*{Active substance (s)}*

*European Pharmacopoeia full standard term should be used for pharmaceutical form.*

*Name of active substance should appear in all national languages or Latin without any brackets or further explanations. Latin should never be combined with any another language.*

## 2. STATEMENT OF ACTIVE SUBSTANCE(S)

*Statement of active substance should be in national languages. In case of 3 and more active substances Latin may be used.*

## 3. LIST OF EXCIPIENTS

*Should appear in all national languages or Latin.*
*Latin should never be combined with any another language.*
*Express qualitatively only those excipients known to have a recognised action or effect and included in guideline on "Excipients in the Label and Package Leaflet of Medicinal Products for Human Use" (The rules governing medicinal products in the European Union, Volume 3B). However, if the medicinal product is a parenteral, a topical or an eye preparation or if used for inhalation, all excipients must be stated.*

## 4. PHARMACEUTICAL FORM AND CONTENTS

*European Pharmacopoeia short standard term may be used for pharmaceutical form if space on the package is not sufficient.*

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

*European Pharmacopoeia standard term should be used.*
Read the package leaflet before use.

## 6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT SHOULD 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

*Words "Expiry date" are endorsed to appear in all national languages.*

For terms on Expiry date see Appendix IV on the European Medicines Agency website
http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2009/10/WC500004426.pdf

## 9. SPECIAL STORAGE CONDITIONS

## 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

*{Name and address}*
*<{tel}>*
*<{fax}>*
*<{e-mail}>*
*Should not be translated.*
*Only name of the Member State should appear in national language.*

## 12. MARKETING AUTHORISATION NUMBER(S)

## 13. BATCH NUMBER

*Word "Batch" is endorsed to appear in all national languages.*

For terms on Batch number see Appendix IV on the European Medicines Agency website
http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2009/10/WC500004426.pdf

## 14. GENERAL CLASSIFICATION FOR SUPPLY

*<Medicinal product subject to medical prescription.>*
*<Medicinal product not subject to medical prescription.>*

## 15. INSTRUCTIONS ON USE

## 16. INFORMATION IN BRAILLE

*<Justification for not including Braille accepted>*

## 17. UNIQUE IDENTIFIER – 2D BARCODE

<2D barcode carrying the unique identifier included.>

<Not applicable.>

## 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]>

<Not applicable.>

**MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS**

**{NATURE/TYPE}**

## 1. NAME OF THE MEDICINAL PRODUCT

*{(Invented) name strength pharmaceutical form}*
*{Active substance (s)}*

*European Pharmacopoeia short standard term may be used for pharmaceutical form if space on the package is not enough.*

*Name of active substance should appear in all national languages or Latin without any brackets or further explanations. Latin should never be combined with any another language.*

## 2. NAME OF THE MARKETING AUTHORISATION HOLDER

*{Name}*

## 3. EXPIRY DATE

For terms on Expiry date see Appendix IV on the European Medicines Agency website http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2009/10/WC500004426.pdf

Otherwise, digits indicating month and year may appear without any further references.

## 4. BATCH NUMBER

For terms on Batch number see Appendix IV on the European Medicines Agency website http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2009/10/WC500004426.pdf

Otherwise, batch number may appear without any further references.

## 5. OTHER

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

**{NATURE/TYPE}**

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

*{(Invented) name strength pharmaceutical form}*
*{Active substance (s)}*
*<Route of administration>*

*European Pharmacopoeia short standard term may be used for pharmaceutical form.*

*Name of active substance should appear in all national languages or Latin without any brackets or further explanations. Latin should never be combined with any another language.*

*European Pharmacopoeia standard term should be used for route of administration.*

## 2. METHOD OF ADMINISTRATION

## 3. EXPIRY DATE

For terms on Expiry date see Appendix IV on the European Medicines Agency website http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2009/10/WC500004426.pdf

Otherwise, digits indicating month and year may appear without any further references.

## 4. BATCH NUMBER

For terms on Batch number see Appendix IV on the European Medicines Agency website http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2009/10/WC500004426.pdf

Otherwise, batch number may appear without any further references.

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

*European Pharmacopoeia short standard term may be used for pharmaceutical form.*

## 6. OTHER