

**FOOD AND DRUGS AUTHORITY**

LABELLING OF DRUGS

**TO BE SUBMITTED AS ELECTRONIC COPIES**

CONFIDENTIAL

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# Acknowledgement

The Food and Drugs Authority (FDA) acknowledges the technical support of the World Health Organization (WHO) in the development of this guideline.

**PARTICULARS TO APPEAR ON THE <OUTER PACKAGING> <AND> <THE IMMEDIATE PACKAGING>**

(Outer packaging or, where there is no outer packaging on the immediate packaging

**{NATURE/TYPE}**

|  |  |
| --- | --- |
| **1.** | **NAME OF THE MEDICINAL PRODUCT** |

{(Invented) name strength pharmaceutical form}

{Active substance(s)}

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

|  |  |
| --- | --- |
| **3.** | **LIST OF EXCIPIENTS** |

List of excipients of known safety concern (e.g., lactose, gluten, metabisulfites, parabens, ethanol, tartrazine) should be stated on the secondary product label. [http://www.ema.europa.eu/docs/en.............](http://www.ema.europa.eu/docs/en..........)

|  |  |
| --- | --- |
| **4.** | **PHARMACEUTICAL FORM AND CONTENTS** |

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

Read the package leaflet before use.

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

Keep out of the reach and sight of children.

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

|  |  |
| --- | --- |
| **8.** | **EXPIRY DATE** |

*[For terms on Batch number and Expiry date see Appendix 3 (ref. Appendix IV)]*

|  |  |
| --- | --- |
| **9.** | **SPECIAL STORAGE CONDITIONS** |

*[For storage conditions statements see Appendix 3 (ref.* [*Appendix III)*](http://www.emea.eu.int/htms/human/qrd/AppIIIs6/2927703en.pdf)*]*

**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 <MANUFACTURER> HOLDER** |

{Name and Location Address}

<{tel}>

<{fax}>

<{e-mail}>

|  |  |
| --- | --- |
| **13.** | **BATCH NUMBER** |

*[For terms on Batch number and Expiry date see appendix 3 (ref. Appendix IV)]*

|  |  |
| --- | --- |
| **14.** | **<ADVICE ON> GENERAL CLASSIFICATION FOR SUPPLY** |

<Medicinal product subject to medical prescription.>

<Medicinal product not subject to medical prescription.>

|  |  |
| --- | --- |
| **15.** | **DIRECTIONS FOR USE** |

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

**{NATURE/TYPE}**

|  |  |
| --- | --- |
| **1.** | **NAME OF THE MEDICINAL PRODUCT** |

{(Invented) name strength pharmaceutical form}

{Active substance(s)}

|  |  |
| --- | --- |
| **2.** | **NAME OF THE MANUFACTURER** |

{Name}

|  |  |
| --- | --- |
| **3.** | **EXPIRY DATE** |

*[For terms on Batch number and Expiry date see appendix 3 (ref. Appendix IV)]*

|  |  |
| --- | --- |
| **4.** | **BATCH NUMBER** |

*[For terms on Batch number and Expiry date see appendix 3 (ref. Appendix IV)]*

|  |  |
| --- | --- |
| **5.** | **OTHER** |

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

*(Applicable to containers less than or equal to 10ml capacity that are marketed in an outer* pack such as a carton where the outer pack bears all the required information)

**{NATURE/TYPE}**

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

{(Invented) name strength pharmaceutical form}

{Active substance(s)}

{Route of administration}

|  |  |
| --- | --- |
| **2.** | **METHOD OF ADMINISTRATION** |

|  |  |
| --- | --- |
| **3.** | **EXPIRY DATE** |

*[For terms on Batch number and Expiry date see appendix 3 (ref. Appendix IV)]*

|  |  |
| --- | --- |
| **4.** | **BATCH NUMBER** |

*[For terms on Batch number and Expiry date see appendix 3 (ref. Appendix IV)]*

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

|  |  |
| --- | --- |
| **6.** | **OTHER** |