

**PARTICULARS TO APPEAR ON THE OUTER PACKAGING**

**OUTER BOX**

**1. NAME OF THE MEDICINAL PRODUCT**

[Nationally completed name]

loperamide hydrochloride

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

Each oral lyophilisate contains 2 mg of loperamide hydrochloride

**3. LIST OF EXCIPIENTS**

Contains aspartame (E951)

See leaflet for further information

**4. PHARMACEUTICAL FORM AND CONTENTS**

Oral lyophilisate.

6 Oral lyophilisates

10 Oral lyophilisates

12 Oral lyophilisates

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

Oral use.

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**

**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**

[To be completed nationally]

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

[To be completed nationally]

**13. BATCH NUMBER**

BN

**14. GENERAL CLASSIFICATION FOR SUPPLY**

[To be completed nationally]

**15. INSTRUCTIONS ON USE**

Read the package leaflet for dosage instructions.

Store in the original package.

The oral lyophilisate should be placed on your tongue, where it dissolves and can be swallowed with the saliva. No liquid intake is needed for the oral lyophilisate.

Intended for **use for acute attacks of diarrhoea** in adults and adolescents aged 12 years and over.

**Dosage**

| Age                                | Initial dose         | Repeat dose   | Max. daily dose      |
|------------------------------------|----------------------|---|----------------------|
| Adolescents aged 12 years and over | 1 oral lyophilisate  | 1 oral lyophilisate after each loose stool, not earlier than 1 hour after the initial dose. | 4 oral lyophilisates |
| Adults                             | 2 oral lyophilisates | 1 oral lyophilisate after each loose stool, not earlier than 1 hour after the initial dose. | 6 oral lyophilisates |

Do not exceed the max. daily dose.

Do not take for attacks lasting longer than 2 days.

Replace lost fluid by drinking more liquid than usual.

To remove the oral lyophilisate from the blister:

lift the edge of the foil; peel off the foil completely; tip the oral lyophilisate out; remove the oral lyophilisate from the blister.

Do not push oral lyophilisate through foil.

[To be completed nationally]

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| <b>16. INFORMATION IN BRAILLE</b> |
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[To be completed nationally]

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| <b>17. UNIQUE IDENTIFIER – 2D BARCODE</b> |
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<Not applicable>

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| <b>18. UNIQUE IDENTIFIER - HUMAN READABLE DATA</b> |
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<Not applicable>