**PARTICULARS TO APPEAR ON THE OUTER PACKAGING**

**CARTON**

## 1. NAME OF THE MEDICINAL PRODUCT

[Product name] 2.5 mg hard capsules
[Product name] 5 mg hard capsules
[Product name] 7.5 mg hard capsules
[Product name] 10 mg hard capsules
[Product name] 15 mg hard capsules
[Product name] 20 mg hard capsules
[Product name] 25 mg hard capsules

lenalidomide

## 2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each capsule contains lenalidomide hydrochloride hydrate corresponding to 2.5 mg lenalidomide.
Each capsule contains lenalidomide hydrochloride hydrate corresponding to 5 mg lenalidomide.
Each capsule contains lenalidomide hydrochloride hydrate corresponding to 7.5 mg lenalidomide.
Each capsule contains lenalidomide hydrochloride hydrate corresponding to 10 mg lenalidomide.
Each capsule contains lenalidomide hydrochloride hydrate corresponding to 15 mg lenalidomide.
Each capsule contains lenalidomide hydrochloride hydrate corresponding to 20 mg lenalidomide.
Each capsule contains lenalidomide hydrochloride hydrate corresponding to 25 mg lenalidomide.

## 3. LIST OF EXCIPIENTS

## 4. PHARMACEUTICAL FORM AND CONTENTS

Hard capsules

*[2.5 mg/5 mg/10 mg/15 mg:]*
7 hard capsules
7 x 1 hard capsules
21 hard capsules
21 x 1 hard capsules

*[7.5 mg/20 mg/25 mg:]*
21 hard capsules
21 x 1 hard capsules

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

Read the package leaflet before use.

Oral use.
Swallow whole. Do not break, open or chew the capsules.

## 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

Lenalidomide is expected to be harmful to an unborn child.

## 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

Return unused medicines to the pharmacist.

## 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

Lot

## 14. GENERAL CLASSIFICATION FOR SUPPLY

[To be completed nationally]

## 15. INSTRUCTIONS ON USE

## 16. INFORMATION IN BRAILLE

[Product name] 2.5 mg
[Product name] 5 mg
[Product name] 7.5 mg

[Product name] 10 mg
[Product name] 15 mg
[Product name] 20 mg
[Product name] 25 mg

[To be completed nationally]

## 17. UNIQUE IDENTIFIER – 2D BARCODE

2D barcode carrying the unique identifier included.

## 18. UNIQUE IDENTIFIER – HUMAN READABLE DATA

PC:
SN:
NN:

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

**BLISTER**

## 1. NAME OF THE MEDICINAL PRODUCT

[Product name] 2.5 mg hard capsules
[Product name] 5 mg hard capsules
[Product name] 7.5 mg hard capsules
[Product name] 10 mg hard capsules
[Product name] 15 mg hard capsules
[Product name] 20 mg hard capsules
[Product name] 25 mg hard capsules

lenalidomide

## 2. NAME OF THE MARKETING AUTHORISATION HOLDER

[To be completed nationally]

## 3. EXPIRY DATE

EXP

## 4. BATCH NUMBER

Lot

## 5. OTHER