

**PARTICULARS TO APPEAR ON THE OUTER PACKAGING**

**CARTON FOR BLISTER**

**1. NAME OF THE MEDICINAL PRODUCT**

<PRODUCT NAME> 30 mg film-coated tablets

<PRODUCT NAME> 60 mg film-coated tablets

<PRODUCT NAME> 90 mg film-coated tablets

cinacalcet

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

Each tablet contains 30 mg cinacalcet (as hydrochloride).

Each tablet contains 60 mg cinacalcet (as hydrochloride).

Each tablet contains 90 mg cinacalcet (as hydrochloride).

**3. LIST OF EXCIPIENTS**

**4. PHARMACEUTICAL FORM AND CONTENTS**

Film-coated tablet

14 tablets

28 tablets

30 tablets

84 tablets

98 tablets

14x1 tablets

28x1 tablets

30x1 tablets

84x1 tablets

98x1 tablets

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

Read the package leaflet before use.

oral 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**

Lot

**14. GENERAL CLASSIFICATION FOR SUPPLY**

[To be completed nationally]

**15. INSTRUCTIONS ON USE**

**16. INFORMATION IN BRAILLE**

<PRODUCT NAME> 30 mg  
<PRODUCT NAME> 60 mg  
<PRODUCT NAME> 90 mg

**17. UNIQUE IDENTIFIER – 2D BARCODE**

2D barcode carrying the unique identifier included.

**18. UNIQUE IDENTIFIER – HUMAN READABLE DATA**

PC  
SN  
NN

THIS IS A REPRESENTATION OF AN ELECTRONIC RECORD THAT WAS SIGNED ELECTRONICALLY AND THIS PAGE IS THE MANIFESTATION OF THE ELECTRONIC SIGNATURE

## Teva Pharmaceuticals Europe B.V

### 1.3.1 label-outer packaging-carton for blisters

#### APPROVALS

Signed by	Meaning of Signature	Server Date
Sunita Hadawale	Regulatory Affairs Approval	03-Apr-2020 09:10:54 AM