

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

OUTER CARTON

1. NAME OF THE MEDICINAL PRODUCT

Sacubitril/Valsartan Teva 24 mg/26 mg Film-coated Tablets
Sacubitril/Valsartan Teva 49 mg/51 mg Film-coated Tablets
Sacubitril/Valsartan Teva 97 mg/103 mg Film-coated Tablets

sacubitril/valsartan

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each 24 mg/26 mg film-coated tablet contains sacubitril sodium equivalent to 24.3 mg sacubitril and valsartan disodium equivalent to 25.7 mg valsartan.

Each 49 mg/51 mg film-coated tablet contains sacubitril sodium equivalent to 48.6 mg sacubitril and valsartan disodium equivalent to 51.4 mg valsartan.

Each 97 mg/103 mg film-coated tablet contains sacubitril sodium equivalent to 97.2 mg sacubitril and valsartan disodium equivalent to 102.8 mg valsartan.

3. LIST OF EXCIPIENTS

4. PHARMACEUTICAL FORM AND CONTENTS

Film-coated Tablet

For Sacubitril/Valsartan Teva 24 mg/26 mg Film-coated Tablets

28 film-coated tablets
30 film-coated tablets
56 film-coated tablets
20x1 film-coated tablets
28x1 film-coated tablets
30x1 film-coated tablets
56x1 film-coated tablets
196x1 film-coated tablets

For Sacubitril/Valsartan Teva 49 mg/51 mg Film-coated Tablets

28 film-coated tablets
56 film-coated tablets
60 film-coated tablets
168 film-coated tablets
20x1 film-coated tablets
28x1 film-coated tablets
56x1 film-coated tablets
60x1 film-coated tablets
196x1 film-coated tablets

For Sacubitril/Valsartan Teva 97 mg/103 mg Film-coated Tablets

28 film-coated tablets
56 film-coated tablets
60 film-coated tablets
168 film-coated tablets
20x1 film-coated tablets
56x1 film-coated tablets
60x1 film-coated tablets
196x1 film-coated tablets

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

Store in the original package in order to protect from moisture.

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

MA Holder:
TEVA GmbH
Graf-Arco-Str. 3
89079 Ulm
Germany

12. MARKETING AUTHORISATION NUMBER(S)

PA22579/004/001
PA22579/004/002
PA22579/004/003

13. BATCH NUMBER

Lot:

14. GENERAL CLASSIFICATION FOR SUPPLY

POM

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

Sacubitril/Valsartan Teva 24 mg/26 mg
Sacubitril/Valsartan Teva 49 mg/51 mg
Sacubitril/Valsartan Teva 97 mg/103 mg

17. UNIQUE IDENTIFIER – 2D BARCODE

<2D barcode carrying the unique identifier included.>

18. UNIQUE IDENTIFIER – HUMAN READABLE DATA

PC:
SN:

MINIMUM PARTICULARS TO APPEAR ON BLISTERS

BLISTER

1. NAME OF THE MEDICINAL PRODUCT

Sacubitril/Valsartan Teva 24 mg/26 mg Film-coated Tablets
Sacubitril/Valsartan Teva 49 mg/51 mg Film-coated Tablets
Sacubitril/Valsartan Teva 97 mg/103 mg Film-coated Tablets

sacubitril/valsartan

2. NAME OF THE MARKETING AUTHORISATION HOLDER

Teva GmbH

3. EXPIRY DATE

EXP:

4. BATCH NUMBER

Lot:

5. OTHER