PARTICULARS TO APPEAR ON THE OUTER PACKAGING

OUTER CARTON for Blister and Unit-Dose Blister – EU full/reduced harmonized labelling text (5 mg + 10 mg)

Procedure FI/H/1370/001-002/DC:
Reduced harmonized labelling text is applicable for *multilingual packages* for the following proposed MS clusters:
- Cyprus, Greece

1. NAME OF THE MEDICINAL PRODUCT

Tofacitinib STADA 5 mg film-coated tablets
Tofacitinib STADA 10 mg film-coated tablets
tofacitinib

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each film-coated tablet contains 5 mg of tofacitinib (as tofacitinib citrate).
Each film-coated tablet contains 10 mg of tofacitinib (as tofacitinib citrate).

3. LIST OF EXCIPIENTS

Contains lactose. See leaflet for further information.

4. PHARMACEUTICAL FORM AND CONTENTS

Film-coated tablets

[Blister]
56 film-coated tablets
112 film-coated tablets
182 film-coated tablets

[Unit dose blister]
56x1 film-coated tablets
112x1 film-coated tablets
182x1 film-coated tablets

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.
For 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

STADA Arzneimittel AG
Stadastrasse 2-18, 61118
Bad Vilbel, Germany

12. MARKETING AUTHORISATION NUMBER(S)

PA0593/053/001
PA0593/053/002

13. BATCH NUMBER

Lot

14. GENERAL CLASSIFICATION FOR SUPPLY

Medicinal product subject to medical prescription.

15. INSTRUCTIONS ON USE

< In CMS BE only>:

‘QR code to be included’ + <URL>
See QR code for package leaflet.>

QR code for package leaflet

16. INFORMATION IN BRAILLE

Tofacitinib STADA 5 mg
Tofacitinib STADA 10 mg

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 and Unit-Dose Blister – EU full/reduced harmonized labelling text (5 mg + 10 mg)

Procedure FI/H/1370/001-002/DC:
Reduced harmonized labelling text is applicable for *multilingual packages* for the following proposed MS clusters:

- Spain, Netherlands
- France, Portugal, Romania
- Czechia, Croatia, Hungary, Ireland, Malta, Slovenia, Slovakia
- Germany, Austria
- Cyprus, Greece

1. NAME OF THE MEDICINAL PRODUCT

Tofacitinib STADA 5 mg film-coated tablets
Tofacitinib STADA 10 mg film-coated tablets
tofacitinib

2. NAME OF THE MARKETING AUTHORISATION HOLDER

STADA Arzneimittel AG

3. EXPIRY DATE

EXP

4. BATCH NUMBER

Lot

5. OTHER

Mon., Tue., Wed., Thu., Fri., Sat., Sun.
Morning: Sun as symbol
Evening: Moon as symbol