PARTICULARS TO APPEAR ON THE OUTER PACKAGING

BOX

1. NAME OF THE MEDICINAL PRODUCT

Edoxaban Krka 15 mg film-coated tablets
Edoxaban Krka 30 mg film-coated tablets
Edoxaban Krka 60 mg film-coated tablets

edoxaban

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each tablet contains edoxaban tosylate monohydrate equivalent to 15 mg edoxaban.
Each tablet contains edoxaban tosylate monohydrate equivalent to 30 mg edoxaban.
Each tablet contains edoxaban tosylate monohydrate equivalent to 60 mg edoxaban.

3. LIST OF EXCIPIENTS

Contains dextrates (glucose).
See leaflet for further information.

4. PHARMACEUTICAL FORM AND CONTENTS

film-coated tablet

Edoxaban Krka 15 mg film-coated tablets
10 film-coated tablets
10 x 1 film-coated tablet
Edoxaban Krka 30 mg and 60 mg film-coated tablets
10 film-coated tablets
14 film-coated tablets
28 film-coated tablets
30 film-coated tablets
56 film-coated tablets
60 film-coated tablets
84 film-coated tablets
90 film-coated tablets
98 film-coated tablets
100 film-coated tablets
10 x 1 film-coated tablet
14 x 1 film-coated tablet
28 x 1 film-coated tablet
30 x 1 film-coated tablet
56 x 1 film-coated tablet
60 x 1 film-coated tablet
84 x 1 film-coated tablet
90 x 1 film-coated tablet

98 x 1 film-coated tablet
100 x 1 film-coated tablet

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

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

KRKA, d.d., Novo mesto, Šmarješka cesta 6, 8501 Novo mesto, Slovenia

12. MARKETING AUTHORISATION NUMBER

PA1347/115/001
PA1347/115/002
PA1347/115/003

13. BATCH NUMBER

Lot

14. GENERAL CLASSIFICATION FOR SUPPLY

Medicinal product subject to medical prescription.

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

edoxaban krka 15 mg
edoxaban krka 30 mg
edoxaban krka 60 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 OR STRIPS

BLISTER

1. NAME OF THE MEDICINAL PRODUCT

Edoxaban Krka 15 mg film-coated tablets
Edoxaban Krka 30 mg film-coated tablets
Edoxaban Krka 60 mg film-coated tablets

edoxaban

2. NAME OF THE MARKETING AUTHORISATION HOLDER

KRKA

3. EXPIRY DATE

EXP

4. BATCH NUMBER

Lot

5. OTHER

Calendar pack
Mon.
Tue.
Wed.
Thu.
Fri.
Sat.
Sun.

PATIENT ALERT CARD

PATIENT ALERT CARD

Edoxaban Krka
film-coated tablets
edoxaban

Please keep this card with you at all times.

Present it to your healthcare professional, pharmacist, surgeon or dentist before any medical treatment or intervention.

PATIENT INFORMATION

Patient name:

Date of birth:

In case of emergency, please contact:

Name:

Phone no:

TREATMENT INFORMATION
(To be completed by physician)

Edoxaban Krka has been prescribed at a once-daily dose of: mg

Started on: / (mm/yy)

Blood type:

Other medicines/conditions:

PRESCRIBER INFORMATION

For more information or in case of emergency, please contact:

Physician's name:

Phone number, practice stamp:

Signature of physician:

INFORMATION FOR HEALTHCARE PROFESSIONALS

- Edoxaban Krka is an oral anticoagulant factor Xa inhibitor.

- When an invasive procedure is required, Edoxaban Krka should be stopped at least 24 hours beforehand, and appropriate caution exercised.
- Edoxaban Krka may increase the risk of bleeding. In case of clinically significant bleeding, stop treatment immediately.
- Coagulation tests such as international normalised ratio (INR), prothrombin time (PT), or activated partial thromboplastin time (aPTT) are not a useful measure of the effect of Edoxaban Krka. However, a calibrated anti-Factor Xa assay may help inform clinical decisions.

Please consult the Summary of Product Characteristics (SmPC) for more information.

Krka [LOGO]

ABOUT YOUR TREATMENT

You have been prescribed Edoxaban Krka, an anticoagulant medicine, which thins your blood and helps prevent you from suffering blood clots. It is important that you take your medicine exactly as instructed by your doctor.

- If you miss a dose, take it immediately and then continue the following day as normal – do not take double the prescribed dose in a single day.
- Do not start any other medications (including over the counter) without consulting your doctor.
- Do not stop taking Edoxaban Krka without consulting your doctor as this can increase your risk of developing a blood clot.
- Please read the Patient Information Leaflet found inside each pack of Edoxaban Krka.

WHEN TO SEEK MEDICAL ADVICE

RISK OF BLEEDING

Taking an anticoagulant medicine such as Edoxaban Krka can increase your risk of bleeding. It is therefore important to be aware of the possible signs and symptoms of bleeding and to speak to your doctor **immediately** if you experience any of the following:

- Bruising or bleeding under the skin
- Blood in the urine
- Coughing up blood
- Vomiting blood or material that looks like ground coffee
- Nose bleeds or cuts that take a long time to stop bleeding
- Tar-coloured stools
- Dizziness or sudden headache
- Unexplained tiredness
- Abnormal vaginal bleeding, including heavier or prolonged menses

Please talk to your doctor if you experience any unusual symptoms.