Package leaflet: Information for the user

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

▼This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Lixiana is and what it is used for

Lixiana contains the active substance edoxaban and belongs to a group of medicines called anticoagulants. This medicine helps to prevent blood clots from forming. It works by blocking the activity of factor Xa, which is an important component of blood clotting.

Lixiana is used in adults to:

- **prevent blood clots in the brain** (stroke) **and other blood vessels in the body** if you have a form of irregular heart rhythm called nonvalvular atrial fibrillation and at least one additional risk factor.

- **treat blood clots in the veins of the legs** (deep vein thrombosis) **and in the blood vessels in the lungs** (pulmonary embolism), and to **prevent blood clots from re-occurring** in the blood vessels in the legs and/or lungs.

2. What you need to know before you take Lixiana

Do not take Lixiana:

- if you are allergic to edoxaban or any of the other ingredients of this medicine (listed in section 6)
- if you are actively bleeding
- if you have a disease or condition that increases the risk of serious bleeding (e.g. stomach ulcer, injury or bleeding in the brain, or recent surgery of the brain or eyes)
- if you are taking other medicines to prevent blood clotting (e.g. warfarin, dabigatran, rivaroxaban, apixaban or heparin), except when changing anticoagulant treatment or while getting heparin through a venous or arterial line to keep it open
- if you have a liver disease which leads to an increased risk of bleeding
- if you have uncontrolled high blood pressure
- if you are pregnant or breast feeding

Warnings and precautions

Talk to your doctor or pharmacist before taking Lixiana,

- if you have an increased risk of bleeding, as could be the case if you have any of the following conditions:
    - endstage kidney disease or if you are on dialysis
    - severe liver disease
    - bleeding disorders
    - a problem with the blood vessels in the back of your eyes (retinopathy)
    - recent bleeding in your brain (intracranial or intracerebral bleeding)
    - problems with the blood vessels in your brain or spinal column
- if you have a mechanical heart valve

Lixiana 15 mg is only to be used when changing from Lixiana 30 mg to a vitamin K antagonist (e.g. warfarin) (see section 3. How to take Lixiana).

If you need to have an operation:
It is very important to take Lixiana before and after the operation exactly at the times you have been told by your doctor. If possible, Lixiana should be stopped at least 24 hours before an operation. Your doctor will determine when to restart Lixiana.

Children and adolescents
Lixiana is not recommended in children and adolescents under 18 years of age. There is no information on its use in children and adolescents.

Other medicines and Lixiana
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

If you are taking any of the following:
- some medicines for fungal infections (e.g. ketoconazole)
- medicines to treat abnormal heart beat (e.g. dronedarone, quinidine, verapamil)
- other medicines to reduce blood clotting (e.g. heparin, clopidogrel or vitamin K antagonists such as warfarin, acenocoumarol, phenprocoumon or dabigatran, rivaroxaban, apixaban)
- antibiotic medicines (e.g. erythromycin)
- medicines to prevent organ rejection after transplantation (e.g. ciclosporin)
- anti-inflammatory and pain-relieving medicines (e.g. naproxen or acetylsalicylic acid (aspirin))

- antidepressant medicines called selective serotonin reuptake inhibitors or serotonin-norepinephrine reuptake inhibitors

Tell your doctor before taking Lixiana, because these medicines may increase the effects of Lixiana and the chance of unwanted bleeding. Your doctor will decide, if you should be treated with Lixiana and if you should be kept under observation.

If you are taking any of the following:
- some medicines for treatment of epilepsy (e.g. phenytoin, carbamazepine, phenobarbital)
- St John's Wort, a herbal product used for anxiety and mild depression
- rifampicin, an antibiotic

If any of the above apply to you, tell your doctor before taking Lixiana, because the effect of Lixiana may be reduced. Your doctor will decide if you should be treated with Lixiana and if you should be kept under observation.

Pregnancy and breast-feeding
Do not take Lixiana if you are pregnant or breast-feeding. If there is a chance that you could become pregnant, use a reliable contraceptive while you are taking Lixiana. If you become pregnant while you are taking Lixiana, immediately tell your doctor, who will decide how you should be treated.

Driving and using machines
Lixiana has no or negligible effects on your ability to drive or use machines.

3. How to take Lixiana

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

How much to take

The recommended dose is one **60 mg** tablet once daily.

- **If you have impaired kidney function**, the dose may be reduced to one **30 mg** tablet once daily by your doctor.
- **If your body weight is 60 kg or lower**, the recommended dose is one **30 mg** tablet once daily.
- **If your doctor has prescribed medicines known as P-gp inhibitors:** ciclosporin, dronedarone, erythromycin, or ketoconazole, the recommended dose is one **30 mg** tablet once daily.

How to take the tablet
Swallow the tablet, preferably with water.
Lixiana can be taken with or without food.

Your doctor may change your anticoagulant treatment as follows:

Changing from vitamin K antagonists (e.g. warfarin) *to Lixiana*
Stop taking the vitamin K antagonist (e.g. warfarin). Your doctor will need to do blood measurements and will instruct you when to start taking Lixiana.

Changing from non-VKA oral anticoagulants (dabigatran, rivaroxaban, or apixaban) to Lixiana
Stop taking the previous medicines (e.g. dabigatran, rivaroxaban, or apixaban) and start Lixiana at the time of the next scheduled dose.

Changing from parenteral anticoagulants (e.g. heparin) to Lixiana
Stop taking the anticoagulant (e.g. heparin) and start Lixiana at the time of the next scheduled anticoagulant dose.

Changing from Lixiana to vitamin K antagonists (e.g. warfarin)
If you currently take 60 mg Lixiana:
Your doctor will tell you to reduce your dose of Lixiana to a 30 mg tablet once daily and to take it together with a vitamin K antagonist (e.g. warfarin). Your doctor will need to do blood measurements and will instruct you when to stop taking Lixiana.

If you currently take 30 mg (dose reduced) Lixiana:
Your doctor will tell you to reduce your dose of Lixiana to a 15 mg tablet once daily and to take it together with a vitamin K antagonist (e.g. warfarin). Your doctor will need to do blood measurements and will instruct you when to stop taking Lixiana.

Changing from Lixiana to non-VKA oral anticoagulants (dabigatran, rivaroxaban, or apixaban)
Stop taking Lixiana and start the non-VKA anticoagulant (e.g. dabigatran, rivaroxaban, or apixaban) at the time of the next scheduled dose of Lixiana.

Changing from Lixiana to parenteral anticoagulants (e.g. heparin)
Stop taking Lixiana and start the parenteral anticoagulant (e.g. heparin) at the time of the next scheduled dose of Lixiana.

Patients undergoing cardioversion:
If your abnormal heartbeat needs to be restored to normal by a procedure called cardioversion, take Lixiana at the times your doctor tells you to prevent blood clots in the brain and other blood vessels in your body.

If you take more Lixiana than you should
Tell your doctor immediately if you have taken too many Lixiana tablets.
If you take more Lixiana than recommended, you may have an increased risk of bleeding.

If you forget to take Lixiana
You should take the tablet immediately and then continue the following day with the once daily tablet as usual. Do not take a double dose on the same day to make up for a forgotten dose.

If you stop taking Lixiana
Do not stop taking Lixiana without talking to your doctor first, because Lixiana treats and prevents serious conditions.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Like other similar medicines (medicines to reduce blood clotting), Lixiana may cause bleeding which may potentially be life-threatening. In some cases the bleeding may not be obvious.

If you experience any bleeding event that does not stop by itself or if you experience signs of excessive bleeding (exceptional weakness, tiredness, paleness, dizziness, headache or unexplained swelling) consult your doctor immediately.
Your doctor may decide to keep you under closer observation or change your medicine.

Overall list of possible side effects:

Common (may affect up to 1 in 10 people):
- Stomach ache
- Abnormal liver blood tests
- Bleeding from the skin or under the skin
- Anaemia (low levels of red blood cells)
- Bleeding from the nose
- Bleeding from the vagina
- Rash
- Bleeding in the bowel
- Bleeding from the mouth and/or throat
- Blood found in your urine
- Bleeding following an injury (puncture)
- Bleeding in the stomach
- Dizziness
- Feeling sick
- Headache
- Itching

Uncommon (may affect up to 1 in 100 people):
- Other types of bleeding
- Bleeding in the eyes
- Bleeding from a surgical wound following an operation
- Blood in the spit when coughing
- Bleeding in the brain
- Reduced number of platelets in your blood (which can affect clotting)
- Allergic reaction
- Hives

Rare (may affect up to 1 in 1,000 people):
- Bleeding in the muscles
- Bleeding in joints
- Bleeding in the abdomen
- Bleeding in the heart
- Bleeding inside the skull
- Bleeding following a surgical procedure

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via

Ireland
HPRA Pharmacovigilance
Earlsfort Terrace, IRL – Dublin 2
Tel: +353 1 6764971, Fax: +353 1 6762517
Website: www.hpra.ie
e-mail: medsafety@hpra.ie

United Kingdom
Yellow Card Scheme
Website: www.mhra.gov.uk/yellowcard.
Or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Lixiana

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and on each blister after EXP. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Lixiana contains

- The active substance is edoxaban (as tosilate).
  Lixiana 15 mg: Each tablet contains 15 mg edoxaban (as tosilate).
  Lixiana 30 mg: Each tablet contains 30 mg edoxaban (as tosilate).
  Lixiana 60 mg: Each tablet contains 60 mg edoxaban (as tosilate).
- The other ingredients are:
  Lixiana 15 mg: Tablet core: mannitol (E421), pregelatinised starch, crospovidone, hydroxypropylcellulose, magnesium stearate (E470b).
  Lixiana 30 mg: Tablet core: mannitol (E421), pregelatinised starch, crospovidone, hydroxypropylcellulose, magnesium stearate (E470b).
  Lixiana 60 mg: Tablet core: mannitol (E421), pregelatinised starch, crospovidone, hydroxypropylcellulose, magnesium stearate (E470b).
- Film coat:
  Lixiana 15 mg: hypromellose (E464), macrogol 8000, titanium dioxide (E171), talc, carnauba wax, iron oxide red (E172), iron oxide yellow (E172).
  Lixiana 30 mg: hypromellose (E464), macrogol 8000, titanium dioxide (E171), talc, carnauba wax, iron oxide red (E172).
  Lixiana 60 mg: hypromellose (E464), macrogol 8000, titanium dioxide (E171), talc, carnauba wax, iron oxide yellow (E172).

What Lixiana looks like and contents of the pack

Lixiana 15 mg film-coated tablets are orange, round-shaped (6.7 mm diameter) and debossed with "DSC L15" on one side.
They come in blisters in cartons of 10 film-coated tablets or unit dose blisters in cartons of 10 x 1 film-coated tablets.

Lixiana 30 mg film-coated tablets are pink, round-shaped (8.5 mm diameter) and debossed with "DSC L30" on one side.
They come in blisters in cartons of 10, 14, 28, 30, 56, 60, 84, 90, 98 or 100 film-coated tablets or unit dose blisters in cartons of 10 x 1, 50 x 1, or 100 x 1 film-coated tablets.

Lixiana 60 mg film-coated tablets are yellow, round-shaped (10.5 mm diameter) and debossed with "DSC L60" on one side.
They come in blisters in cartons of 10, 14, 28, 30, 56, 60, 84, 90, 98 or 100 film-coated tablets or unit dose blisters in cartons of 10 x 1, 50 x 1, or 100 x 1 film-coated tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Daiichi Sankyo Europe GmbH
Zielstattstrasse 48
81379 Munich
Germany

Manufacturer

Daiichi Sankyo Europe GmbH
Luitpoldstrasse 1
85276 Pfaffenhofen
Germany

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

België/Belgique/Belgien
Daiichi Sankyo Belgium N.V.-S.A
Tél/Tel: +32-(0) 10 48 95 95

България
Daiichi Sankyo Europe GmbH
Tel: +49-(0) 89 7808 0

Česká republika
Merck Sharp & Dohme s.r.o.
Tel: +420 233 010 111

Danmark
MSD Danmark ApS
Tlf: +45 4482 4000

Deutschland
Daiichi Sankyo Deutschland GmbH
Tel. +49-(0) 89 7808 0

Eesti
Daiichi Sankyo Europe GmbH
Tel: +49-(0) 89 7808 0

Ελλάδα
MSD A.Φ.B.E.E.
Τηλ: +30 210 98 97 300

España
Daiichi Sankyo España, S.A.
Tel: +34 91 539 99 11

France
Daiichi Sankyo France S.A.S.
Tél: +33-(0) 1 55 62 14 60

Hrvatska
Daiichi Sankyo Europe GmbH
Tel: +49-(0) 89 7808 0

Ireland
Daiichi Sankyo Ireland Ltd
Tel: +353-(0) 1 489 3000

Ísland
Vistor hf.
Sími: +354 535 7000

Italia
Daiichi Sankyo Italia S.p.A.
Tel: +39-06 85 2551

Κύπρος
Daiichi Sankyo Europe GmbH
Τηλ: +49-(0) 89 7808 0

Latvija
Daiichi Sankyo Europe GmbH
Tel: +49-(0) 89 7808 0

Lietuva
Daiichi Sankyo Europe GmbH
Tel: +49-(0) 89 7808 0

Luxembourg/Luxemburg
Daiichi Sankyo Belgium N.V.-S.A
Tél/Tel: +32-(0) 10 48 95 95

Magyarország
MSD Pharma Hungary Kft.
Tel.: +36 1 888-5300

Malta
Daiichi Sankyo Europe GmbH
Tel: +49-(0) 89 7808 0

Nederland
Daiichi Sankyo Nederland B.V.
Tel: +31-(0) 20 4 07 20 72

Norge
MSD (Norge) AS
Tlf: +47 32 20 73 00

Österreich
Daiichi Sankyo Austria GmbH
Tel: +43-(0) 1 485 86 42 0

Polska
MSD Polska Sp. z o.o.
Tel: +48 22 549 51 00

Portugal
Daiichi Sankyo Portugal, Unip., Lda.
Tel: +351 21 4232010

România
Daiichi Sankyo Europe GmbH
Tel: +49-(0) 89 7808 0

Slovenija
Daiichi Sankyo Europe GmbH
Tel: +49-(0) 89 7808 0

Slovenská republika
Merck Sharp & Dohme, s. r. o.
Tel: +421 (2) 58282010

Suomi/Finland
MSD Finland Oy
Puh/Tel: +358 (0)9 804 650

Sverige
Merck Sharp & Dohme (Sweden) AB
Tel: +46 (0)77 5700488

United Kingdom
Daiichi Sankyo UK Ltd
Tel: +44-(0) 800 028 5122

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Other sources of information
Detailed information on this product is available by scanning the QR Code below with a smartphone. The same information is also available on the following URL: www.dspatient.eu.

QR code to be included

Detailed information on this medicine is available on the European Medicines Agency web site: http://www.ema.europa.eu.