What LIXIANA® is and what it is used for

LIXIANA® contains the active substance edoxaban and belongs to a group of medications called anticoagulants. This medicine helps to prevent blood clots from forming. It works by blocking 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 your body** if you have a form of irregular heart rhythm called nonvalvular atrial fibrillation
- **Treat blood clots** in the veins of your legs (deep vein thrombosis) and in the blood vessels of your lungs (pulmonary embolism), and to **prevent blood clots** from reoccurring in the blood vessels of your legs and/or lungs

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
- If you are actively bleeding
- If you have a disease or condition in an organ of the body that increases the risk of serious bleeding (eg, stomach ulcer, injury or bleeding in the brain, recent surgery of the brain or eyes)
- If you are taking other medicines to prevent blood clotting (eg, 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 are pregnant or breast-feeding
What you need to know before you take LIXIANA® (continued)

Warnings and precautions
Talk to your doctor or pharmacist before taking LIXIANA®

Take special care with LIXIANA®
If you have increased risk of bleeding, as could be the case in such situations as:
• End stage kidney disease or if you are on dialysis
• Severe liver disease
• Bleeding disorders
• Active ulcer or a recent ulcer of your stomach or bowel
• 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
• A recent operation on your brain, spinal column, or eye
If you have a mechanical heart valve.
If you need to have an operation:
It is important to remind your medical team at the hospital that you are taking LIXIANA®. LIXIANA® should be stopped as soon as possible before an operation, preferably at least 24 hours before the procedure. Your doctor or pharmacist will tell you when to stop taking LIXIANA® before the operation and when to restart it afterwards.

Children and adolescents
LIXIANA® is not recommended in children and adolescents under 18 years of age. There is not enough 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.

The following medicines may increase the effects of LIXIANA® and increase the chance for unwanted bleeding:
• Some medicines for fungal infections (eg, ketoconazole)
• Medicines to treat abnormal heart beat (eg, dronedarone)
• Other medicines to reduce blood clotting (eg, heparin, clopidogrel, or vitamin K antagonists such as warfarin, acinocoumarol, and phenprocoumon)
• Antibiotic medicine (eg, erythromycin)
• Medicines to prevent organ rejection after transplantation (eg, cyclosporine)
• Anti-inflammatory and pain relieving medicines (eg, naproxen or acetylsalicylic acid [aspirin])

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 closer observation.

Pregnancy and breast-feeding
If you are pregnant or breast-feeding, do not take LIXIANA®. 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.
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:
  – To prevent blood clots in the brain (stroke) and other blood vessels in your body
  – To treat blood clots in the veins of your legs and blood clots in the blood vessels
    of your lungs, and for preventing blood clots from recurring

• Your doctor may prescribe you with one 30-mg tablet once-daily if:
  – You have impaired kidney function
  – Your body weight is 60 kg or lower
  – You are also prescribed drugs known as P-gp inhibitors: cyclosporine,
    dronedarone, erythromycin, ketoconazole, quinidine, or verapamil

Swallow the tablet preferably with water. LIXIANA® can be taken with or without food.

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 intake 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.
Possible side effects and when to act

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):
• Abnormal liver blood tests
• Bleeding from the skin or under the skin
• Anaemia
• 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

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

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

If you get any side effects, talk to your doctor or pharmacist.

Reporting of side effects

If you experience any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.
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 can be stored at normal room temperature and 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.

Contents of the pack and other information

What LIXIANA® contains

• The active substance is edoxaban tosylate. Each tablet contains 15 mg, 30 mg, or 60 mg of edoxaban tosylate

• The other ingredients are:
  – Tablet core: mannitol (E421), pregelatinised starch, crospovidone, hydroxypropylcellulose, magnesium stearate (E470b)
  – Film coat: hypromellose (E464), macrogol 8000, titanium dioxide (E171), talc, carnauba wax, iron oxide red (15 and 30 mg tablets only) (E172), iron oxide yellow (15 and 60 mg tablets only) (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 “osc L15” on one side.
LIXIANA® 30-mg film-coated tablets are pink, round-shaped (6.5 mm diameter), and debossed with “osc L30” on one side.
LIXIANA® 60-mg film-coated tablets are yellow, round-shaped (10.5 mm diameter), and debossed with “osc L60” on one side.

Marketing Authorisation Holder
Daiichi Sankyo Europe GmbH
Zielstattstrasse 48
81379 Munich
Germany

Manufacturer
Daiichi Sankyo Europe GmbH
Luitpoldstrasse 1
85276 Pfaffenhofen
Germany

www.lixianapatient.com

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