FASS

Edoflusio

M

Sandoz AS

Filmdragerad tablett 60 mg

(Tillhandahålls ej)

Aktiv substans:

Edoxaban

ATC-kod:

B01AF03

Läkemedel från Sandoz AS omfattas av Läkemedelsförsäkringen.

Miljöpåverkan

Miljöinformationen för edoxaban är framtagen av företaget Organon Sweden för Lixiana

Miljörisk: Risk för miljöpåverkan av edoxaban kan inte uteslutas då det inte finns tillräckliga ekotoxikologiska data.
Nedbrytning: Det kan inte uteslutas att edoxaban är persistent, då data saknas.
Bioackumulering: edoxaban har låg potential att bioackumuleras.

Detaljerad miljöinformation

Detailed background information

Edoxaban, as the tosylate monohydrate salt, is used therapeutically as an oral medication to reduce the risk of stroke and systemic embolism in patients with nonvalvular atrial fibrillation and for the treatment of deep vein thrombosis and pulmonary embolism. (Ref II)

The solubility of edoxaban tosylate decreases with increasing pH. It is slightly soluble in water, pH 3 to 5 buffer, very slightly soluble at pH 6 to 7. (Ref IV) The terminal elimination half-life of edoxaban following oral administration is 10 - 14 hours. Edoxaban is eliminated primarily as unchanged drug in urine (50% of the total clearance). Metabolism and biliary/intestinal excretion account for the remaining clearance. (Ref II)

Environmental Risk Classification

Predicted Environmental Concentration (PEC)

PEC is calculated according to the following formula:

PEC (µg/L) = $(A*10^9*(100-R))/(365*P*V*D*100) = 1.37*10^{-6}*A(100-R)$

PEC = 0.0245 µg/L

Where:
A = 178.79 kg (total sold amount API in Sweden year 2021, data from IQVIA). *Reduction of A may be justified based on metabolism data.*

R =0 % removal rate (due to loss by adsorption to sludge particles, by volatilization, hydrolysis or biodegradation) = 0 if no data is available.

P = number of inhabitants in Sweden = $10*10^6$

V (L/day) = volume of wastewater per capita and day = 200 (ECHA default) (Ref. I)

D = factor for dilution of waste water by surface water flow = 10 (ECHA default) (Ref. I)

Predicted No Effect Concentration (PNEC)

Ecotoxicological studies
No data available

Environmental risk classification (PEC/PNEC ratio)
PEC/PNEC could not be calculated due to lack of ecotoxicity data which justifies the phrase "Risk of environmental impact of edoxaban cannot be excluded, since no ecotoxicity data are available."

Degradation
Degradability: No degradability data are available.

Justification of chosen degradation phrase:
No degradability data are available. The phrase "The potential for persistence of edoxaban cannot be excluded, due to lack of data" is thus chosen.

Bioaccumulation
Partitioning coefficient:
Log Kow (Log Pow) = -1.455 (Ref III)

Justification of chosen bioaccumulation phrase:
Since log K_{ow} < 4 the substance has low potential for bioaccumulation.

References

I. ECHA, European Chemicals Agency. 2008 Guidance on information requirements and chemical safety assessment. http://guidance.echa.europa.eu/docs/guidance_document/information_requirements_en.htm
II. European Medicines Agency. Committee for Medicinal Products for Human Use (CHMP) (2015) Assessment report. Lixiana. International non-proprietary name: edoxaban. EMA/321083/2015. Dated 23 April 2015. Available at:

https://www.ema.europa.eu/en/documents/assessment-report/lixiana-epar-public-assessment-report_en.p
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III. ECHA database Brief Profile - ECHA (europa.eu)

IV. HSDB for Endoxaban Toxylate Hazardous Substances Data Bank (HSDB) : 8406 - PubChem (nih.gov)