FASS

Aclasta®

Sandoz AS

Infusionsvätska, lösning 5 mg
(Klar, färglös lösning)

Läkemedel för behandling av bensjukdomar, bisfosfonater

Aktiv substans:
Zoledronsyra (vattenfri)

ATC-kod:
M05BA08

Läkemedel från Sandoz AS omfattas av Läkemedelsförsäkringen.
Läkemedlet distribueras också av företag som inte omfattas av Läkemedelsförsäkringen, se Förpackningar.

Miljöpåverkan

Miljöinformationen för zoledronsyra (vattenfri) är framtagen av företaget Accord Healthcare AB för Zoledronic Acid Accord, Zoledronic acid Accord

Miljörisk: Risk för miljöpåverkan av zoledronsyra (vattenfri) kan inte uteslutas då ekotoxikologiska data saknas.
Nedbrytning: Det kan inte uteslutas att zoledronsyra (vattenfri) är persistent, då data saknas.
Bioackumulering: Zoledronsyra (vattenfri) har låg potential att bioackumuleras.

Detaljerad miljöinformation

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 = $0,04376 * 10^{-3}$ µg/L

Where:

A = 0.3194 kg (total sold amount API in Sweden year 2022, data from IQVIA. Data has been converted to represent the water free amount zoledronic acid).
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 ecotoxicity data are available.

Environmental risk classification (PEC/PNEC ratio)

The PEC/PNEC ratio could not be calculated since there is no ecotoxicity data available, hence justifying the phrase: *"Risk of environmental impact of zoledronic acid cannot be excluded, since no ecotoxicity data are available."*

According to the European Medicines Agency guideline on environmental risk assessment of medicinal products (EMA/CHMP/SWP/4447/00), use of zoledronic acid is unlikely to represent a risk for the environment, because the predicted environmental concentration (PEC) is below the action limit 0.01 µg/L.

Degradation*

No data are available, justifying the degradation phrase: *"The potential for persistence of zoledronic acid cannot be excluded, due to lack of data."*

Bioaccumulation

Partitioning coefficient:
Log P_{ow}= -3.9 (predicted value using ChemAxon). (Reference II)
Justification of chosen bioaccumulation phrase:
Since log $P_{ow} < 4$ the substance has low potential for bioaccumulation.

Excretion (metabolism)

Zoledronic acid is not metabolised and is excreted unchanged via the kidney. Over the first 24 hours, 39 ± 16% of the administered dose is recovered in the urine, while the remainder is principally bound to bone tissue. From the bone tissue it is released very slowly back into the systemic circulation and eliminated via the kidney. (Reference III)

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. Wishart DS, Feunang YD, Guo AC, Lo EJ, Marcu A, Grant JR, Sajed T, Johnson D, Li C, Sayeeda Z, Assempour N, Iynkkaran I, Liu Y, Maciejewski A, Gale N, Wilson A, Chin L, Cummings R, Le D, Pon A, Knox C, Wilson M. DrugBank 5.0: a major update to the DrugBank database for 2018. Nucleic Acids Res. 2017 Nov 8. doi: 10.1093/nar/gkx1037. Available at https://go.drugbank.com/drugs/DB00399 [2023-05-11]
III. European Medicines Agency, Zometa: EPAR-Product information (2021-06-04). Available at https://www.ema.europa.eu/en/documents/product-information/zometa-epar-product-information_en.pdf [2023-05-11]