FASS

Mozobil

Sanofi AB

Injektionsvätska, lösning 20 mg/ml
(klar, färglös till svagt gul)

Immunstimulerande medel

Aktiv substans:
Plerixafor

ATC-kod:
L03AX16

Läkemedel från Sanofi AB omfattas av Läkemedelsförsäkringen.
Läkemedlet distribueras också av företag som inte omfattas av Läkemedelsförsäkringen, se Förpackningar.

Miljöpåverkan

Plerixafor

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

Detaljerad miljöinformation

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 = $7.40*10^{-7}$ µg/l

Where:
A = 0.0054 kg (total sold amount API in Sweden year 2022, data from IQVIA)

R = 0% removal rate (due to loss by adsorption to sludge particles, by volatilization, hydrolysis or biodegradation)
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 of dilution of waste water by surface water flow = 10 (ECHA default) (Ref I)

Predicted No Effect Concentration (PNEC)
Ecotoxicological studies
No ecotoxicity data available.

Environmental Risk Rlassification (PEC/PNEC ratio)
The PEC/PNEC ratio could not be calculated since no ecotoxicity results are available, hence justifying the phrase: *"Risk of environmental impact of plerixafor 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 plerixafor 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 available, therefore the degradation phrase should be: *"The potential for persistence of plerixafor cannot be excluded, due to lack of data."*

Bioaccumulation
Partitioning coefficient:
Log K_{ow} = 0.94 at pH 7 (OECD 107) (Ref II)

Justification of chosen bioaccumulation phrase: Since log K_{ow} < 4 at pH 7, plerixafor has low potential for bioaccumulation.

Excretion (metabolism)
In healthy subjects (0.24 mg/kg) approximately 70% of the parent drug is excreted in urine in the first 24 hours. Metabolism does not involved CYP isoenzymes. (Ref III).
The pharmacological activity of possible metabolites is not known.

References

I. ECHA, European Chemicals Agency, 2008 Guidance on information requirements and chemical safety assessment. Available at https://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-
II. Evotec Report: REP/DS/0538: AMD3100 Physical Characterization (2004)
III. Law V et al. DrugBank 4.0: shedding new light on drug metabolism. Nucleic Acids Res. 2014 Jan 1;42(1):D1091-7. Available at https://www.drugbank.ca/drugs/DB06809