FASS

Mycamine

Astellas Pharma

Pulver till koncentrat till infusionsvätska, lösning 100 mg
(Vitt, kompakt pulver.)

Övriga antimykotika för systemiskt bruk

Aktiv substans:
Mikafungin

ATC-kod:
J02AX05

Läkemedel från Astellas Pharma omfattas av Läkemedelsförsäkringen.

Miljöpåverkan

Mikafungin

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

Detaljerad miljöinformation

Environmental Risk Classification
Predicted Environmental Concentration (PEC) in water 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 = **0,00006 µg/L**
A: 0.4648 kg (sold amount API in Sweden year 2022 from IQVIA).
R: 0 % removal rate (due to loss by adsorption to sludge particles, by voloatilization, hydrolysis or biodegradation) = 0 since no data is available
P: $10*10^6$ (number of inhabitants in Sweden)
V: 200 L/day (volume of wastewater per capita and day) (ECHA default) (Ref.1)
D: 10 (factor for dilution of wastewater by surface water flow) (ECHA default) (Ref.1)

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

LogP

LogP for micafungin is reported as -1.5 (Ref.2) and is therefore concluded to have a low potential to bioaccumulate (Ref.3).

References

1. ECHA, European Chemicals Agency. 2008 Guidance on information requirements and chemical safety assessement.
https://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assess
, accessed 17-Jan-2024.
2. Micafungin | C56H71N9O23S | CID 477468 - PubChem (nih.gov), accessed 17-Jan-2024.
3.
https://medlem.lif.se/globalassets/fass-medlemswebb/fass-databasen/environmental-classification-of-pharmaceu
, accessed 17-Jan-2024.