

Iclusig

M R F_f

Incyte Biosciences

Filmdragerad tablett 15 mg

(Vit, bikonvex, rund, filmdragerad tablett med en diameter på cirka 6 mm, med "A5" präglat på ena sidan.)

Antineoplastiskt medel, proteinkinashämmare.

Aktiv substans:

Ponatinib

ATC-kod:

L01EA05

Läkemedel från Incyte Biosciences omfattas av Läkemedelsförsäkringen.

Läkemedlet distribueras också av företag som inte omfattas av Läkemedelsförsäkringen, se Förpackningar.

Miljöpåverkan

Ponatinib

Miljörisk: Risk för miljöpåverkan av ponatinib kan inte uteslutas då ekotoxikologiska data saknas.

Nedbrytning: Det kan inte uteslutas att ponatinib är persistent, då

data saknas.

Bioackumulering: Ponatinib har hög potential att bioackumuleras.

Detaljerad miljöinformation

Environmental Risk Classification

Predicted Environmental Concentration (PEC)

PEC is based on following data:

$$\text{PEC } (\mu\text{g/L}) = (A \cdot 10^9 \cdot (100 - R)) / (365 \cdot P \cdot V \cdot D \cdot 100)$$

$$\text{PEC } (\mu\text{g/L}) = 1.37 \cdot 10^{-6} \cdot A \cdot (100 - R)$$

A (kg/year) = total sold amount API in the most recent sales data for Sweden (2022).

R (%) = 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 = $10 \cdot 10^6$

V (L/day) = volume of wastewater per capita and day = 200 (ECHA default) (Ref.1)

D = factor for dilution of waste water by surface water flow = 10 (ECHA default) (Ref.1)

(Note: The factor 10^9 converts the quantity used from kg to μg).

A = 0,4408 kg. The total sold amount of ponatinib hydrochloride in Sweden year 2019, data from Quintiles IQVIA (Ref.2)

R = 0

$$\text{PEC} = 1.37 \cdot 10^{-6} \cdot 0,4408 \cdot (100 - 0) = 0,00006039 \mu\text{g/L}$$

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

Predicted No Effect Concentration (PNEC)

The risk of environmental impact of ponatinib cannot be excluded, since no ecotoxicity data are available.

Degradation

The potential for persistence of ponatinib cannot be excluded, due to lack of data.

Bioaccumulation

Ponatinib has an estimated $\log K_{ow} = 4,32$. (Ref.3)

The $\log K_{ow}$ is thus >4 , which indicates that "Ponatinib has high potential for bioaccumulation."

References

1. ECHA, European Chemicals Agency.
October 2012 Version: 2.1 Guidance on information requirements and chemical safety assessment.
http://guidance.echa.europa.eu/docs/guidance_document/informa

2. Data from IQVIA, total sold amount API in the most recent sales data for Sweden (2022).
3. Ponatinib, National Center for Biotechnology Information. Pubchem Compound Database, Estimation Program Interface (EPI);
<https://pubchem.ncbi.nlm.nih.gov/compound/24826799#section=>
(accessed Sep 13, 2018).