

Atarax

UCB Nordic

Filmdragerad tablett 25 mg
(vita, avlånga, med brytskåra)

Lugnande medel

Aktiv substans:

Hydroxizin

ATC-kod:

N05BB01

Läkemedel från UCB Nordic omfattas av Läkemedelsförsäkringen.

M R F

Miljöpåverkan

Hydroxizin

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

Nedbrytning: Det kan inte uteslutas att hydroxizin är persistent, då data saknas.

Bioackumulering: Hydroxizin har låg potential att bioackumuleras.

Detaljerad miljöinformation

Predicted Environmental Concentration (PEC)

PEC is calculated according to the following formula:

$$\text{PEC } (\mu\text{g/L}) = (A \times 10^9 (100-R)) / (365 \times P \times V \times D \times 100) = 1.5 \times 10^{-6} \times A(100-R)$$

$$\text{PEC} = 0.09 \mu\text{g/L}$$

Where:

A = 606.56 kg (total sold amount API in Sweden year 2020, data from IQVIA).

R = removal rate = 0 % (no data available), assuming zero removal (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 waste water 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 is available.

Environmental risk classification (PEC/PNEC ratio)

Since no ecotoxicity data is available the PEC/PNEC cannot be calculated, hence justifying the environmental risk classification phrase: *"Risk of environmental impact of hydroxyzine cannot be excluded, since no ecotoxicity data are available"*.

Degradation

No degradation data is available therefore the degradation phrase should be: *"The potential for persistence of hydroxyzine cannot be excluded, due to lack of data"*.

Bioaccumulation

Partitioning coefficient:

An experimentally derived Log K_{ow} of 2.58 at neutral pH (method unknown) (Ref II)

Since Log K_{ow} < 4 at pH 7, hydroxyzine has low potential for bioaccumulation, justifying the phrase: *"Hydroxyzin has low potential for bioaccumulation"*.

Excretion (metabolism)

Hydroxyzine is excreted to < 1 % as parent compound. The most important metabolite cetirizine is active (also a H1 antagonist with potency assumed similar to mother compound) and eliminated intact in urine corresponding to 25 % of the mother compound. (Ref III)

References

- I. ECHA, European Chemicals Agency. 2016. Guidance on information requirements and chemical safety assessment . Available at:
<https://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety->
- II. UCB Pharma Material Safety Data Sheet, Document number: RSDE02F2707, 2007-06-01
- III. SPC (Summary of Product Characteristics) Atarax, UCB Nordic.