

Nimotop[®]

Bayer

Filmdragerad tablett 30 mg

(gula, 10 mm, märkta med Bayerkors och SK)

Kalciumantagonist

Aktiv substans:

Nimodipin

ATC-kod:

C08CA06

Läkemedel från Bayer omfattas av Läkemedelsförsäkringen.

M R F

Miljöpåverkan

Nimodipin

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

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

Bioackumulering: Det kan inte uteslutas att nimodipin kan bioackumuleras, då data saknas.

Detaljerad miljöinformation

Environmental Risk Classification

Predicted Environmental Concentration (PEC)

PEC is calculated according to the following formula:

$$\text{PEC } (\mu\text{g/L}) = (A \cdot 10^9 \cdot (100 - R)) / (365 \cdot P \cdot V \cdot D \cdot 100) = 1.37 \cdot 10^{-6} \cdot A \cdot (100 - R) = 0.00048 \mu\text{g/L}$$

Where:

A = 3.53 kg (total sold amount API in Sweden year 2021, data from IQVIA / LIF).

R = X % 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) (Reference I)

D = factor for dilution of wastewater by surface water flow = 10 (ECHA default) (Reference I)

Environmental risk classification (PEC/PNEC ratio)

Justification of chosen environmental risk phrase:

Due to a lack of ecotoxicological data the PNEC and the risk quotient could not be determined. This qualifies for the risk phrase "Risk of environmental impact of nimodipine cannot be excluded, since no ecotoxicity data are available".

Degradation

Justification of chosen degradation phrase:

There is no data on degradation which qualifies for the phrase "The potential for persistence of nimodipine cannot be excluded, due to lack of data".

Bioaccumulation

Justification of chosen bioaccumulation phrase:

There is no data on bioaccumulation which qualifies for the risk phrase "The potential for bioaccumulation of nimodipine cannot be excluded, due to lack of data".

References

- I. Guidance on information requirements and Chemical Safety Assessment Chapter R.16: Environmental exposure assessment. V3.0, Feb. 2016.