

Sabrilex[®]**M R F****Sanofi AB**

Filmdragerad tablett 500 mg

(vita, ovala, bikonvexa med skåra, märkta SABRILEX på ena sidan, 9×17 mm)

Antiepileptikum

Aktiv substans:

Vigabatrin

ATC-kod:

N03AG04

Läkemedel från Sanofi AB omfattas av Läkemedelsförsäkringen.

Miljöpåverkan

Vigabatrin

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

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

Bioackumulering: Vigabatrin har låg potential att bioackumuleras.

Detaljerad miljöinformation

Environmental Risk Classification

Predicted Environmental Concentration (PEC)

PEC is calculated according to the following formula:

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

$$\text{PEC} = 0.022 \mu\text{g/L}$$

Where:

A = 157.2 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 = $10 \cdot 10^6$

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)

No ecotoxicological study results are available.

Environmental Risk Classification (PEC/PNEC ratio)

A PEC/PNEC ratio cannot be calculated due to lack of data, thus justifying the phrase: *"Risk of environmental impact of vigabatrin cannot be excluded, since no ecotoxicity data are available"*.

Degradation

No degradation data is available, hence justifying the degradation phrase:

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

Bioaccumulation

Partition coefficient

Log K_{ow} = -2.16 at pH 7

(OECD 107)

(Ref II)

Justification of chosen bioaccumulation phrase:

Since $\log K_{ow} < 4$ at pH 7, vigabatrin has low potential for bioaccumulation.

Excretion (metabolism)

Vigabatrin is not extensively metabolised. No metabolites have been identified in plasma.

Vigabatrin is eliminated by renal excretion with a half-life of 5-8 hours. About 70 % of one oral single dose was excreted unchanged in the urine for the first 24 hours.

References

- I. ECHA, European Chemicals Agency, 2008 Guidance on information requirements and chemical safety assessment.
<https://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment>

- II. Henczi, M., Nagy, J., Weaver, D.F., 1995. Determination of Octanol-water Partition Coefficients by an HPLC method for Anticonvulsant Structure-activity studies. *Journal of Pharmacy and Pharmacology*. 47, 345-347.
- III. SmPC of Sabrilex, retrieved from SE MPA website 2021-03-17, find [here](#).