

Buprefarm



Orifarm Generics AB

Depotplåster 15 mikrog/timme

(Rektangulärt beigefärgat plåster med rundade hörn märkt med "Buprenorfin" och "15 µg/h" i blå färg. Plåsterstorlek: 18,75 cm².)



Narkotikaklass: IV - Narkotika med medicinsk användning

Särskilt läkemedel

Analgetika, opioider, oripavinderivat

Aktiv substans:

Buprenorfin

ATC-kod:

N02AE01

Läkemedel från Orifarm Generics AB omfattas av Läkemedelsförsäkringen.

Miljöpåverkan

Miljöinformationen för buprenorfin är framtagen av företaget Camurus för Buvidal

Miljörisk: Risk för miljöpåverkan av buprenorfin kan inte uteslutas då det inte finns tillräckliga ekotoxikologiska data.

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

Bioackumulering: Buprenorfin har låg potential att bioackumuleras.

Detaljerad miljöinformation

Environmental Risk Classification

Predicted Environmental Concentration (PEC)

PEC is calculated according to the following formula:

$$\text{PEC } (\mu\text{g/L}) = (A \cdot 10^9 \cdot (100 - R)) / (365 \cdot P \cdot V \cdot D \cdot 100) = 1.37 \cdot 10^{-6} \cdot 47.31 \cdot (100 - 0)$$

Where:

A = 47.31 kg (total sold amount buprenorphine and buprenorphine hydrochloride in Sweden year 2022, data from IQVIA).

R = % removal rate (due to loss by adsorption to sludge particles, by volatilization, hydrolysis or biodegradation) = 0 if no data is available. (*If R is not equal to 0 this should be justified under the degradation section*)

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

PEC = 0.0064 µg/L

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

Predicted No Effect Concentration (PNEC)

No data available

Environmental risk classification (PEC/PNEC ratio)

No data available.

Degradation

No data available.

Bioaccumulation

Partitioning coefficient: Log Dow = 3.7 at pH 7 (guideline OECD 107). (Ref II)

Justification of chosen bioaccumulation phrase: Since log Dow < 4 at pH 7, the substance has low potential for bioaccumulation.

Excretion (metabolism)

Buprenorphine is oxidatively metabolised by 14-N-dealkylation to N-desalkyl-buprenorphine (also known as norbuprenorphine) via cytochrome P450 CYP3A4 and by glucuroconjugation of the parent molecule and the dealkylated metabolite. Norbuprenorphine is a µ-opioid agonist with weak intrinsic activity.

As the main metabolite is pharmacologically active, no reduction of A in the PEC calculation has been made.

References

- I. ECHA, European Chemicals Agency. 2008 Guidance on information requirements and chemical safety assessment. http://guidance.echa.europa.eu/docs/guidance_document/information_requirements_en.htm
- II. Volic, N., 2020. Determination of physico-chemical properties of Buprenorphine: partition coefficient at pH5 and pH7 using shake flask method; partition coefficient at pH 9 using slow-stirring method. Charles River Laboratories Den Bosch, Study No. 20186155