

Impugan[®]

Teva

Tablett 40 mg

(vita till gulaktiga, plana med delskåra 8 mm märkta CJJ)

Loop-diuretikum (kortverkande, snabbverkande), antihypertonikum

Aktiv substans:

Furosemid

ATC-kod:

C03CA01

Läkemedel från Teva omfattas av Läkemedelsförsäkringen.

M R F_f

Miljöpåverkan

Miljöinformationen för furosemid är framtagen av företaget Orifarm Generics AB för Furix Retard, Furix®, Furosemid Copyfarm, Furosemide Claris

Miljörisk: Användning av furosemid har bedömts medföra försumbar risk för miljöpåverkan.

Nedbrytning: Furosemid är potentiellt persistent.

Bioackumulering: Furosemid har låg potential att bioackumuleras.

Detaljerad miljöinformation

Environmental Risk Classification

Predicted Environmental Concentration (PEC)

PEC is calculated according to the following formula:

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

$$\text{PEC} = 0.37 \mu\text{g/L}$$

Where:

A = 2696.87 kg (total sold amount API in Sweden year 2020, data from IQVIA).

R = 0% 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 = $1 \cdot 10^7$

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)

Predicted No Effect Concentration (PNEC)

Ecotoxicological studies:

Algae (*Pseudokirchneriella subcapitata*):

EC_{50} 72 h = 142 mg/L (guideline OECD 201) (Ref.2)

Crustacean - Fresh water flea (*Daphnia magna*):

EC_{50} 48 h = 239 mg/L (guideline OECD 202) (Ref.2)

Fish - Sheepshed minnow (*Cyprinodon variegatus variegatus*):

LC_{50} 96 h = 497 mg/L (guideline OECD 203) (Ref.2)

$PNEC$ = 142 $\mu\text{g/L}$ (justification of chosen assessment factor)

$PNEC$ ($\mu\text{g/L}$) = lowest $EC_{50}/1000$ where 1000 is the assessment factor used. EC_{50} for *Pseudokirchneriella subcapitata* has been used as for this calculation since it is the most sensitive of the three tested species.

Environmental risk classification (PEC/PNEC ratio)

$PEC/PNEC$ = $0.37 \mu\text{g/L} / 142 \mu\text{g/L} = 0.0026$

$PEC/PNEC < 0.1$ which justifies the phrase "Användning av läkemedlet har bedömts medföra försumbar risk för miljöpåverkan."

Degradation

Test results from "closed bottle test" (OECD guideline 301D) shows that the biological degradation is 0% in 28 days (Ref. 2). There is no information regarding the metabolites.

Furosemide is potentially persistent.

Bioaccumulation

Partitioning coefficient:

$\log K_{ow} \leq 0$ at pH 7, test method used to determine $\log K_{ow}$ is a HPLC with C_{18} analytical column (Ref.2)

Since $\log K_{ow} < 4$, the substance has low potential for bioaccumulation.

References

1. 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
2. Nycomed AB, "Test Results for the Test Substance Furosemide", Report No. R 196-05, date 2005-06-14.