FASS

Lepheton®

MRx EF

Meda

Oral lösning

(Färglös till svagt gulfärgad, oral viskös lösning med smak av anis, honung och apelsin.)

Beroendeframkallande medel.
Iakttag största försiktighet vid förskrivning av detta läkemedel.

Hostdämpande medel med efedrin

Aktiva substanser:

Efedrin (vattenfritt)

Etylmorfin

ATC-kod:

R05DA20

Läkemedel från Meda omfattas av Läkemedelsförsäkringen.

Miljöpåverkan

Efedrin (vattenfritt)

Miljörisk: Risk för miljöpåverkan av efedrin kan inte uteslutas då ekotoxikologiska data saknas.
Nedbrytning: Det kan inte uteslutas att efedrin är persistent, då data saknas.
Bioackumulering: Efedrin har låg potential att bioackumuleras.

Detaljerad miljöinformation

Environmental Risk Classification

Predicted Environmental Concentration (PEC)
PEC is calculated according to the following formula:
PEC (µg/L) = $(A*10^{9}*(100-R))/(365*P*V*D*100) = 1.5*10^{-6}$ *A(100-R)

PEC = 0,0298 µg/L

Where:
A = 198,768 kg (total amount API of ephedrine hydrochloride and ephedrine sulfate in Sweden year 2018, data from IQVIA). (Ref. 1)
R = removal rate = 0% (no data available)
P = number of inhabitants in Sweden = $9*10^{6}$
V (L/day) = volume of waste water per capita and day = 200 (ECHA default) (Ref. 2)
D = factor for dilution of waste water by surface water flow = 10 (ECHA default) (Ref. 2)

Ecotoxicological studies
No ecotoxicological data available.

Degradation
No degradation data available.

Bioaccumulation

An experimentally derived log K_{ow} of 1,13 (unknown method) (Ref. 3) indicates that ephedrine has low potential for bioaccumulation.

Log K_{ow} < 4 which justifies use of the phrase “Ephedrine has low potential for bioaccumulation”.

Excretion (metabolism)

During 24 hours, 55-75% is excreted as the unchanged substance through urine. The metabolism takes place mainly in the liver through N-demethylation to the main metabolite norephedrine -phenylpropanolamine, which is pharmacologically active with central stimulant properties. (Ref. 4)

References:

1. Data from IQVIA ”Consumption assessment in kg for input to environmental classification v1 - updated 2019 (data 2018)”.
2. ECHA, European Chemicals Agency. Guidance on information requirements and chemical safety assessment. Ver 2.1, 2011.
3. Avdeef, A (1997), ChemID+, US National Library of Medicin.
4. SPC (Summary of Product Characteristics) Lepheton, 2018-07-18, FASS.se.

Etylmorfin

Miljörisk: Risk för miljöpåverkan av etylmorfin kan inte uteslutas då ekotoxikologiska data saknas.
Nedbrytning: Det kan inte uteslutas att etylmorfin är persistent, då data saknas.
Bioackumulering: Etylmorfin har låg potential att bioackumuleras.

Detaljerad miljöinformation

Environmental Risk Classification

Predicted Environmental Concentration (PEC)
PEC is calculated according to the following formula:
$PEC(\mu g/L) = (A*10^{9}*(100-R))/(365*P*V*D*100) = 1.5*10^{-6}*A(100-R)$

PEC = 0,051 µg/L

Where:
A = 338,06581 kg (total amount API of ethylmorphine hydrochloride in Sweden year 2018, data from IQVIA). (Ref. 1)
R = removal rate = 0% (no data available)
P = number of inhabitants in Sweden = $9*10^{6}$
V (L/day) = volume of waste water per capita and day = 200 (ECHA default) (Ref. 2)
D = factor for dilution of waste water by surface water flow = 10 (ECHA default) (Ref. 2)

Ecotoxicological studies
No ecotoxicological data available.

Degradation
No degradation data available.

Bioaccumulation
An estimated Log P of 1,77 (Ref. 3) indicates that ethylmorphine has low potential for bioaccumulation.

Log P < 4 which justifies use of the phrase “Ethylmorphine has low potential for bioaccumulation”.

Excretion (metabolism)

Ethylmorphine is metabolised through N-demethylation to norethylmorphine and through O-deethylation to morphine, reactions catalysed by different forms of cytochrome P450 (CYP 2D6 and CYP 3A4).
Ethylmorphine and its metabolites are mainly excreted via the kidneys as conjugates with glucoronic acid. After 48 hours, about 70% of a given dose was found in the urine. (Ref. 4)

References:

1. Data from IQVIA ”Consumption assessment in kg for input to environmental classification v1 - updated 2019 (data 2018)”.
2. ECHA, European Chemicals Agency. Guidance on information requirements and chemical safety assessment.
3. Meylan WM and Howard PH (1995), ChemID+, US National Library of Medicin, National Institutes of Health.
4. SPC (Summary of Product Characteristics) Cocillana-Etyfin, 2018-07-25, FASS.se