

Morfin-Skopolamin Meda

! ♦ M R_s EF

Meda

Injektionsvätska, lösning 10 mg/ml + 0,4 mg/ml

Avregistreringsdatum: 2024-03-31 (Tillhandahålls ej) (Klar färglös till svagt gulbrun lösning)

♦♦♦ Narkotikaklass: II - Narkotika med medicinsk användning

Särskilt läkemedel

Narkotiskt analgetikum+spasmolytikum

Aktiva substanser (i bokstavsordning):

Hyoscin

Morfin

ATC-kod:

N02AG01

För information om det avregistrerade läkemedlet omfattas av Läkemedelsförsäkringen, kontakta Läkemedelsförsäkringen.

Läs mer om avregistrerade läkemedel

Miljöpåverkan

Hyoscin

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

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

Bioackumulering: Hyoscin har låg potential att bioackumuleras.

Detaljerad miljöinformation

Environmental Risk Classification

Predicted Environmental Concentration (PEC)

PEC is calculated according to the following formula:

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

$$\text{PEC} = 2.07 \cdot 10^{-4} \mu\text{g/L}$$

Where:

A = 1.51 kg (total amount API of hyoscine, hyoscine butylbromide, hyoscine metonitrate, hyoscyamine sulfate and hyoscine hydrobromide in Sweden year 2020, data from IQVIA)* (Ref. 1)

R = removal rate = 0% (no data available)

P = number of inhabitants in Sweden = $10 \cdot 10^6$

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)

*All products and enantiomers containing the same API and all salts of the API should be taken into account when the sales data is presented.

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

Ecotoxicological studies

No ecotoxicological data available.

Degradation

No degradation data available.

Bioaccumulation

An experimentally derived Log P_{ow} of 0.98 (unknown method) (Ref. 3) indicates that hyoscine has low potential for bioaccumulation.

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

Excretion (metabolism)

Hyoscine is likely eliminated through glucuronidation or sulphate conjugation and excretion of unchanged hyoscine in the urine constitute approximately 5% of a given dose. (Ref. 4)

References:

1. Data from IQVIA "Consumption assessment in kg for input to environmental classification - updated 2021 (data 2020)".
2. ECHA, European Chemicals Agency. Guidance on information requirements and chemical safety assessment. Ver 2.1, 2011

3. Sangster (1994), ChemID+, US National Library of Medicine, National Institutes of Health
4. SPC (Summary of Product Characteristics) Morfin-Skopolamin Meda, 2016-06-01, FASS.se.

Morfin

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

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

Bioackumulering: Morfin har låg potential att bioackumuleras.

Detaljerad miljöinformation

Environmental Risk Classification

Predicted Environmental Concentration (PEC)

PEC is calculated according to the following formula:

$$\text{PEC } (\mu\text{g/L}) = (A \cdot 10^9 \cdot (100 - R)) / (365 \cdot P \cdot V \cdot D \cdot 100) = 1,5 \cdot 10^{-6} \cdot A(100 - R)$$

$$\text{PEC} = 0.0060 \mu\text{g/L}$$

Where:

A = 40.08 kg (total sold amount API of morphine hydrochloride (trihydrate) and morphine sulfate (pentahydrate) in Sweden year 2020, data from IQVIA) (Ref. 1)

R = removal rate = 0% (no data available)

P = number of inhabitants in Sweden = $10 \cdot 10^6$

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)

Ecotoxicology

No ecotoxicological data available.

Degradation

No degradation data available

Bioaccumulation

An experimentally derived $\text{Log } P_{ow}$ of 0.89 (unknown method) (Ref. 3) indicates that morphine has a low potential for bioaccumulation.

$\text{Log } P_{ow} < 4$ which justifies use of the phrase "Morphine has low potential for bioaccumulation".

Excretion (metabolism)

Elimination of morphine occurs mainly through glucuronidation, and excretion of unchanged morphine in urine constitutes $<0.1\%$. Morphine-6-glucoronide is excreted via urine, which means that morphine-6-glucoronide may accumulate in case of impaired renal function. Impaired hepatic and renal function affects elimination of the substance. (Ref. 4)

References:

1. Data from IQVIA "Consumption assessment in kg for input to environmental classification - updated 2021 (data 2020)".
2. ECHA, European Chemicals Agency. Guidance on information requirements and chemical safety assessment. Ver 2.1, 2011
3. Avdeef A., et al. (1996), ChemID+, US National Library of Medicine, National Institutes of Health
4. SPC (Summary of Product Characteristics) Morfin Meda, 2018-11-02, FASS.se.