

## Levopidon



DNE Pharma

Tablett 30 mg

(Tillhandahålls ej)



Narkotikaklass: II - Narkotika med medicinsk användning

### Aktiv substans:

Levometadon

### ATC-kod:

N07BC05

Läkemedel från DNE Pharma omfattas av Läkemedelsförsäkringen.

## Miljöpåverkan

### Levometadon

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

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

Bioackumulering: Levometadon har låg potential att bioackumuleras.

### Detaljerad miljöinformation

#### Predicted Environmental Concentration (PEC)

PEC is calculated according to the following formula:

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

$$\text{PEC} = 1.37 \cdot 10^{-5} \mu\text{g/L}$$

Where:

A = 0.10 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 =  $10 \cdot 10^6$

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)**

#### **Ecotoxicological studies**

No data is available.

### **Environmental risk classification (PEC/PNEC ratio)**

It is not possible to calculate the environmental risk classification (PEC/PNEC ratio) due to lack of data.

#### *Summary phrases for the environmental risk:*

Risk of environmental impact of levomethadone cannot be excluded, since no ecotoxicity data are available.

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

#### **Degradation**

No data is available.

#### *Summary phrases for degradation:*

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

#### **Bioaccumulation**

##### *Partitioning coefficient:*

LogP = 3.9 (computed, pH unknown)

(Ref. II)

##### *Justification for chosen bioaccumulation phrase:*

Since  $\log P < 4$ , levomethadone has low potential for bioaccumulation.

#### **Excretion (metabolism)**

32 metabolites of methadone have been identified. Two pharmacologically active metabolites stand for only 2 % of the administered dose. Methadone and its metabolites accumulate mainly in lungs, liver, kidneys, spleen and muscles.

Methadone and its metabolites are eliminated by the kidneys and bile. At high doses, elimination is via the kidneys, the main elimination pathway. If the dose exceeds 160 mg, approximately 60 % is excreted as unchanged methadone. 10-45 % of total excreted amount is excreted in bile.

(Ref. III)

#### **References**

- I. ECHA, European Chemicals Agency. 2008 Guidance on information requirements and chemical safety assessment; find here
- II. Levomethadone at PubChem, retrieved from PubChem 2022-02-18; find here
- III. SmPC Levopidon oral solution, retrieved from SE MPA 2022-02-03; find here