

**Tibinide<sup>®</sup>****M R F****Viartis**

Tablett 300 mg

(vit, rund, plan med brytskåra, 10 mm)

Medel mot tuberkulos

**Aktiv substans:**

Isoniazid

**ATC-kod:**

J04AC01

Läkemedel från Viartis omfattas av Läkemedelsförsäkringen.

## Miljöpåverkan

### Miljöinformationen för isoniazid är framtagen av företaget Meda för Nydrazid

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

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

Bioackumulering: Isoniazid har låg potential att bioackumuleras.

# Detaljerad miljöinformation

## Environmental Risk Classification

### *Predicted Environmental Concentration (PEC)*

PEC is calculated according to the following formula:

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

$$PEC = 0,012 \mu\text{g/L}$$

Where:

A = 86,3964 kg (total amount API of isoniazid in Sweden year 2021, 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)

### *Predicted No Effect Concentration (PNEC)*

#### Ecotoxicological studies

*Daphnia magna* (Crustacean) (Ref. 3)

EC<sub>50</sub> 24 hours (immobility): 0,406 mg/L (OECD 202, 1984)

*Daphnia magna* (Crustacean) (Ref. 4)

EC<sub>50</sub> 24 hours (immobility): 84,6 mg/L (OECD 202, 1980)

Risk of environmental impact of isoniazid cannot be excluded, since there is not sufficient ecotoxicity data available.

### **Degradation**

No degradation data available.

### **Bioaccumulation**

An experimentally derived  $\text{Log } K_{ow}$  of -0,70 (unknown method) (Ref. 5) indicates that isoniazid has low potential for bioaccumulation.

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

### **Excretion (metabolism)**

Within 24 hours between 75 and 95% of a given dose is excreted via the kidneys, mostly as inactive metabolite. Less than 10% is excreted via feces. Predominant excretion products in urine are N-acetylisoniazid and isonicotinic acid. (Ref. 6)

### **References:**

1. Data from IQVIA "Consumption assessment in kg for input to environmental classification v1 - updated 2022 (data 2021)".
2. ECHA, European Chemicals Agency. Guidance on information requirements and chemical safety assessment.
3. Calleja et al. (1994), Food and Chemical Toxicology leuvers M. Mixture toxicity of the anti-inflammatory drugs diclofenac, ibuprofen, naproxen and a32 (2) p173-187.
4. Lillius H et al. (1994), Aquatic Toxicology 30 p47-60.
5. Hansch C et al. (1995), ChemID+, US National Library of Medicine, National Institutes of Health.

**6. SPC (Summary of Product Characteristics) Tibinide,  
2015-11-18, FASS.se.**