

## Vitaros

### Ferring

Kräm 2 mg/g

(Tillhandahålls ej) (Vit till benvit kräm)

Medel vid erektil dysfunktion

### Aktiv substans:

Alprostadil

### ATC-kod:

G04BE01

Läkemedel från Ferring omfattas av Läkemedelsförsäkringen.

## Miljöpåverkan

### Alprostadil

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

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

Bioackumulering: Alprostadil har låg potential att bioackumuleras.

### Detaljerad miljöinformation

Environmental Risk Classification

#### Predicted Environmental Concentration (PEC)

PEC is calculated according to the following formula:

$$PEC(\mu\text{g/L}) = (A \cdot 10^9 \cdot (100 - R)) / (365 \cdot P \cdot V \cdot D \cdot 100) = 1.5 \cdot 10^{-6} \cdot A \cdot (100 - R)$$

$$PEC = 0,000016941 \mu\text{g/L}$$

Where:

A = 0,1129 kg (total amount API in Sweden year 2018, data from IQVIA).

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

P = number of inhabitants in Sweden =  $9 \cdot 10^6$

V (L/day) = volume of waste water 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)

According to the European Medicines Agency guideline on environmental risk assessment of medicinal products (EMA/CHMP/SWP/4447/00), use of Alprostadil 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 of 3,20 (unknown method) (Ref. 2) indicates that Alprostadil has low potential for bioaccumulation.

Log P < 4 which justifies use of the phrase "Alprostadil has low potential for bioaccumulation".

### **References:**

1. ECHA, European Chemicals Agency. Guidance on information requirements and chemical safety assessment. Ver 2.1, 2011.

[http://echa.europa.eu/documents/10162/13643/information\\_requirements\\_r2\\_en.pdf](http://echa.europa.eu/documents/10162/13643/information_requirements_r2_en.pdf)

2. Avdeef A et al. (1995), ChemID+, US National Library of Medicine, National Institutes of Health, <http://chem.sis.nlm.nih.gov/chemidplus/chemidheavy.jsp>