

## In 2023, we formalized our approach to disclose information on UCB pharmaceuticals potentially entering the environment (PiE).

We will continue to strengthen our efforts to minimize the environmental risks in our medicines' lifecycle, which happens:

- Through patients' excretions, where the majority of our material outflow lies, and for which an environmental risk assessment is performed following recognized standards, and submitted to Regulatory Authorities;
- Through our manufacturing activities and our water management, where we will formalize safe discharge measures and disclose our compliance;
- Through disposal of unused medicines, where we are developing targeted communication plans to ensure that any unused medicines enter the correct waste stream.

Initially, we are disclosing the environmental risk level of our medicines when they are released in the environment through patient excretions. Environmental risk refers to the potential adverse effect that pharmaceuticals could have on the natural environment when they enter the ecosystem, and more specifically the aquatic compartment (surface waters) after medicines have been excreted by patients. In all cases for which data has been generated, the risk has been determined as low to insignificant. The environmental risk level of UCB's medicines provided in the table was assessed from data generated via our marketing authorization applications.

These assessments use conservative, worst-case assumptions on environmental exposure, considering the maximum expected use of UCB's medicines; and the maximum potential concentration in water, with no degradation of pharmaceuticals occurring in the human body nor sewage treatment.

The Predicted Environmental Concentration (PEC) – i.e. the quantity of pharmaceuticals expected to be released in the environment – of each medicine, disclosed below, is most probably overestimated. To classify environmental risk, the PEC is divided by the Predicted No Effect Concentration (PNEC) which is the maximum quantity of pharmaceuticals under which no harm to nature is expected. The PNEC is calculated following the European Medicines Agency guideline<sup>1</sup> by using the worst ecotoxicity value available for the pharmaceutical.

---

<sup>1</sup> Guideline on the environment risk assessment of medicinal products for human use; EMEA/CHMP/SWP/4447/00 corr 2; 01. June 2006

The result of the PEC/PNEC ratio defines the environmental risk level, aligned with scientific recommendations<sup>2</sup>, as such:

- PEC/PNEC below 0.1: Insignificant environmental risk level
- PEC/PNEC between 0.1 & 1: low environmental risk level
- PEC/PNEC between 1 & 10: medium environmental risk level
- PEC/PNEC higher than 10: high environmental risk level

For medicines marketed before 2006, data were not required by regulatory authorities. In these cases, UCB is committed before the end of 2025 to provide a risk classification either by generating data, or based on data from reliable scientific literature if available, to avoid duplication of ecotoxicological testing on three trophic levels.

Information on PEC and PNEC are available **through each medicines' hyperlink**, showcasing how the environmental risk level was calculated based on scientific data:

UCB's Brand Name	Generic Name	Environmental Risk Level
<a href="#">BIMZELX</a> <sup>®</sup>	<i>bimekizumab</i>	Insignificant <sup>(a)</sup>
<a href="#">BRIVIACT</a> <sup>®</sup>	<i>brivaracetam</i>	Insignificant
<a href="#">CIMZIA</a> <sup>®</sup>	<i>certolizumab pegol</i>	Insignificant <sup>(a)</sup>
CIRRUS <sup>®</sup>	<i>levocetirizine / pseudoephedrine</i>	NA <sup>(b)</sup>
<a href="#">EVENTITY</a> <sup>®</sup>	<i>romosozumab</i>	Insignificant <sup>(a)</sup>
<a href="#">FERRO SANOL</a> <sup>®</sup>	<i>ferrous(II) glycine sulphate complex</i>	Insignificant <sup>(a)</sup>
<a href="#">FINTEPLA</a> <sup>®</sup>	<i>fenfluramine</i>	Insignificant
<a href="#">KEPPRA</a> <sup>®</sup>	<i>levetiracetam</i>	Insignificant
NAYZILAM <sup>®</sup>	<i>midazolam</i>	NA <sup>(b)</sup>
<a href="#">NEUPRO</a> <sup>®</sup>	<i>rotigotine</i>	Low
<a href="#">RYSTIGGO</a> <sup>®</sup>	<i>rozanolixizumab-noli</i>	Insignificant <sup>(a)</sup>
<a href="#">VIMPAT</a> <sup>®</sup>	<i>lacosamide</i>	Insignificant
<a href="#">XYREM</a> <sup>®</sup>	<i>sodium oxybate</i>	Insignificant
XYZAL <sup>®</sup>	<i>levocetirizine</i>	NA <sup>(b)</sup>
<a href="#">ZYLBRISQ</a> <sup>®</sup>	<i>zilucoplan</i>	Insignificant
ZYRTEC <sup>®</sup>	<i>cetirizine</i>	NA <sup>(b)</sup>

(a) Due to their nature, vitamins, electrolytes, amino acids, peptides, proteins, carbohydrates and lipids are unlikely to result in a significant risk to the environment so no PEC nor PNEC has been calculated.

(b) Insufficient data available yet

<sup>2</sup> Wennmalm A, Gunnarsson B. Pharmaceutical management through environmental product labeling in Sweden. Environ Int. 2009 Jul;35(5):775-7. doi: 10.1016/j.envint.2008.12.008. Epub 2009 Feb 3. PMID: 19193440.