AstraZeneca's Environmental Risk Summaries

As part of AstraZeneca's commitment to data transparency, this website provides environmental risk summaries for the Active Pharmaceutical Ingredients (APIs) in our global brands. These summaries are prepared using the environmental information (data and studies) generated to support our marketing approval applications and credible scientific literature.

For each API, the potential environmental risk is determined as the ratio between the Predicted Environmental Concentration (PEC) of the API in the aquatic environment (e.g., rivers) and the Predicted No Effect Concentration (PNEC).
The PNEC of an API is the threshold (derived from the available ecotoxicity data) below which no adverse effects on the ecosystem are expected to occur. The PNEC is estimated by division of the lowest value for toxicity with the relevant assessment factor, as outlined by the European Chemicals Agency[1] and European Medicines Agency[2]. For human pharmaceuticals, it is primarily the aquatic compartment that is of interest, since human medicines may be excreted partly or wholly unchanged by patients, prior to entering the sewage system and ultimately rivers and other surface waters.
The PEC is calculated for a worst-case scenario, which assumes no API breakdown (metabolism) by the patient or any removal/degradation of the API during sewage treatment (unless otherwise stated) and uses the total sales volumes for the API in the country with the highest per capita use[3]. The per capita use is calculated using the sales of all AstraZeneca products that contain a given API. Because some APIs are also sold by other companies, we do maintain oversight of the environmental risk posed these APIs through our EcoPharmacoVigilance (EPV) programme[4]. We track the environmental risks of a product after launch via literature monitoring for emerging data on exposure and effects.

The derived environmental risk quotient (PEC/PNEC ratio) is assigned to one of four risk categories. These categories are consistent with the classification system[5] for environmental information on www.fass.se, the web version of the Swedish Prescribing guide.

The risk categories are as follows:

PEC/PNEC ≤ 0.1	Use of the substance has been considered to result in **insignificant** environmental risk.
0.1 < PEC/PNEC ≤ 1	Use of the substance has been considered to result in **low** environmental risk.
1 < PEC/PNEC ≤ 10	Use of the substance has been considered to result in **moderate** environmental risk.
PEC/PNEC > 10	Use of the substance has been considered to result in **high** environmental risk.

Our medicines are approved in a county-specific manner and for defined uses and the information we provide for patients is governed by local regulations. For this reason, our environmental risk summaries are listed alphabetically by the active pharmaceutical ingredient name and include no reference to product names or indication. To view the environmental risk summary document for an API, which includes results of environmental fate and ecotoxicity studies and detailed information on how the PEC has been calculated, click on the API name in the table below.

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[1] Guidance on information requirements and chemical safety assessment, 2008, Chapter R.10: Characterisation of dose [concentration]-response for environment http://guidance.echa.europa.eu/docs/guidance_document/information_requirements_en.htm

[2] Guideline on the Environmental Risk Assessment of Medicinal Products for Human Use, 2006, EMEA/CPMP/SWP/4447/00 corr[2]. http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2009/10/WC500003978.pdf

[3] Per capita use is calculated from kg sales data provided by IQVIA (https://www.iqvia.com) and population data taken from Eurostat (http://ec.europa.eu/eurostat) for countries in Europe and https://data.worldbank.org/country/ for rest of world.

[4] For more information on EPV, please see https://www.astrazeneca.com/sustainability/environmental-protection/pharmaceuticals-in-the-environment.html.

[5] Environmental classification of pharmaceuticals at www.fass.se: Guidance for pharmaceutical companies. 2012. https://www.fass.se/pdf/Environmental_classification_of_pharmaceuticals-120816.pdf

Active Pharmaceutical Ingredient (API)	Environmental Risk
Acalabrutinib	Insignificant
Aclidinium bromide	*
Albuterol sulfate	Insignificant
Anastrozole	Insignificant
Andexanat alfa	Insignificant**
Anifrolumab	Insignificant**
Asfotase alfa	Insignificant**
Atenolol	Insignificant
Bambuterol hydrochloride	Insignificant
Benralizumab	Insignificant**
Bicalutamide	Insignificant
Budesonide	Insignificant
Bupivacaine	Insignificant
Candesartan cilexetil	Insignificant
Ceftaroline fosamil	Insignificant
Chlorthalidone	Insignificant
Cilgavimab	Insignificant**
Clomethiazole edisilate	Insignificant
Dapagliflozin	Insignificant
Durvalumab	Insignificant**
Eculizumab	Insignificant**
Esomeprazole sodium/magnesium	Insignificant
Exenatide	Insignificant**
Felodipine	Low
Formoterol fumarate	Insignificant
Fulvestrant	Low
Gefitinib	Insignificant
Glycopyrronium	*
Goserelin acetate	Insignificant**
Hydrochlorothiazide	Insignificant
Influenza vaccine	Insignificant**

Active Pharmaceutical Ingredient (API)	Environmental Risk
Isosorbide-5-mononitrate	Insignificant
Lidocaine hydrochloride	Insignificant
Lisinopril dihydrate	Insignificant
Mepivacaine hydrochloride	Insignificant
Meropenem	Insignificant
Metformin hydrochloride	Low
Metoprolol succinate/tartrate	Low
Moxetumomab pasudotox	Insignificant**
Naloxegol	Insignificant
Naproxen	Insignificant
Nifedipine	*
Nirsevimab	Insignificant**
Olaparib	Insignificant
Omeprazole	Insignificant***
Osimertinib	Low
Palivizumab	Insignificant**
Pramlintide	Insignificant**
Prilocaine hydrochloride	Insignificant
Propofol	Low
Propranolol hydrochloride	Low
Quetiapine fumarate	Insignificant
Ramipril	Insignificant
Ravulizumab	Insignificant**
Roflumilast	Insignificant
Ropivacaine hydrochloride	Insignificant
Rosuvastatin calcium	Insignificant
Saxagliptin	Insignificant
Sebelipase alfa	Insignificant**
Selumetinib hydrogen sulphate	Insignificant
Sitagliptin	Insignificant
Sodium zirconium cyclosilicate	Insignificant**

Active Pharmaceutical Ingredient (API)	Environmental Risk
Tamoxifen citrate	Low
Terbutaline sulphate	Insignificant
Tezepelumab	Insignificant**
Ticagrelor	Insignificant
Tixagevimab	Insignificant**
Trastuzumab deruxtecan	Insignificant
Tremelimumab	Insignificant**
Vandetanib	Insignificant
Zafirlukast	Insignificant
Zolmitriptan	Insignificant

* Insufficient data available, see PDF document.

** A PEC/PNEC ratio has not been calculated. The active pharmaceutical ingredient consists of amino acids/peptides/proteins/carbohydrates/lipids, due to their nature, these products are expected to undergo rapid and extensive degradation and are therefore unlikely to pose a significant risk in the environment.

*** Esomeprazole is the single (S-) enantiomer of the racemate Omeprazole. In the absence of comprehensive environmental data for omeprazole, the more scientifically robust long-term data set for esomeprazole has been used to calculate the PNEC and total sales of both esomeprazole and omeprazole are included in the calculation of the PEC.

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