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 (API) found in our global brands. The summaries are consistent with the environmental information provided as part of our marketing applications, or where this is not available, from currently available data including scientific literature, where appropriate.

For each API, the potential environmental risk is calculated from 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), which is the concentration, based on available tests, below which no adverse effects on the ecosystem are expected to occur. 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, subsequently entering the sewage system and ultimately rivers and other surface waters. The PEC is calculated using a worst-case scenario, assuming no metabolism by the patient or removal/degradation of the API during sewage treatment and using the total sales volumes for the API in the European country with the highest per capita use[1]. The sales volumes are based on all human medicines containing the API, including products marketed by other companies, where applicable. The PNEC is estimated by division of the lowest value for toxicity with the relevant assessment factor, as outlined by the European Chemicals Agency[2] and European Medicines Agency[3].

The environmental risk is divided into four different categories depending on the PEC/PNEC ratio. The categories, described below, are consistent with the classification system[4] 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.

Environmental risk data relating to our medicines

The table below provides an overview of the environmental risk of AstraZeneca's medicines. This information will be updated, if appropriate, as new data become available. The active pharmaceutical ingredients are listed alphabetically by their generic name. Where an API is used in a combination

[1] Per captia use calculated from kg sales data provided by IMS Health, MIDAS International Data 2016 (www.imshealth.com) for 22 European markets (Austria, Belgium, Bulgaria, Croatia, Czech Republic, Denmark, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Netherlands, Norway, Poland, Romania, Slovakia, Spain, Sweden, Switzerland and United Kingdom), and population data taken from Eurostat (http://ec.europa.eu/eurostat).

[2] 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

[3] 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

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

product (a medicine that contains more than one API) the brand name is followed by the generic name of the additional API contained within the product, in parenthesis.

For detailed information on the environmental fate/degradation/toxicity data as well as the calculation of the potential environmental risk, click on the generic compound name in the table below.

Generic name	AstraZeneca Brand name	Therapy area	Environmental Risk
Aclidium bromide	Eklira Duaklir (formoterol fumerate)	Respiratory	*
Anastrozole	Arimidex	Oncology	Insignificant
Atenolol	Tenormin/Tenormine/Prenormine/ Atenol Nif-Ten (nifedipine) Tenoretic, (chlorthalidone)	Cardiovascular & Metabolic Disease	Insignificant
Bambuterol hydrochloride	Bambec and Oxeol	Respiratory	Insignificant
Bicalutamide	Casodex	Oncology	Insignificant
Budesonide	Pulmicort Rhiocort Symbicort (formoterol fumerate)	Respiratory	Insignificant
Bupivacaine hydrochloride	Marcaine and Sensorcaine	Neuroscience	Insignificant
Candesartan cilexetil	Atacand Atacand Duo (Felodipine) Atacand Plus (hydrochlorothiazide)	Cardiovascular & Metabolic Disease	Insignificant
Ceftaroline fosamil	Zinforo	Infection and Vaccines	Insignificant
Chlorthalidone	Tenoretic (atenolol)	Cardiovascular & Metabolic Disease	Insignificant
Dapagliflozin	Forxiga Xigduo (metformin) Qtern (saxagliptin)	Cardiovascular & Metabolic Disease	insignificant
Esomeprazole sodium/magnesium	Nexium Vimovo (naproxen)	Gastrointestinal	Insignificant
Exenatide	Bydureon	Cardiovascular & Metabolic Disease	Insignificant**
Felodipine	Plendil/Modip/Splendil/Munobal/ Flodil Atacand Duo (candesartan)	Cardiovascular & Metabolic Disease	Low
Formoterol fumarate	Oxis Symbicort (budesonide) Duaklir (Aclidium bromide)	Respiratory	Insignificant

Generic name	AstraZeneca Brand name	Therapy area	Environmental Risk
Fulvestrant	Faslodex	Oncology	Low
Gefitinib	Iressa	Oncology	Insignificant
Goserelin acetate	Zoladex	Oncology	Insignificant**
Hydrochlorothiazide	Zestoretic (lisinopril dehydrate) Atacand Plus (candesartan cilexetil)	Cardiovascular & Metabolic Disease	Insignificant
Influenza vaccine live	Fluenz	Infection and Vaccines	Low**
Isosorbide-5-mononitrate	Imdur/Duronitrin	Cardiovascular & Metabolic Disease	Insignificant
Lidocaine hydrochloride	Xylocaine EMLA (prilocaine)	Neuroscience	Insignificant
Lisinopril dihydrate	Zestril Zestoretic (hydrochlorothiazide)	Cardiovascular & Metabolic Disease	Insignificant
Mepivacaine hydrochloride	Carbocaine	Neuroscience	Insignificant
Meropenem	Merrem/Meronem	Infection and Vaccines	Insignificant
Metformin hydrochloride	Kombiglyze (saxagliptin) Xigduo (dapagliflozin)	Cardiovascular & Metabolic Disease	Low
Metoprolol succinate/tartrate	Seloken/Seloken ZOK/Toprol-XL/ Betaloc/Betaloc ZOK Logimax (felodipine)	Cardiovascular & Metabolic Disease	Low
Naloxegol	Movantik/Moventig	Neuroscience	Insignificant
Naproxen	Vimovo (espmeprazole)	Gastrointestinal	Low
Nifedipine	Nif-Ten (atenolol)	Cardiovascular & Metabolic Disease	*
Olaparib	Lynparza	Oncology	Insignificant
Omeprazole	Losec/Gastroloc/Mopral/Omepral/ Prilosec	Gastrointestinal	Insignificant***
Osimertinib mesylate	Tagrisso	Oncology	Insignificant
Palivizumab	Synagis	Infection and Vaccines	Insignificant**
Pramlintide	Symlin	Cardiovascular & Metabolic Disease	Insignificant**

Generic name	AstraZeneca Brand name	Therapy area	Environmental Risk
Prilocaine hydrochloride	Citanest Citanest Adrenaline (adrenaline) EMLA (lidocaine)	Neuroscience	Insignificant
Propofol	Diprivan	Neuroscience	Low
Propranolol hydrochloride	Inderal	Cardiovascular & Metabolic Disease	Low
Quetiapine fumarate	Seroquel	Neuroscience	Low
Ramipril	Ramace/Hypren/Pramace/Unipril/ Vesdil. Unimax (felodipine)	Cardiovascular & Metabolic Disease	Insignificant
Roflumilast	Daxas	Respiratory	Insignificant
Ropivacaine hydrochloride monohydrate	Naropin	Neuroscience	Insignificant
Rosuvastatin calcium	Crestor	Cardiovascular & Metabolic Disease	Low
Saxagliptin	Onglyza Kombiglyze (metformin) Qtern (dapagliflozin)	Cardiovascular & Metabolic Disease	Insignificant
Tamoxifen citrate	Nolvadex	Oncology	Insignificant
Terbutaline sulphate	Bricanyl Respules	Respiratory	Insignificant
Ticagrelor	Brilinta/Brilique	Cardiovascular & Metabolic Disease	Insignificant
Vandetanib	Caprelsa	Oncology	Insignificant
Zafirlukast	Accolate/Accoleit/Vanticon	Respiratory	Insignificant
Zolmitriptan	Zomig/Zomig Rapimelt/Zomig Nasal Spray/Zomigon	Neuroscience	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 very rapid and extensive degradation and are unlikely to result in a significant risk to the environment.

*** Omeprazole is the R-enantiomer of the racemate Esomeprazole (S-enantiomer). 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.