

Water: Proposed FDA revision

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REQUEST FOR COMMENTS

Background: The number of adverse effects (AEs) listed in package inserts for drugs approved by the Food and Drug Administration (FDA) has increased dramatically. In a *New England Journal of Medicine* commentary published about five years ago, the mean number of listed AEs was 75. Under the new administration, the FDA is interested in overseeing more aspects of public health but is seeking to limit needless worry about possible AEs. With the intention of eliminating the listing of AEs that occurred during trials but which were most likely not related to the investigated drug, food, supplement or device, the following proposed handout was developed to meet a Congressionally-mandated directive to make Americans aware of public health hazards that they may not be adequately aware of. This document is not final and may be modified by your comments.

PROPOSED PACKAGE INSERT FOR WATER

Introduction: Water is a ubiquitous chemical that occurs naturally in the environment, often combined or contaminated with other chemicals as well as biological and non-organic substances too numerous to mention. In its pure form, it is a chemical composed of two parts of hydrogen to one of oxygen. Altered chemical forms of H₂O are not used for drinking and therefore do not

come under the purview of the FDA. Currently, water composed of deuterated hydrogen atoms is the only available form of this drug, which is used primarily in nuclear reactors.

Water was approved in 2020 by an expert committee, which voted 9–3 with two abstentions, to approve FDA's approval of water for non-research uses.

Current status: There are numerous brand names of water available, all having between 80 and 120% of the stated pharmacological activity of the basic formulation of generic H₂O, approved by the FDA in 2020.

Pharmacology: The chemical activity of this drug is still undergoing testing. It is used primarily to satisfy electrolyte requirements in both individual cells as well as in various organs. It provides a substrate for the numerous chemical reactions within each cell, allowing them to travel from one structure to another. It suppresses the hypothalamic hormone vasopressin and is therefore the drug of choice for suppressing the discomforting sensation of thirst. It is important in temperature regulation through sweating, in digestion, and in numerous other physiological processes.

As widely used and as important as this drug is, its use, as is true of all drugs, may contain hidden dangers, whose importance is magnified greatly by its widespread use. For example, one

recent study showed the average concentration of one liter of bottled water was 325 microplastic particles, and linked extended use to negative health outcomes – from cardiovascular disease to autoimmune conditions. Another study revealed that some products contained higher than FDA-recommended levels of arsenic (10 parts per billion (ppb)). Below are some common warnings PCPs might want to advise their patients, or use to prepare an office handout.

Water's potential side effects*:

1. If water is not swallowed very carefully, some may go down the trachea (aspiration) which can lead to coughing, bronchitis, pneumonia and death.
2. Coughing or laughing when drinking water may cause the fluid to go up the nose, leading to sinus infection, which may cause brain abscesses, sepsis and death.
3. Excessive water intake may cause hyponatremia, which can lead to confusion, seizures and death.
4. Excessive intake of water and other water-based liquids such as beer, increases the likelihood of hyponatremia, which may lead to confusion, seizures and death
5. Inadequate water intake may contribute to constipation. This may become severe, leading to complete blockage, causing “toxic megacolon” and possible death.

6. Excessive water intake leads to increased urination. This may lead to fainting in men (who urinate while standing), poor sleeping at night, leading to increased walking at night, leading to falls, and possible death.

7. Increased urination may lead to urinary urgency, causing older people to need to rush to get to the toilet, leading to increased risk of falling, which may cause hip fracture or brain trauma, leading to a need for major surgery, and death.

8. Excessive water drinking, especially at night, may cause incontinence, which may cause awakening and a need to get out of bed and change the sheets. This increases the risk of falls, which may lead to death.

9. Drinking water when driving increases the risk of motor vehicle accidents, leading to property damage, maiming and death.

10. Drinking water when driving leads to the increased need to urinate, which may lead to bladder urgency, leading to reckless driving and an increased risk of death.

11. Aspirating water in its frozen form can lead to blockage of the trachea, causing hypoxia and death.

12. Water increases the risk of worsened congestive heart failure which may lead to death.

13. Water increases the severity of fluid retention and swelling in the feet and legs. This increases the risk of falls due to increased heaviness of legs, as well as increased urination at night (see # 8) and may lead to death.

14. Other clear and colorless liquids such as bleach, vodka and cleaning solvents are often mistaken for water and swallowed without consideration of the consequences of such a mistake. Depending on the quantity imbibed, this may lead to death.

As is true for all medications, know your drugs and drink with care!

Please email your suggestions to the editor emeritus at:

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*Potential side effects are based on adverse event reporting from several double-blind, placebo-controlled trials of water vs. water substitute for the treatment of diverse disorders including thirst,¹⁻⁷ diaphoresis,⁸⁻¹¹ hypernatremia,¹²⁻³³ oliguria.³⁴⁻³⁹ (Reference citations available via the Freedom of Information Act.)

April Fools!

Author

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