

Black Box Drugs: Would Your Doctor Take These?

Presented by ConsumerSafety.org

Pradaxa (Blood Clots)

Pradaxa is an anticoagulant that helps prevent the formation of blood clots. In patients over 75, there is a [statistically significant trend](#) toward internal bleeding when taking this drug. Its mechanism of action involves blocking a natural enzyme called “thrombin” which causes blood to clot.

Why It's Black Boxed

- Increases stroke + cardiovascular event risk when discontinued before completing course
- Increases epidural + spinal hematoma (swelling of clotted blood within body tissue)

Source: <https://online.epocrates.com/u/10b5941/Pradaxa/Black+Box+Warnings>

Adderall (ADHD)

Adderall is a stimulant, amphetamine drug usually used to treat ADHD but is also frequently used recreationally by college students and other young adults for its effects on concentration/focus.

Why It's Black Boxed

- Addictive/likely to be abused
- Increased risk of sudden death and cardiovascular events

Source: https://www.accessdata.fda.gov/drugsatfda_docs/label/2007/011522s040lbl.pdf

Xanax (Anxiety)

Xanax is a benzodiazepine drug used for anxiety. It can also be used to manage phobic behaviors and specific conditions like social anxiety. It's a sedative. Xanax should never be used in patients with a history of drug abuse, due to its addictive potential. The drug is contraindicated in patients with glaucoma.

Why It's Black Boxed

- Taking Xanax along with opioids may cause sedation and respiratory disorders
- It should only be taken along with other opioid drugs if absolutely necessary and all other options covered
- Minimum dosage is recommended
- Patient needs to be monitored for sedation while taking Xanax

Source: https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/018276s052lbl.pdf

Ciprofloxacin (Bacterial Infection)

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Cipro is a member of a class of antibiotics called “fluoroquinolones.” This class of drugs stop bacteria from reproducing by altering their DNA replication pathway. Cipro is used to treat bacterial infections of all different types like chronic bronchitis, infectious diarrhea, urinary tract infections (UTIs) and more. Cipro is not recommended in the pediatric (under 18 years) population due to adverse reactions compared to controls.

Why It's Black Boxed

- Increases potential for inflammatory conditions like tendinitis
- Increases potential to develop nervous system damage resulting in neuropathy or negative central nervous system (CNS) effects

Sources: <https://www.rxlist.com/cipro-drug.htm>

https://www.accessdata.fda.gov/drugsatfda_docs/label/2005/019537s057,020780s019bl.pdf

Levothyroxine (Hypothyroidism)

Hypothyroidism is a disease commonly caused by autoimmune issues or radiation therapy. Levothyroxine has the same molecular structure as the hormone thyroxine, which the body produces. Thyroxine, or “T4” as it's commonly known, is secreted by the thyroid gland and regulates activity of various organs in the body. Levothyroxine is taken in pill form to treat hypothyroidism, a condition that's diagnosed by low levels of circulating thyroid hormone.

Why It's Black Boxed

- Consumers taking this drug off-label for weight loss may be at increased risk for a variety of ailments
- High doses may cause toxicity

Source: <https://online.epocrates.com/u/10b43/levothyroxine/Black+Box+Warnings>

Vicodin (Pain relief)

Vicodin is a synthetic drug formed by combining acetaminophen (the active ingredient in Tylenol) and hydrocodone, which is an extremely powerful opioid. It's commonly prescribed for pain relief after surgery, and even after less serious surgery like wisdom teeth removal.

Why It's Black Boxed

- Highly addictive
- Increased risk of respiratory depression
- Risk of fatalities from accidental consumption (especially in unaccompanied minors)
- Risk to fetus if taken during pregnancy
- Significantly increased risk of liver damage/failure

Source: <https://online.epocrates.com/u/10b1391/Vicodin/Black+Box+Warnings>

Zoloft (Depression)

Zoloft is an antidepressant in the category of selective serotonin reuptake inhibitors (SSRIs). These drugs work by blocking the uptake of serotonin in the brain, increasing circulating levels.

Why It's Black Boxed

- Increased risk of suicide in several demographics (children, adolescents, young adults)

Source: <https://online.epocrates.com/u/10b1444/Zoloft/Black+Box+Warnings>

Atenolol (High Blood Pressure)

Atenolol is a beta blocker drug. It works by blocking the release of epinephrine and other stimulatory chemicals in the body that raise blood pressure. Patients must avoid drinking alcohol when on atenolol and discontinue use after major surgery. Blood pressure needs to be monitored when using the drug.

Why It's Black Boxed

- Patients who discontinue use of atenolol abruptly are likely to get increased angina (chest pain) and arrhythmias

Source: <https://online.epocrates.com/drugs/15011/atenolol/Black-Box-Warnings>

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