



Pharmafactz

Clinical Pharmacy

Top List of Black Box Warnings!

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What are “black box warnings”?

A black box warning – often referred to as simply a “boxed warning” – is the strongest warning issued by the FDA in the United States on drugs that carry specific health risks – serious or life-threatening adverse effects.

When a black-box warning is issued, it informs healthcare providers and prescribers of serious [adverse effects of specific drugs](#) and enhances their clinical judgment. For example: when atypical antipsychotics were assigned a black box warning for use in patients with dementia (as it increases the risk of death) – prescription use of antipsychotics for this population declined thereafter.

The same is true for many other medicines, too. For instance, when the antidiabetic drug – rosiglitazone – was issued a black box warning, use of that medicine declined by almost three-quarters. Prescribers seek alternative medicine choices to reduce any potential risk to the affected population.

Here, we have put together a list of black-box warnings that both prescribers and pharmacists must know. Bear in mind that this is not intended to be a complete list of black box warnings.

List of Black Box Warnings!

Drug/Drug Class	Examples	Warning
Antipsychotics	Quetiapine Haloperidol Olanzapine Risperidone	Increased mortality in older patients with dementia-related psychosis.
Atypical antipsychotic	Clozapine	Agranulocytosis
Fluoroquinolones	Ciprofloxacin Moxifloxacin Levofloxacin	Increased risk of tendon rupture/damage. This risk is heightened in elderly patients, and in those who take corticosteroids.
SSRIs	Paroxetine Fluoxetine Sertraline	Increased risk of suicidal ideation, particularly in younger patients. Same risk with most other antidepressants, such as SNRIs.

Drug/Drug Class	Examples	Warning
	Fluvoxamine Escitalopram	
Antiarrhythmic	Amiodarone	Increased risk of pulmonary toxicity, hepatotoxicity, and heart block.
Antimalarials	Mefloquine	Increased risk of neuropsychiatric effects such as anxiety, depression, seizures, hallucinations, and loss of balance.
Monoclonal antibody	Natalizumab	Increased risk of progressive multifocal leukoencephalopathy (PML).
Progestins	Medroxyprogesterone	Reduced bone density, particularly in premenopausal women. This effect is reversible once the medicine is discontinued.
Fatty acids	Valproic acid	Hepatotoxicity Pancreatitis
Opioids	Oxycodone Morphine Hydrocodone Fentanyl	Risk of addiction, misuse, abuse. Life-threatening respiratory depression.
Long-acting beta-2 agonists	Formoterol Salmeterol	Increased risk of asthma-related death. Should be used in combination with an inhaled corticosteroid such as fluticasone or budesonide.
Sodium blockers	Carbamazepine Lamotrigine	Life-threatening skin reactions such as Stevens-Johnson syndrome, DRESS syndrome, and toxic epidermal necrolysis (TEN).
Direct thrombin inhibitor	Dabigatran	Blood clot formation that can cause permanent paralysis if the drug is injected into the patient's spinal/epidural area; or have a spinal puncture.
Xanthine oxidase inhibitor	Febuxostat	Increased risk of serious cardiovascular events.

Drug/Drug Class	Examples	Warning
Tyrosine kinase inhibitors	Nilotinib	Increased risk of QT prolongation.
Thiazolidinediones	Pioglitazone	Increased risk of heart failure.
Tetracyclines	Tigecycline	Increased risk of death when given IV for serious infections such as ventilator-associated pneumonia and complicated intra-abdominal infections.
IBS medicine	Linaclotide	Increased risk of serious dehydration in children under 6-years. Linaclotide should be avoided in 6-18 years, too.
Tyrosine kinase inhibitor	Cabozantinib	Holes forming in the stomach (GI perforation), as well as the risk of GI fistulas.

That's it for now! Check back to our pharmacy blog soon for even more exclusive content on the must-know facts about drugs and medicines!