

Black Box Warnings (BBW)

What are they?

A warning to alert of **POTENTIAL** major risks of medication or to communicate important instructions for safe use.

It is required to be on the medication by the Food and Drug Administration (FDA) if it carries safety risks.

Why is my child's doctor prescribing this?

The benefit they are getting from the medicine may be more important than the side effect.

Should I be worried?

Just because a medication or biologic product has a Black Box Warning does not mean it cannot be safely used in your child.

What are some drugs with BBW?

Drug	Warning
Ibuprofen®	Serious gastrointestinal bleed
Adderall®	High potential for abuse
Singulair®	Behavior and mood-related changes

Example of a BBW:



FDA "Black Box" Warning Label

The Food and Drug Administration (FDA) requires the following "black box" warning on all methylphenidate drugs, including Ritalin, which means that medical studies indicate Ritalin carries a significant risk of serious, or even life-threatening, adverse effects.

WARNING

RITALIN-SR IS A FEDERALLY CONTROLLED SUBSTANCE (CII) BECAUSE IT CAN BE ABUSED OR LEAD TO DEPENDENCE. KEEP RITALIN-SR IN A SAFE PLACE TO PREVENT MISUSE AND ABUSE. SELLING OR GIVING AWAY RITALIN-SR MAY HARM OTHERS, AND IS AGAINST THE LAW. TELL YOUR DOCTOR IF YOU OR YOUR CHILD HAVE (OR HAVE A FAMILY HISTORY OF) EVER ABUSED OR BEEN DEPENDENT ON ALCOHOL, PRESCRIPTION MEDICINES OR STREET DRUGS.

Why does the medication have this warning?

- A black box warning is only to alert you and your doctor to possible side effects. This side effect may be rare, or it may not apply to your child.
- An adverse reaction can be prevented or reduced in seriousness if the medication is used correctly.

What should I do if my child takes one of these medications?

- It is important that you understand the risks and the benefits of the medication.
- **IF** your child does experience an adverse event, parents are encouraged to report it to their doctor.



How do I know if my child's medication has a BBW?

- The doctor should talk with you and the patient about it before prescribing the medication.
- The text is surrounded by a black border and appears on the label of the drug, package insert and other patient information that describes the medication. See the example to the left.