



What is off-label medication use?

A medication may be effective in treating a single condition or multiple conditions. The medication ideally should be studied and approved for treatment of each condition.

Off-label medication use can be thought of in two broad categories:

1. A medication being used for a different condition than approved by Health Canada;
2. A medication used for a condition, but outside of certain specifications approved by Health Canada such as use of a different dosage, duration, route of administration or in a different age group (i.e. children and adolescents).



Why is off-label medication use common in children and adolescents?

Medications are often not studied in patients under 18 years of age for multiple reasons. Often, it is due to children and adolescents being excluded from medication studies as they may respond differently than adults due to their changing body composition, rapid periods of growth, and developing organ systems.

Health Canada does not regulate off-label medication use and places prescribing responsibility in the hands of your child's health care team. This highlights the importance of maintaining a consistent, open relationship with your child's doctor and health care team.

The Food and Drug Administration (FDA) is the medication approval agency in the United States, similar to Health Canada. Some medications, though not approved by Health Canada, have been studied and are approved by the FDA for use in children and adolescents.



Building a relationship with your child's health care team

Working together is essential for successful treatment of your child's condition. The health care team performs a detailed history and examination of your child to assess if he or she is at increased risk of side effects from medications. The team reviews current medication trials and practice guidelines for your child's condition. With your input, they weigh the potential benefits and risks of medication use.

Since there is less certainty about the benefits and risks with off-label medication use, careful monitoring of your child for signs of improvement and side effects during and after prescribing an off-label medication is necessary.

Questions you should feel comfortable asking your child's health care team



- Are there effective non-medication treatments for my child's condition?
- Why is an off-label medication recommended for my child?
- Has this medication been studied in children and adolescents?
- Is this medication commonly prescribed for children and adolescents?

Developed by the health care professionals of the Child & Adolescent Mental Health Programs and reviewed by the staff of the Kelty Resource Centre.