

Off-label Medication Use in children and adolescents

What is off-label medication use?

A medication can be effective in treating a single condition or multiple conditions. The medication ideally should be studied and approved for treatment of each condition. Health Canada approves medications for specific conditions, in certain ways.

If your child's doctor prescribes off-label medication use:

- The medication will be used for a condition other than those approved by Health Canada, *and/or*
- The medication will be used in ways other than those specifically approved by Health Canada. For example, at a different dose, duration, route of administration (by mouth, skin, injection), or in a different age group (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 several reasons. Often children and adolescents are not part of medication studies. They may respond to medication differently than adults because of their changing bodies, rapid 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. **It is very important to have 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 have been studied and are approved by the FDA for use in children and adolescents, even though they are not approved by Health Canada for this use.

Building a relationship with your child's health care team

- Your relationship with your child's health care team is an important part of your child's treatment. The health care team will ask about your child's history in detail, and examine your child to assess if they are at increased risk of side effects from medications. Your child's team also 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 information about the benefits and risks with off-label medication use, you and your child's health care team must monitor your child for signs of improvement and side effects during and after an off-label medication is prescribed.

Your child's health care team welcomes your questions.

Feel free to ask:

- 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?
- Or any other questions you might have