



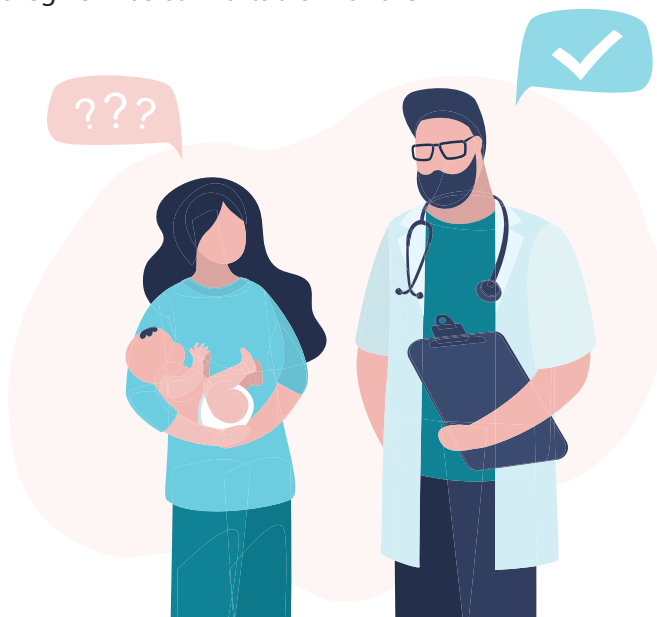
“Off-Label” Medication Use: What You Need to Know

The term “off-label” refers to the use of a medication that is different from what Health Canada has approved to be marketed in Canada. For example, when research shows that the benefits in using the medication in new ways outweighs the risks, prescribers may wish to provide this option to their patients. Off-label use includes prescribing a medication for a new health condition or for a different age group. Many medications are prescribed for children on an “off-label” basis because the medication was not well studied in this age group when it was originally approved. It is important to know when a medication is being used “off-label” and understand the risks and benefits of its use.

SafeMedicationUse.ca received a report describing an infant for whom a blood pressure medication was prescribed. The family caregiver felt uneasy about the prescription because they were aware that the medication had not been approved for use in infants. The caregiver asked questions to understand the benefits of using this medication in a very young patient, as well as the research supporting this off-label use. The medication was started only after the caregiver was comfortable with the information provided.

SafeMedicationUse.ca has the following tips to help consumers be better informed when a medication is prescribed for off-label use:

- Talk to your health care provider about the reasons for using any new medication.
- Use the [5 Questions to Ask](#) to better understand
 - how this medication compares with other treatment options;
 - the benefits and risks of using this medication, including the research that supports off-label use; and
 - any special instructions to follow or side effects to know about (the information about off-label use may not appear in the handout from your pharmacy or in product information found online).



This newsletter was developed in collaboration with Best Medicines Coalition and Patients for Patient Safety Canada.

Recommendations are shared with healthcare providers, through the ISMP Canada Safety Bulletin, so that changes can be made together.

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