

Guiding Principles for Assigning Auxiliary Labels for Outpatient Medications at BCCA

Methods

1. BCCA pharmacy practice leaders and the medication safety pharmacist developed the basic guiding principles for assigning auxiliary labels as follows:
 - a. Auxiliary label information enhances but does not replace patient handouts or verbal counselling.
 - b. A maximum of four auxiliary labels will be used due to container size limitation and to avoid alert fatigue.
 - i. Exceptions: additional labels may be affixed to a medication container:
 - for clinical trials drug requirements
 - as a one-time communication/reminder for indicating:
 - brand name change
 - returning unused medication to pharmacy
 - order of medication use e.g. “Use first”
 - c. A Hazardous Drug label will be affixed to all medications found on the BCCA Hazardous drug list once the policies at different Health Authorities have been harmonized (date to be announced). Details of safe handling and disposal would not be addressed by auxiliary labels. Rather, such information should be addressed by pharmacist counselling and a separate patient information handout on safe handling and disposal.
 - d. “Keep out of reach of children” auxiliary labels will not be used as this warning is universally implied with all medications.
 - e. The prioritization of auxiliary labels used will be ranked as follows:
 - i. Hazardous drugs
 - ii. Storage requirement – this is of immediate importance since it affects the drug’s potency
 - iii. Efficacy related issues including administration instructions (e.g., “Take with food”) and “Do not crush/chew” label for drugs with special formulations (e.g., sustained release or enteric coating)
 - iv. Toxicity related issues, including interactions, side effects, and pregnancy warning labels for drugs with mandated pregnancy monitoring programs (e.g., thalidomide)
 - v. Other clinically relevant warnings not addressed by previous categories
 - f. Each drug will be reviewed individually and variations to above prioritization may be made if clinically required.

2. Most common labels will be assigned as indicated below; other labels will be investigated as appropriate:

Label	Inclusion criteria
Hazardous	- Includes drugs listed as hazardous on BCCA Hazardous Drug list; pharmacist to counsel patient on hazard per patient safe handling handout
Biohazardous	- Includes drugs listed as biohazardous on BCCA Hazardous Drug list; pharmacist to counsel patient on biohazard per specific Cancer Drug Manual (CDM) patient handout and/or patient safe handling handout
Do not crush or swallow whole	- Includes drugs with a product characteristic such as enteric coating or modified release where crushing would destroy the integrity of the product, thus potentially affecting bioavailability - Excludes drugs with reasons solely related to safe handling (this warning will be addressed for hazardous drugs in the patient safe handling handout)
Plenty of water	- Includes drugs which are nephrotoxic or have specific recommendations for the consumption of large quantities of fluid (e.g., cyclophosphamide) - Excludes drugs reported solely to cause hyperuricemia or for those drugs recommended to administer with a "large" glass of water
Empty stomach	- Recommendation will reflect standardized definition of empty stomach: 1 h before meals and 2-3 h after meals as per standard label; therefore the clinical significance of nonstandard recommendations must be considered on a case by case.
Drowsiness, dizziness	- Includes drugs with strong cautions regarding somnolence or dizziness affecting functioning; where possible, inclusion is confirmed in the British National Formulary (BNF) - Excludes drugs solely with fatigue-related effects
Protect from sun	- Includes drugs with strong phototoxic reactions OR black box or other strong warnings; where possible, inclusion is confirmed in BNF
Alcohol	- Includes drugs with interactions with alcohol (e.g., disulfiram-like reaction with metronidazole) - Excludes drugs solely with additive dizziness/drowsiness
Grapefruit juice	- Includes drugs with evidence-based interactions: 1. listed in eCPS section on grapefruit interactions 2. with such caution in product monograph 3. neither 1 or 2, but reported as clinical cases in medical literature or accepted interaction database - Excludes those drugs with theoretical interactions solely based on CYP enzyme mechanisms (such as CYP 3A4)
Spacing of antacid	- Includes drugs with evidence-based interactions with antacids. Spacing will be standardized to two hours before or after the drug.
Avoid ASA	- Includes drugs with a documented ASA interaction only - Excludes drugs solely with platelet effects

Label	Inclusion criteria
Pregnancy	<ul style="list-style-type: none"> - Includes drugs with pregnancy monitoring programs (e.g., thalidomide, lenalidomide) mandated by Health Canada or the US Food and Drug Administration - Excludes drugs solely designated as pregnancy category X or with pregnancy cautions secondary to warnings of a class effect unless there is a mandated pregnancy monitoring program for the drug in question

3. Confirmation with other reference sources:

- a. cautions included in other reference sources (e-CPS, Lexicomp, etc.) but without supporting evidence in the CDM (or vice versa) will require further investigation on a case by case basis (see table below)

CDM	e-CPS	Label Recommended
Y	Y	Y
Y	–	investigate
–	Y	investigate
–	–	N