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Notice

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Release of the Updated Guidance Document: *Bulk Forming Laxatives - Labelling Standard*

The updated Therapeutic Products Directorate (TPD) Guidance Document, *Bulk Forming Laxatives - Labelling Standard* is now available.

This labelling standard replaces the 1994 version of *Bulk Forming Laxatives - Labelling Standard*. With the coming-into-force of the *Natural Health Products Regulations* in 2004, several products previously regulated as pharmaceutical drugs are now classified as natural health products (NHPs). In updating this labelling standard, ingredients which are no longer considered to be pharmaceuticals (for example, bran, cellulose, karaya, malt soup extract, and psyllium ingredients) were removed. These ingredients are now regulated NHPs. Although sodium carboxymethylcellulose is still regulated as a pharmaceutical, this listing was also removed since no reference for its current use as a laxative could be found in Health Canada's internal database. Lastly, language in the "warnings" and "usual claims" sections of the *Bulk-Forming Laxatives - Labelling Standard* was revised for greater clarity.

This labelling standard is effective immediately.

For questions or comments regarding the content of the guidance, please contact:

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BULK-FORMING LAXATIVES - LABELLING STANDARD

NOTE: In the case of applications for drugs which fit the criteria of this labelling standard, it is not necessary to conduct an assessment to determine if bioequivalence, pharmacodynamic/clinical studies or pharmaceutical equivalence data must be submitted.

Active Ingredients

- Methylcellulose
- Polycarbophil

Bulk-Forming Action: Increases bulk and amount of water in the stool, making it softer and easier to pass.

Usual Claims:

- Gentle relief of occasional constipation;
- Promotes bowel movement by increasing bulk volume and water content;
- Bulk-forming laxative;
- To relieve irregularity.

Warnings:

- Do not use in the presence of abdominal pain, nausea, fever or vomiting (this refers to signs of appendicitis or inflamed bowel).
- Do not take any type of laxative for more than one (1) week, unless your physician has ordered a special schedule for you.
- A laxative should not be taken within two (2) hours of another medicine because the desired effect of the other medicine may be reduced.

Directions:

1. Drink a full glass (250 mL or 8 ounces) of water with each dose.
2. Produces bowel movement in 12 to 72 hours (3 days).
3. Do not swallow in dry form.

Note: This labelling standard only describes some requirements that are specific to this class of drugs. Manufacturers are also responsible for adhering to applicable requirements in the *Food and Drugs Act, Food and Drug Regulations*, and associated guidance documents.

Dosage: Children under 2 years - consult physician

Ingredients	Adult to 12 years.	Children 6 to 12 years	Children 2 to 6 years
Methylcellulose	4 to 6 grams (max/day) 0.45 - 3 grams/dose	3 grams (max/day) 1 to 1.5 grams/dose	consult physician
Polycarbophil	4 grams (max/day) 1 gram/dose	2 grams (max/day) 0.5 grams/dose	1 gram (max/day) 0.5 grams/dose