

PUBLIC COMMUNICATION
Health Canada Endorsed Important Safety Information on
Maalox® Multi Action (bismuth subsalicylate)



May 17, 2010

Subject: *Maalox Multi Action* (bismuth subsalicylate) and confusion with other *Maalox* liquid products

Novartis Consumer Health Canada Inc., in consultation with Health Canada, would like to bring to your attention important safety information about the differences between our product *Maalox Multi Action* and other Maalox liquid products. It is important to know that *Maalox Multi Action* and other Maalox liquid products have similar names, labels and packaging, but contain very different ingredients.

Maalox Multi Action contains bismuth subsalicylate, which is related to acetylsalicylic acid (ASA). The unintentional use of bismuth subsalicylate by some people taking certain medicines or who have certain health conditions, could cause serious side effects. For example, people taking medicine for thinning the blood have an increased risk of bleeding if taking *Maalox Multi Action*.

There have been Canadian reports of serious adverse events that have been reported in patients using *Maalox Multi Action* instead of other Maalox liquid products.

Maalox Multi Action and other Maalox liquid products have similar names, labels and packaging, which if confused, have the potential to cause serious side effects.

Maalox Multi Action and other Maalox liquid products contain different ingredients and are not interchangeable.

In particular, *Maalox Multi Action* contains bismuth subsalicylate which is related to ASA.

Maalox Multi Action is not recommended for:

- people with stomach ulcers, bleeding disorders or allergies to acetylsalicylic acid (ASA)
- pregnant women
- children and teenagers with a recent viral infection such as chicken pox
- people taking certain medicines for diabetes, gout or arthritis, or medicine for thinning the blood
- people taking medicines that contain ASA.

Patients should check with their doctor or pharmacist if they are unsure of which Maalox product to use.

Maalox Multi Action contains bismuth subsalicylate. It is used to relieve upset stomach and diarrhea. All other Maalox liquid products are used as antacids and contain aluminum or magnesium hydroxide, calcium or magnesium carbonate, plus simethicone for relief of gas or sodium alginate for relief of acid reflux.

When selecting a Maalox liquid product, consumers should read product labels carefully, including warnings, to ensure that they choose the appropriate Maalox liquid product for their specific condition.

Ask your doctor or pharmacist for help if you are unsure.

Novartis Consumer Health Canada Inc. is working with Health Canada to change the name, label and packaging of *Maalox Multi Action* to make the product differences more easily understood.

Managing marketed health product-related adverse reactions depends on health care professionals and consumers reporting them. Reporting rates determined on the basis of spontaneously reported post-marketing adverse reactions are generally presumed to underestimate the risks associated with health product treatments. Any case of serious or unexpected adverse reactions in patients receiving any Maalox liquid product should be reported to Novartis Consumer Health Canada Inc. or Health Canada at the following addresses:

Novartis Consumer Health Canada Inc.
2233 Argentia Road, Suite 205, West Tower
Mississauga, ON, L5N 2X7
Telephone: 1-888-788-8181

Any suspected adverse reaction can also be reported to:

Canada Vigilance Program
Marketed Health Products Directorate
HEALTH CANADA
Address Locator: 0701D
Ottawa, Ontario, K1A 0K9
Tel: 613-957-0337 or Fax: 613-957-0335
CanadaVigilance@hc-sc.gc.ca

To report an Adverse Reaction, consumers and health professionals may call toll free:
Telephone: 1-866-234-2345
Fax: 1-866-678-6789

Postage paid labels, Canada Vigilance Reporting Forms and the Adverse Reaction Reporting Guidelines can be found on the MedEffect™ Canada Web site in the [Adverse Reaction Reporting](#) section. The Reporting Form is also in the *Canadian Compendium of Pharmaceuticals and Specialties*.

For other health product inquiries related to this communication, please contact Health Canada at:

Marketed Health Products Directorate (MHPD)
MHPD_DPSC@hc-sc.gc.ca
Telephone: 613-954-6522
Fax: 613-952-7738

Should you have any questions regarding the use of *Maalox Multi Action* or any other Maalox liquid product, please contact Novartis Consumer Health Canada Inc. at the address or telephone number listed above.