



LUBRICANT LAXATIVES

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.

Medicinal Ingredients

- Mineral Oil (Heavy)

Lubricant Action: An agent that lubricates the contents of the intestinal tract, thereby promoting bowel movement.

Usual Claims:

- lubricant laxative
- for relief of occasional constipation

Warnings: As for all classes.

Directions:

1. Oral dosage form produces results in 6 to 8 hours.
2. Rectal dosage form produces results in 2 to 15 minutes.
3. Commonly administered at bedtime.

NOTE: This labelling standard describes those requirements that are specific to this class of drugs. Other requirements described in the **Regulations to the Food and Drugs Act** and in the **Guide for the Labelling of Drugs for Human Use** should also be met.

Dosage:

Children under 6 years - consult physician

<u>Ingredients</u>	<u>Adult to 12 years</u>	<u>Maximum</u>	<u>Children 6 to 12 years</u>
Mineral Oil (Oral)	15 ml	45 ml	5 to 15 ml

Children under 2 years - consult physician

<u>Ingredients</u>	<u>Adult to 12 years</u>	<u>Maximum</u>	<u>Children 2 to 12 years</u>
Mineral Oil (Rectal)	120 ml	single dose	60 ml

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