SIMETICONE

RESTIME®

40mg/mL Suspension (Oral Drops)

Gastrointestinal Drug (Antiflatulent)

FORMULATION
Each mL suspension (oral drops) contains:
Simeticone, USP..... 40 mg

PRODUCT DESCRIPTION
Simeticone (Restime®) Suspension (Oral Drops) is a thick, reddish-pink suspension with fru strawberry odor, and sweet strawberry flavor.

WHAT IS IN THE MEDICINE?
This product contains simeticone, a water-repellant that relieves bloating and gassiness by lowering surface tension of gas bubbles in the gastrointestinal (GI) tract leading them to coalesce and be expelled.

STRENGTH OF THE MEDICINE
Please see ***formulation.***

WHAT IS THE MEDICINE USED FOR?
• This medicine is used to relieve discomfort due to the accumulation of gas in the stomach and intestines including sensations of bloating, pressure, fullness or stuffed feeling which can be caused certain food (e.g., carbonated drinks, legumes, potatoes, infant formula, etc.), air swallowing, and dyspeps

• For the relief of symptoms of excess gas associated with colic.

HOW MUCH AND HOW OFTEN SHOULD YOU USE THIS MEDICINE?
Shake well before use.

Age	Recommended Dose (Orally, 4 times daily, given after meals and at bedtime)
Birth to under 2 years	20 mg (0.5 mL)
2 to 12 years	40 mg (1 mL)
	Or, as prescribed by a physician.

• Fill enclosed dropper to recommended dosage level and dispense slowly into the baby's mouth, toward the inner cheek.

WHEN SHOULD YOU NOT TAKE THIS MEDICINE?
If the child is allergic to simeticone or any ingredient in the product.

UNDESIRABLE EFFECTS
There have been no reports of undesirable effects after ingestion of simeticone. A very severe allergic reaction is rare. However, if you notice any undesirable effects, consult your doctor immediately.

WHAT OTHER MEDICINE OR FOOD SHOULD BE AVOIDED WHILE TAKING THIS MEDICINE?
Reduce air swallowing by avoiding fizzy, carbonated drinks, and food that may increase gas in the stomach.

WHAT SHOULD YOU DO IF YOU MISS A DOSE?
If you miss a dose, just take the next dose if still needed for the condition being treated and the subsequent doses at the recommended time or schedule.

HOW SHOULD YOU KEEP THIS MEDICINE?
Keep the product out of reach and sight of children.
Store at temperatures not exceeding 30°C.

SIGNS AND SYMPTOMS OF OVERDOSAGE
There have been no cases of overdosage reported with simeticone use. If overdosage is suspected, consult a doctor immediately.

WHAT TO DO IF YOU HAVE TAKEN MORE THAN THE RECOMMENDED DOSAGE?
If you have taken more than the recommended dosage, consult a doctor.

CARE THAT SHOULD BE TAKEN WHEN TAKING THIS MEDICINE?
• Take the medicine after meals and at bedtime for best results.
• Do not take more than the recommended dose.
• Do not use after the expiry date on the label.

WHEN SHOULD YOU CONSULT YOUR DOCTOR?
• If any undesirable effect occurs.
• If symptoms persist.

AVAILABILITY
Simeticone (Restime®) Suspension (Oral Drops) in amber bottle of 10 mL.

ADVERSE DRUG REACTION REPORTING STATEMENT
For suspected adverse drug reaction, seek medical attention immediately and report to the FDA at www.fda.gov.ph **AND** Unilab at (+632) 858-1000 or productsafety@unilab.com.ph. By reporting undesirable effects, you can help provide more information on the safety of this medicine.

DATE OF FIRST AUTHORIZATION: January 2011
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