

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 pink suspension, strawberry odor and 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 MEDICINEPlease see **Formulation**.**WHAT IS THIS 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 by certain food (e.g., carbonated drinks, legumes, potatoes, infant formula, etc.), air swallowing, and dyspepsia.
- For the relief of symptoms of excess gas associated with colic.

HOW MUCH AND HOW OFTEN SHOULD YOU USE THIS MEDICINE?

- This medicine should be taken orally (by mouth) 4 times a day after meals and at bedtime.
- Fill enclosed dropper to recommended dosage level and dispense slowly into the baby's mouth.
- SHAKE WELL BEFORE USE.

Birth to <2 years old: 20 mg (0.5 mL)Children 2 to 12 years old: 40 mg (1 mL)

Or, as recommended by a doctor.

WHEN SHOULD YOU NOT TAKE THIS MEDICINE?

If the child is allergic to simeticone or to 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.

Do not double the dose.

HOW SHOULD YOU KEEP THIS MEDICINE?

Store at temperatures not exceeding 30°C.

Keep the product out of sight and reach of children.

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 WHEN 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 effects occur
- If symptoms persist

AVAILABILITY**Simeticone (Restime®) Suspension (Oral Drops)**

(DRP-9898) in amber bottle of 10 mL

For suspected adverse drug reaction, seek medical attention immediately and report to the FDA at www.fda.gov.ph AND Unilab at +632-8-**UNILAB**-1 (+632-8-**864522**-1) for Metro Manila or toll-free +1-800-10-UNILAB-1 for provinces, or e-mail 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**DATE OF REVISION OF PATIENT INFORMATION LEAFLET:** April 2021 (CCDS 17-034)

Manufactured by

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