PACKAGE INSERT TEMPLATE FOR SIMETHICONE TABLET/CAPSULE

Brand or Product Name
[Product name] Tablet….mg
[Product name] Capsule….mg

Name and Strength of Active Substance(s)
Simethicone…. mg

Product Description

[Visual description of the appearance of the product (eg colour, markings etc)
eg White to slightly yellowish biconvex tablets marked '40' on one side

Pharmacodynamics

Simethicone is liquid dimethicone activated with finely divided silicon dioxide to enhance the defoaming properties of the silicone.
Simethicone acts by decreasing the surface tension of gas bubbles, thus facilitating their coalescence and expulsion as flatus or belching.
It also prevents the formation and accumulation of mucus-enclosed pockets of gas in digestive tract.
Simethicone facilitates the passage of gas through bowel lumen and allows patients to excrete a greater volume of gas at one time, thereby reducing the number of flatus events. Thus, less residual gas is present to cause uncomfortable or painful pressure in the stomach and intestines.

Pharmacokinetics

Simethicone is pharmacologically inert and is not absorbed from the gastrointestinal tract nor does it interfere with gastric secretion or absorption of nutrients. Following oral administration, the drug is excreted in faeces unchanged.

Indication

Indicated for the relief of discomfort and pain caused by excessive gas in the stomach and intestines in conditions such as flatulence and post operative gaseous distention.

To eliminate gas, air and foam from the gastrointestinal tract prior to endoscopic examination to enhance visualization and prior to radiography examination to reduce gas shadows

Recommended Dosage

Adults

40 to 125 milligrams (40-360mg for extensive upper gastrointestinal gas) four times a day

The maximum daily dose of simethicone (unless otherwise directed by physician) should be limited to 480 - 500 milligrams

To be taken after meals and at bedtime.

Paediatrics

2-12 yrs: 40 mg ORALLY 4 times daily after meals and at bedtime; maximum 240 mg/day

Chewable tablets
Chew the tablets thoroughly before swallowing to enable the medicine to work faster and more completely.

Mode of Administration
Oral

Contraindications
Hypersensitivity to simethicone
Known or suspected intestinal perforation and obstruction

Warnings and Precautions

Do not exceed recommended dosage
Should relief not be obtained (especially in children), kindly consult a doctor/pharmacist.

Interactions with Other Medicaments

Simethicone reduces the bioavailability of phenytoin slightly; take simethicone 2 hours before or after phenytoin.

Concomitant use of levothyroxine and simethicone may decrease levothyroxine efficacy by binding to and delaying or preventing levothyroxine absorption, potentially resulting in hypothyroidism. If concurrent use of levothyroxine and simethicone is required, administration of these agents should be separated by at least 4 hours

Statement on Usage During Pregnancy and Lactation

Pregnancy
Fetal risk is minimal when used in pregnant women or women of childbearing potential.

Lactation
Infant risk cannot be ruled out.
Available evidence and/or expert consensus are inconclusive or are inadequate for determining infant risk when used during breastfeeding. Weigh the potential benefits of drug treatment against potential risks before prescribing this drug during breastfeeding.

Adverse Effects / Undesirable Effects

Although oral administration of simethicone is generally well tolerated when used as directed, the following adverse reactions have been observed on rare occasions: diarrhea (mild), nausea, regurgitation, vomiting, bloating, heartburn, and constipation

Overdose and Treatment

As simethicone is not absorbed into the body there is no likelihood of an overdose

Storage Conditions
[e.g. Store below….°C]

Dosage Forms and Packaging Available
[Packaging type & pack size]

Name and Address of Manufacturer
[Name & full address of manufacturer]

Name and Address of Marketing Authorization Holder
[Name & full address of marketing authorization holder]

Date of Revision of Package Insert
[day/month/year]