

## Summary of Product Characteristics

### 1 NAME OF THE MEDICINAL PRODUCT

IMOGAS 240 mg, soft capsule

### 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule contains  
Simeticone 240.00 mg

For a full list of excipients, see section 6.1.

### 3 PHARMACEUTICAL FORM

Soft capsule.  
Egg-shaped transparent soft capsule.

### 4 CLINICAL PARTICULARS

#### 4.1 Therapeutic Indications

Symptomatic treatment of abdominal distension (flatulence) in adults and adolescents (from the age of 15 years).

#### 4.2 Posology and method of administration

Oral use.  
Reserved for use in adults (from the age of 15 years).  
Take one capsule at the end of each main meal with a glass of water.  
Do not exceed 3 soft capsules per day.  
The duration of treatment is restricted to 10 days.

#### 4.3 Contraindications

Hypersensitivity to simeticone or to any of the excipients listed in section 6.1.

#### 4.4 Special warnings and precautions for use

If the symptoms persist or worsen, or in the event of prolonged constipation, the patient should seek medical advice.  
Simeticone is not recommended for the treatment of infant colic because of limited information on its safety in infants and children.

#### 4.5 Interaction with other medicinal products and other forms of interaction

Interaction studies have not been performed.

#### 4.6 Fertility, pregnancy and lactation

For simeticone no clinical data on exposed pregnancies are available. Animal studies are insufficient with respect to toxicity to reproduction (see section 5.3).

No effect during pregnancy is anticipated since systemic exposure to simeticone is negligible. Imogas can be used during pregnancy.

No effect on the breastfed newborn/infant is anticipated since the systemic exposure of the breastfeeding woman to simeticone is negligible. Imogas can be used during breast-feeding.

#### 4.7 Effects on ability to drive and use machines

Simeticone has no or negligible influence on the ability to drive and use machines

#### 4.8 Undesirable effects

Adverse drug reactions (ADRs) identified during post-marketing experience with simeticone are presented in the table below, the frequencies are provided according to the following convention:

Very common  $\geq 1/10$

Common  $\geq 1/100$  and  $< 1/10$

Uncommon  $\geq 1/1,000$  and  $< 1/100$

Rare  $\geq 1/10,000$ , and  $< 1/1,000$

Very rare  $< 1/10,000$

Not known cannot be estimated from the available data

System Organ Class	Frequency	Adverse Reaction
Gastro-Intestinal Disorders	Not known	Nausea Vomiting Constipation Abdominal Pain
Skin and subcutaneous Disorders	Not known	Angioedema Rash Pruritus
Immune System Disorders	Not known	Hypersensitivity reactions such as face oedema and dyspnoea

#### **Reporting of suspected adverse reactions**

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: [www.hpra.ie](http://www.hpra.ie); E-mail: [medsafety@hpra.ie](mailto:medsafety@hpra.ie).

#### 4.9 Overdose

No case of overdose has been reported.

### 5 PHARMACOLOGICAL PROPERTIES

#### 5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Other medicinal products for functional bowel disorders, ATC Code: AO3AX13 (silicones)

Simeticone is a physiologically inert substance, which is therefore pharmacologically inactive. It acts by modifying the surface tension of gas bubbles, thus causing their coalescence.

#### 5.2 Pharmacokinetic properties

Following oral administration, simeticone is not absorbed and passes through the digestive tract before being excreted in an unchanged form.

Bioavailability:  
Simeticone is not absorbed.

### **5.3 Preclinical safety data**

There are no preclinical data considered relevant to clinical safety other than data included in other sections of the SPC. Simeticone is chemically inert and is not absorbed systemically. Systemic toxic effects are therefore unlikely.

## **6 PHARMACEUTICAL PARTICULARS**

### **6.1 List of excipients**

Gelatine  
Glycerol

### **6.2 Incompatibilities**

Not applicable.

### **6.3 Shelf life**

3 years

### **6.4 Special precautions for storage**

This medicinal product does not require any special storage conditions.

### **6.5 Nature and contents of container**

10, 20 or 30 soft capsules in heat-formed blister strips (PVC/PVDC/Aluminium).  
Not all pack sizes may be marketed.

### **6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product**

Any unused product or waste material should be disposed of in accordance with local requirements.

## **7 MARKETING AUTHORISATION HOLDER**

McNeil Healthcare (Ireland) Limited  
Airton Road  
Tallaght  
Dublin 24  
Ireland

## **8 MARKETING AUTHORISATION NUMBER**

PA 0823/065/001

## **9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

Date of first authorisation: 1<sup>st</sup> June 2007

Date of last renewal: 26<sup>th</sup> December 2010

**10 DATE OF REVISION OF THE TEXT**

September 2014