SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

<Trade Name> <Strength>

1. QUALITATIVE AND QUANTITATIVE COMPOSITION

Activated charcoal powder, 100%

1. PHARMACEUTICAL FORM

Powder

1. CLINICAL PARTICULARS
   1. Therapeutic indications

The symptomatic relief of indigestion, wind, heartburn, dyspepsia, and flatulence.

* 1. Posology and method of administration

Dosage

*Adults, including Elderly and Children over 12 years:*

A teaspoonful of powder mixed into a glass of water taken 3 times a day. Take before or after meals.

*Children under 12 years:* Not recommended.

* 1. Contraindications

Hypersensitivity to the active substance, activated charcoal.

* 1. Special warnings and precautions for use

If taking other medication, consult a pharmacist or doctor before taking activated charcoal powder.

* 1. Interaction with other medicinal products and other forms of interaction

If taking other medication, consult a pharmacist or doctor before taking activated charcoal powder.

Activated charcoal is a powerful adsorbent and may reduce the effect of other medicines.

* 1. Fertility, pregnancy and lactation

activated charcoal powder may be used during pregnancy or breast- feeding.

* 1. Effects on ability to drive and use machines

activated charcoal powder has no influence on the ability to drive and use machines.

* 1. Undesirable effects

Regular use may cause a darkening of the stools.

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 Health Product Vigilance Center; HPVC Thai FDA.

* 1. Overdose

With overdose discontinue medication

1. PHARMACOLOGICAL PROPERTIES
   1. Pharmacodynamic properties

*Pharmacotherapeutic group:* Alimentary Tract and Metabolism

ATC code: A07BA01

Traditionally used to adsorb gastro-intestinal gases, thus relieving the discomfort caused by indigestion, flatulence, dyspepsia, wind and heartburn.

* 1. Pharmacokinetic properties

None available.

* 1. Preclinical safety data

None available.

1. PHARMACEUTICAL PARTICULARS
   1. List of excipients

<Regarding the approval>

* 1. Incompatibilities

None Known.

* 1. Shelf life

<Regarding the approval>

* 1. Special precautions for storage

<Regarding the approval>

* 1. Nature and contents of container

<Regarding the approval>

* 1. Special precautions for disposal

<Regarding the approval>

1. MARKETING AUTHORISATION HOLDER

<Regarding the approval>

1. MARKETING AUTHORISATION NUMBER(S)

<Regarding the approval>

1. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

<Regarding the approval>

1. DATE OF REVISION OF THE TEXT1

<Regarding the approval>