SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

<Trade Name> <Strength>

1. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 128 ml enema contains:

Sodium dihydrogen phosphate dihydrate 10% w/v

Disodium phosphate dodecahydrate 8% w/v

Excipient(s) with known effect:

<Regarding the approval>

For a full list of excipients, see section 6.1.

1. PHARMACEUTICAL FORM

Rectal solution

<Regarding the approval>

1. CLINICAL PARTICULARS
   1. Therapeutic indications

Routine treatment of constipation. Pre-and post-operative cleansing of the bowel, in obstetrics and prior to proctoscopy, sigmoidoscopy or X- ray examination.

* 1. Posology and method of administration

Adults including the elderly

1 enema as required.

Children over 3 years of age

Reduce adult dosage in proportion to body weight.

Children under 3 years of age

Not recommended.

For rectal administration only. The enema may be administered at room temperature or warmed in water before use.

* 1. Contraindications

Hypersensitivity to any of the constituents. Use in patients with inflammatory or ulcerative conditions of the large bowel, in those with increased colonic absorptive capacity e.g. Hirschsprung’s disease and in those with acute gastrointestinal conditions.

* 1. Special warnings and precautions for use

Prolonged use may lead to irritation of the anal canal. Use with caution in patients requiring a reduced sodium intake and electrolyte balance should be maintained during extended use. Use with caution in patients with intestinal obstruction. Care should be taken not to use undue force in administration of the enema especially in the elderly or debilitated patients or those with neurological disorders.

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

None known.

* 1. Fertility, pregnancy and lactation

No special warnings.

* 1. Effects on ability to drive and use machines

Not applicable.

* 1. Undesirable effects

Local irritation. There have been occasional reports of apparent vasovagal attacks occurring in elderly patients following administration of phosphate enemata.

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

There have been no cases of overdosage. In the event of overdosage, electrolyte levels should be monitored and balance restored where appropriate.

1. PHARMACOLOGICAL PROPERTIES
   1. Pharmacodynamic properties

<Trade Name> enema is a solution of sodium dihydrogen phosphate dihydrate and disodium phosphate dodecahydrate. The formulation is equivalent to phosphates enema BP Formula B. Following rectal administration the active ingredients exert their laxative effect via their osmotic properties. The resulting fluid retention in the bowel encourages evacuation.

* 1. Pharmacokinetic properties

Saline laxatives are poorly and slowly absorbed following rectal administration. Under normal usage only minimal absorption is likely to occur.

* 1. Preclinical safety data

There are no preclinical data of relevance to the prescriber which are additional to that already included in other sections of the SPC.

1. PHARMACEUTICAL PARTICULARS
   1. List of excipients

<Regarding the approval>

* 1. Incompatibilities

Not applicable.

* 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>