1.3.1.1 PROFESSIONAL INFORMATION FOR MEDICINES FOR HUMAN USE

SCHEDULING STATUS

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PROPRIETARY NAME AND DOSAGE FORM

GASTROPECT (suspension)

COMPOSITION

Each 5 ml of GASTROPECT contains 1 g of kaolin light and 0,05 g of pectin.

Excipients:

Flavour rich creamy toffee, Nipasept, purified water, saccharin sodium, sucrose

Preservative:

Nipasept 0,14 % *m/v*

Contains sugar: Sucrose 267,50 mg

Contains sweetener: Saccharin sodium 1,25 mg

CATEGORY AND CLASSh

A 11.9 Antidiarrhoeals

PHARMACOLOGICAL ACTION

Pharmacodynamic properties

Kaolin and pectin have adsorbant properties.

INDICATIONS

As adjunct to rest, fluids and appropriate diet in the symptomatic treatment of mild to moderately acute diarrhoea.

CONTRAINDICATIONS

GASTROPECT suspension should not be given to patients with intestinal obstruction, and patients with spastic bowel conditions.

WARNINGS AND SPECIAL PRECAUTIONS

The absorption of other medicines from the gastrointestinal tract can be reduced if administered concomitantly.

Excipients

Sucrose warning:

GASTROPECT contains sucrose which may have an effect on the glycaemic control of patients with diabetes mellitus.

Patients with rare hereditary conditions such as fructose intolerance, glucose-galactose mal-absorption or sucrase-isomaltase insufficiency should not take GASTROPECT.

INTERACTIONS

The absorption of other medicines from the gastrointestinal tract can be reduced if administered concomitantly.

HUMAN REPRODUCTION

Not known.

DOSAGE AND DIRECTIONS FOR USE

Adults:

5 to 10 medicine measures (25 ml to 50 ml) 3 to 4 times daily.

Children:

- **12 years and over:** 5 medicine measures (25 ml) 3 to 4 times daily.
- **6 to 12 years:** 2,5 to 5 medicine measures (12,5 ml to 25 ml) 3 to 4 times daily.
- **3 to 6 years:** 1 to 2,5 medicine measures (5 ml to 12,5 ml) 3 to 4 times daily.

SHAKE THE BOTTLE BEFORE USE.

If the symptoms persist for longer than 48 hours or the condition of the patient deteriorates, the product must be discontinued and a doctor consulted.

In the treatment of diarrhoea it is important that hydration be maintained by administering adequate fluid and electrolytes.

SIDE EFFECTS

Constipation may occur.

Pectin may temporarily increase flatulence and distension, and intestinal obstruction has been reported after administration.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENTS

See SIDE EFFECTS and WARNINGS AND SPECIAL PRECAUTIONS.

Treatment is symptomatic and supportive.

IDENTIFICATION

A pale cream suspension, with a creamy toffee odour.

PRESENTATION

100 ml or 200 ml are packed into an amber polyvinylchloride bottle sealed with a white low density polyethylene snap cap.

2,5 L is packed into a green coloured high density polyethylene tamper evident can sealed with a white linear low density polyethylene tamper evident screw cap.

Not all packs and pack sizes are necessarily marketed.

STORAGE INSTRUCTIONS

Store at or below 25 °C.

Keep in original packaging until required for use.

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER

E/11.9/1546

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION

PHARMACARE LIMITED

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DATE OF PUBLICATION OF THE PROFESSIONAL INFORMATION FOR MEDICINES FOR HUMAN USE

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