1.3.2 PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

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PROPRIETARY NAME AND DOSAGE FORM

GASTROPECT

Suspension

Read all of this leaflet carefully because it contains important information for you

GASTROPECT is available without a doctor's prescription, for you to treat a mild illness.

Nevertheless you still need to use GASTROPECT carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share GASTROPECT with any other person.
- Ask your pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve after 48 hours.

WHAT GASTROPECT CONTAINS

The active substances in each 5 ml of GASTROPECT is 1 g of kaolin light and 0,05 g of pectin.

The other ingredients are flavour rich creamy toffee, Nipasept, purified water, saccharin sodium and sucrose.

Preservative:

Nipasept 0,14 % *m/v*

Contains sugar: Sucrose 267,50 mg

Contains sweetener: Saccharin sodium 1,25 mg

WHAT GASTROPECT IS USED FOR

GASTROPECT is used as an extra treatment to rest, fluids and an appropriate diet in the treatment of the symptoms of mild to moderate diarrhoea.

BEFORE YOU TAKE GASTROPECT

The following must be considered before taking this medicine:

- *Children:* As diarrhoea can cause fluid loss, a severe condition can arise. Therefore, for children under 3 years of age a doctor should be consulted. In older children antidiarrhoeals can be given, but ensure that adequate amounts of fluid are taken to replenish the fluid loss by the body due to the diarrhoea. If at any time you are unsure, please contact your doctor, pharmacist or healthcare provider for further advice.
- *Adults:* In older adults the loss of fluid due to diarrhoea can be very severe, and in addition to using an antidiarrhoeal the patient should also maintain an adequate fluid intake.
- The presence of other medical problems may affect the use of this product, as is in the case of dysentery - if this condition gets worse, a different kind of treatment may be needed. Make sure you tell your doctor, pharmacist or health care provider of these problems, so they can advise you on what to do.

Pregnancy and breastfeeding

GASTROPECT is not absorbed into the body and should therefore not cause any problems.

Always tell your healthcare provider if you are taking any other medicine. If you are pregnant

or breastfeeding your baby, please consult your healthcare provider for advice before taking GASTROPECT.

Important information about some of the ingredients in GASTROPECT

GASTROPECT contains sucrose which may have an effect on the control of your blood sugar if you have diabetes mellitus.

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking GASTROPECT.

Taking other medicines with GASTROPECT

Always tell your healthcare provider if you are taking any other medicines (this includes complementary or traditional medicines).

HOW TO TAKE GASTROPECT

Do not share medicines prescribed for you with any other person.

REMEMBER TO SHAKE THE BOTTLE BEFORE USING THE MEDICINE.

The usual dose is:

For adults: 5 to 10 medicine measures (25 ml to 50 ml) 3 to 4 times a day.

For children:

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

If the symptoms continue for longer than 2 days (48 hours) or if your condition gets worse, do not continue to take this product, and consult your doctor immediately.

It is important to remember to replace the fluid lost by the body and to maintain an adequate diet in addition to taking this medicine. During the first 24 hours you should drink plenty of clear liquids and during the next 24 hours you may eat bland food such as cooked cereals, bread or crackers. Until your condition improves, avoid fruits, vegetables, fried or spicy foods, bran, candy, caffeine or alcoholic beverages as these may worsen your condition.

If you do not drink enough liquid to replace the fluid you are losing while you have the diarrhoea, a serious condition may arise. Check with your doctor immediately if any of the following symptoms occur: a decreased passing of urine, dizziness or lightheadedness, dryness of the mouth, an increased thirst or a wrinkled skin.

If you take more GASTROPECT than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

POSSIBLE SIDE EFFECTS

- Constipation may occur and the pectin in GASTROPECT can temporarily cause swelling of the stomach and an increase in the amount of air/gas in the stomach.
- Blocking of the intestine may also occur after taking GASTROPECT.

Not all side effects reported for GASTROPECT are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking GASTROPECT, please consult your healthcare provider for advice.

STORING AND DISPOSING OF GASTROPECT

Store at or below 25 °C.

Keep in original packaging until required for use.

Do not store in a bathroom.

Do not use after the expiry date stated on the label.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

PRESENTATION OF GASTROPECT

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.

IDENTIFICATION OF GASTROPECT

A pale cream suspension, with a creamy toffee odour.

REGISTRATION NUMBER

E/11.9/1546

NAME, BUSINESS ADDRESS AND TELEPHONE NUMBER OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION

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