

PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986

The medicine is dispensed without a doctor's prescription.

ENCYPALMED

Enteric-coated dragees for the regulation of digestive disturbances

Active ingredients in each dragee:

| | |
|-------------------------------|-------|
| Pancreatin (contains Lactose) | 72 mg |
| Ox bile extract | 35 mg |

For the inactive ingredients in the preparation – see section 6 "Further Information".

Read this leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist. Take the medicine in the correct manner.

1. WHAT IS THE MEDICINE INTENDED FOR?

The medicine is intended for regulation of digestive disturbances.

Therapeutic group: Digestive enzymes and bile salts.

2. BEFORE USING THE MEDICINE

☒ Do not use the medicine:

- if you are sensitive (allergic) to the active ingredients or any of the additional ingredients contained in the medicine or to animal proteins.
- in case of abdominal pains, nausea, vomiting or other signs of appendicitis.
- when suffering from acute pancreatitis.

Special warnings regarding use of this medicine

- Patients on a low-salt diet must consult a doctor before using this medicine.
- Do not use this medicine frequently or for a prolonged period without consulting the doctor.
- If you are sensitive to any food or medicine, inform the doctor before taking the medicine.
- Wait at least two hours between taking this medicine and antacids.
- If the digestive disturbances continue, despite use of the medicine, consult a doctor.

☒ Before treatment with Encypalmed, tell the doctor if:

- you are pregnant or breastfeeding.
- you are suffering, or have suffered in the past, from impaired function of: the liver (severe jaundice), the digestive system (e.g., ulcer), complete biliary obstruction.
- you need a high dosage of Encypalmed and you are suffering from high blood pressure or from impaired kidney function.
- you are suffering from an inflammatory bowel disease such as: Crohn's disease or ulcerative colitis, bowel obstruction.
- you have cystic fibrosis.

☒ If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist. In particular, inform the doctor or pharmacist if you are taking: iron-containing preparations and antacids that contain magnesium and calcium carbonate.

☒ Use of the medicine and food

Take the medicine with or before a meal.

☒ Pregnancy and breastfeeding

If you are pregnant or breastfeeding, consult the doctor before commencing use.

☒ Important information about some of the ingredients in this medicine

The preparation contains lactose, sucrose and sodium.

3. HOW SHOULD YOU USE THE MEDICINE?

Check with the doctor or pharmacist if you are uncertain about its use.

The usual dosage is:

Adults: 2-4 dragees, 3 times a day, with or before meals.

Children: 1-2 dragees, 3 times a day, with or before meals.

Do not exceed the recommended dose.

Since the dragee is coated, do not crush/halve/chew!

Swallow the medicine with water.

If you accidentally took a higher dosage or if a child has accidentally swallowed the medicine, refer immediately to a doctor or proceed to a hospital emergency room, and bring the package of the medicine with you.

How can you contribute to the success of the treatment?

During the course of treatment, maintain a balanced diet of proteins, fats and starches, as per the doctor's or certified dietician's instructions.

Do not take medicines in the dark! Check the label and the dose each time you take the medicine. Wear glasses if you need them.

If you have further questions regarding use of the medicine, consult the doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Encypalmed may cause side effects in some users. Do not be alarmed by the list of side effects. You may not suffer from any of them.

Discontinue use and refer to a doctor immediately if the following effects develop:

Allergic effects (e.g., rash, itching, breathing difficulties, tightness in the chest, swelling of the mouth, lips, face, tongue).

Refer to a doctor if the following effects (very common) do not pass and/or are bothersome:

Constipation, diarrhea.

Additional side effects of unknown frequency:

Dizziness.

If a side effect occurs, if one of the side effects worsens or if you suffer from a side effect not mentioned in this leaflet, consult with the doctor.

5. HOW SHOULD THE MEDICINE BE STORED?

- Avoid poisoning! This medicine, and any other medicine, should be kept in a safe place out of the reach of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.
- Do not use the medicine after the expiry date (exp. date) that appears on the blister and the package. The expiry date refers to the last day of that month.
- Store in a cool and dry place, below 25°C.

6. FURTHER INFORMATION

In addition to the active ingredients, the medicine also contains:

Sucrose, purified talc, charcoal, povidone, frangula bark powder, rhubarb powder, starch, sodium bicarbonate, stearic acid, yellow red and black iron oxide, magnesium stearate, castor oil, carnauba wax, white beeswax, silica, methacrylic acid copolymer, sodium lauryl sulphate, polyethylene glycol, talc, shellac, purified water, sodium benzoate, propyl parahydroxybenzoate, methyl parahydroxybenzoate. Each dragee contains approximately 142 mg sucrose and 2.6 mg sodium.

What does the medicine look like and what are the contents of the package?

Each package contains 40 or 60 round, brown dragees.

Manufacturer and license holder: Trima, Israel Pharmaceutical Products Maabarot Ltd., Kibbutz Maabarot 4023000 Israel.

This leaflet was checked and approved by the Ministry of Health in May 2015.

Registration number of the medicine in the National Drug Registry of the Ministry of Health: 027.66.22433.00

☎ Maabarot 4023000

☎ Israel Pharmaceutical Products **TRIMA**
Maabarot Ltd.