

PATIENT PACKAGE INSERT IN
ACCORDANCE WITH THE PHARMACISTS'
REGULATIONS (PREPARATIONS) - 1996
This medicine is dispensed with a doctor's
prescription only

Spasmalgin Tablets

- **Active ingredients:**
Paracetamol 150 mg
Papaverine HCl 80 mg
Codeine Phosphate 0.4 mg
Atropine Sulphate 0.4 mg
For a list of inactive ingredients in the preparation see section 6 - "Further Information".
- **Read the package insert carefully in its entirety before using this medicine.** This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar.
- This medicine is not intended for children under the age of 12 years.
- Medicines containing codeine should only be used to treat sharp pain (of short duration) of moderate intensity among children and adolescents above the age of 12 years, and only if the pain cannot be treated by pain relievers such as paracetamol or ibuprofen, since use of codeine may increase the risk of respiratory depression.

1. WHAT IS THE MEDICINE INTENDED FOR?

- Analgesic and antispasmodic for the digestive system, the kidneys and the gall bladder.
- **Therapeutic group:**
• Paracetamol: pain reliever, reduces fever.
• Codeine phosphate: opiate pain reliever.
• Papaverine hydrochloride: antispasmodic.
• Atropine: anticholinergic, relaxes smooth muscle.

2. BEFORE USING THE MEDICINE

- **Do not use the medicine if:**
 - you are pregnant or breastfeeding.
 - you are sensitive (allergic) to the active ingredients or to any of the other ingredients contained in the medicine.For the list of inactive ingredients - see section 6 "Further Information".
- in children under the age of 12 years.
- in children and adolescents above the age of 12 and under the age of 18 after a tonsillectomy or adenoidectomy for treatment of obstructive sleep apnea, since these patients are more likely than others to suffer from breathing problems.
- if you know that you produce a significant amount of morphine from a dose of codeine (you belong to the ultra-rapid metabolizers group), as you are at increased risk of suffering from severe side effects when using codeine.

Special warnings regarding use of the medicine

- If you are sensitive to any food or medicine, inform the doctor before taking the medicine.
- Naturally and rarely, in some people's bodies, codeine undergoes metabolism (breakdown) more rapidly than in most of the population. In these rare cases, high amounts of metabolites may accumulate and can cause severe side effects, such as: excessive drowsiness, confusion or shallow breathing. In such cases, the patient should be referred immediately for medical treatment.
- In most cases, it is impossible to know in advance whether a patient belongs to the group of people at risk for this effect.
- If you suffer, or have suffered in the past, from impaired function of: the respiratory system (e.g., asthma), the heart and/or blood vessels, the liver, the kidney/urinary tract, the digestive system (intestinal diseases, diarrhea, reflux esophagitis), the thyroid, the prostate, from spasms, from brain injury, from hypertension, from severe muscle weakness.
- Paracetamol may cause liver damage in the following cases: if given at a higher than the recommended dosage, if given for a prolonged period, if you drink alcoholic beverages during the treatment period and if you take other medicines that affect the liver.
- Prolonged use may cause dependence!
- Do not use this medicine frequently or for a prolonged period without consulting a doctor.
- Paracetamol may interfere with blood sugar test results.
- Atropine may disrupt the results of a gastric acid secretion test - do not take this medicine for 24 hours before the test.
- Do not take other fever- and pain-reducing medicines, or cold medicines, without consulting with a doctor or pharmacist - to prevent paracetamol poisoning/overdose.
- Medicines containing codeine are only used to treat sharp pain (of short duration) of moderate intensity among children above the age of 12 years, and only if the pain cannot be treated by pain relievers such as paracetamol or ibuprofen, since use of codeine may increase the risk of breathing suppression.
- Do not give codeine to children and adolescents above the age of 12 and under the age of 18 after a tonsillectomy or adenoidectomy for treatment of obstructive sleep apnea, since these patients are more likely than others to suffer from breathing problems.
- The medicine is not recommended for children suffering from breathing problems.
- **If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell your doctor or pharmacist.** It is especially important to inform the doctor or pharmacist

if you are taking:

- Aspirin or salicylates
- Medicines that influence the central nervous system (e.g., phenothiazines, sedatives, hypnotics, medicines for Parkinson, for spasms, antihistamines for allergies, anesthetics for surgery and narcotic pain relievers).
- Anticoagulants
- Anti-depressants from the MAOI type
- Other non-steroidal anti-inflammatory preparations or other pain- or fever-reducing medicines
- Anticholinergics (e.g., abdominal antispasmodics)
- Medicines that induce liver enzyme activity, such as barbiturates or phenytoin (for spasms)
- Antispasmodics
- Potassium chloride

Use of the medicine and food: Take the medicine with or after a meal.

Pregnancy and breastfeeding: The medicine is forbidden to use during pregnancy and breastfeeding.

Driving and use of machines: Do not drive or operate dangerous machines while using the medicine since use of this medicine may impair alertness. Children should be cautioned against bicycle riding or playing near road, etc.

3. HOW SHOULD YOU USE THE MEDICINE?

- Always use according to the doctor's instructions. Check with the doctor or pharmacist if you are not sure.
- The dosage and treatment regimen will be determined by the doctor only.
- Do not exceed a dosage of 8 tablets in 24 hours.
- This medicine is not intended for children under the age of 12 years.
- If there is no improvement in your condition within 3 days, refer to the doctor again.

Attention: Wait at least 2 hours between taking this medicine and taking osmotic laxatives, antacids. Likewise, wait 6 hours between taking this medicine and injecting digoxin.

How to use:

- Swallow the medicine with water. The medicine can be taken with or after a meal.
- The tablets can be crushed before use. Do not store crushed tablets.
- **Do not exceed the recommended dose.**
- **If you accidentally took a higher dosage:** If you took an overdose or if a child has accidentally swallowed the medicine, immediately refer to a doctor or proceed to a hospital emergency room and bring the package of the medicine with you.
- **If you forgot to take the medicine:** This medicine is to be taken at specific time intervals as determined by the attending

doctor. If you forgot to take the medicine at the specified time, take a dose as soon as you remember, but do not take a double dose. Take the next dose at the regular time and consult the doctor.

- Adhere to the treatment as recommended by the doctor.
- Do not take medicines in the dark! Check the label and the dose each time you take medicine. Wear glasses if you need them.

4. SIDE EFFECTS

- As with any medicine, use of this medicine may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.
- **Stop using and refer to the doctor as soon as possible if you experience dizziness, blurred vision, accelerated heart rate, appearance of jaundice, abnormal liver activity, hypersensitivity (rash or skin irritation, shortness of breath or difficulty breathing), increased drowsiness, eye pain. In the elderly - confusion and restlessness, difficulty in passing urine, eosinophilia (rare).**
- Additional side effects: dry mouth, constipation, nausea/vomiting, drowsiness, headache, digestive system disturbances, increased sweating.
- If one of the side effects worsens, or if you suffer from a side effect not mentioned in this leaflet, consult the doctor.

5. HOW SHOULD THE MEDICINE BE STORED?

- Avoid poisoning! This medicine and any other medicine must be kept in a closed place out of the reach of children and/or infants 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 package. The expiry date refers to the last day of that month.
- Storage conditions: Store at a temperature below 25°C.

6. FURTHER INFORMATION

- In addition to the active ingredients, the medicine also contains:
Powdered Cellulose, Microcrystalline Cellulose, Lactose, Magnesium Stearate, Colloidal Silicon Dioxide, Sodium Starch Glycolate.
- Each tablet contains 60 mg of lactose and less than 1 mg of sodium.
- What does the medicine look like and what are the contents of the package: Pink tablets packaged in a tray, 30 tablets in a package.
- License holder and address: Sam-On Ltd., Haavoda 25, Bat-Yam.
- 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: 363622208.