

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

Read this package insert carefully in its entirety before using this medicine  
The format of this leaflet was determined by the Ministry of Health and its  
content was checked and approved by it in September 2013

## **SENSAMOL**

### **Caplets**

**Composition:**

Each caplet contains: Paracetamol 500 mg

**Inactive ingredients:**

Carnauba wax, hypromellose, polyethylene glycol, povidone, pregelatinized starch, sodium starch glycolate, starch, stearic acid.

The amount of sodium in each caplet: up to 1 mg.

**Indications:** This medicine is intended for the relief of pain and reduction of fever.

**When should this medicine not be used?**

Do not use this medicine if you are sensitive to any of its ingredients.

**Do not take this medicine without consulting a doctor before starting treatment:**

If you are pregnant or breastfeeding.

If you are suffering, or have suffered in the past, from impaired function of the liver, the kidney/urinary tract, sleep disturbances, alcoholism, jaundice.

**Warnings:** If you have developed skin side effects in the past as a result of taking preparations containing paracetamol, do not take preparations containing paracetamol, so that severe skin effects will not recur.

Paracetamol may cause damage to the liver in the following cases:  
when administered at a dosage higher than the recommended one, when administered for an extended period, when consuming alcoholic beverages during the treatment period, when taking additional medicines that affect the function of the liver.

Do not use this medicine frequently without consulting your doctor (see section "Dosage").

If you are sensitive to any type of food or medicine, inform your doctor before commencing treatment with this medicine.

Avoid taking a high dosage (within the recommended range) of this medicine if you consume alcohol or while fasting.

If you drink 3 or more alcoholic drinks per day, consult your doctor about whether to take this medicine or to use a different analgesic or antipyretic medicine.

Do not take additional medicines for reduction of fever and relief of pain, or cold medicines, without consulting your physician or pharmacist, in order to avoid paracetamol overdose/toxicity.

**Drug interactions:** If you are taking another drug concomitantly or if you have just finished treatment with another medicine, inform the attending doctor,

in order to prevent hazards or lack of efficacy arising from drug interactions. This is especially important for medicines belonging to the following groups: anticoagulants, drugs that increase liver enzyme activity such as barbiturates or phenytoin (anticonvulsants), other analgesics as well as anti-inflammatory drugs (in prolonged use).

Do not take this medicine with other medicines containing paracetamol.

**Side effects:** In addition to the desired effect of the medicine, adverse reactions may occur during the course of taking this medicine.

**Severe side effects:** Paracetamol can, in rare cases, cause severe skin diseases, whose signs can be: redness, rash, blisters, widespread skin damage. Severe skin side effects may occur even if in the past you have taken preparations containing paracetamol as an active ingredient with no problem. If skin side effects occur, discontinue treatment and refer to a doctor immediately!

**Side effects requiring special attention:** Signs of allergy (rash, itching of the skin) - (rare): stop treatment and refer to your doctor.

In the event that you experience side effects not mentioned in this leaflet, or if there is a change in your general health, consult your doctor immediately.

**Adverse reactions and drug interactions in children and infants:**

Parents must inform the attending doctor about any side effects, as well as any additional medicine being taken by the child!

See above for details of side effects and drug interactions.

**Dosage:** Recommended dosage unless otherwise prescribed by your doctor:

**Adults and children over 12 years of age:**

1-2 caplets every 4-6 hours as needed.

Do not exceed 8 caplets per 24 hours.

If fever persists for more than 3 days or if there is no pain relief within 5 days, refer to your doctor.

**Directions for use:** Do not chew! Swallow the medicine with water.

The caplet may be halved. This medicine may be taken with food.

**Avoid poisoning!** This medicine, and all other medicines, must be stored in a safe place out of the reach of children and/or infants, to avoid poisoning.

If you have taken an overdose, or if a child has accidentally swallowed the medicine, proceed immediately to a hospital emergency room and bring the package of the medicine with you even if you feel well, because of the risk of liver damage. Do not induce vomiting unless explicitly instructed to do so by a doctor! Do not take medicines in the dark! Check the label and the dose each time you take your medicine. Wear glasses if you need them.

**Storage:** At room temperature, below 25°C.

Even if kept in their original container and stored as recommended, medicines may be kept for a limited period only. Please note the expiry date of the medicine! In case of doubt, consult the pharmacist who dispensed the medicine to you. Do not store different medications in the same package.

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