

**PATIENT PACKAGE INSERT  
IN ACCORDANCE WITH THE  
PHARMACISTS' REGULATIONS  
[PREPARATIONS] - 1986**

The medicine is dispensed  
without a doctor's prescription

## Supramol 500 Suppositories

### The active ingredient:

Each suppository contains:  
Paracetamol 500 mg

For the list of inactive ingredients, please  
see section 6.

**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.

The medicine is intended for adults and  
children above 12 years of age.

Use it properly. Consult a pharmacist if you  
need further information.

**Refer to a doctor if the fever persists for  
more than 3 days or if the symptoms do  
not pass within 5 days despite use of the  
medicine.**

### 1. WHAT IS THE MEDICINE INTENDED FOR?

- This medicine is used to relieve pain and  
reduce fever.

### Therapeutic group:

Analgesic and antipyretic.

### 2. BEFORE USING THE MEDICINE:

#### ☒ Do not use the medicine if:

Do not use the medicine if you have a  
known sensitivity to any of the ingredients  
of the medicine.

Do not use if you have a severe active  
liver disease.

### Special warnings regarding use of the medicine:

- 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 reactions will not recur.
- If you have any sensitivity to food or  
medicine, inform the doctor.
- The preparation contains paracetamol  
which may cause liver damage in the  
following cases: when administered at a  
higher dosage than recommended, when  
administered for an extended period,  
when consuming alcoholic beverages  
during the treatment period, when  
taking additional medicines that affect  
the liver, when suffering from chronic

malnutrition.

- Avoid taking a high dosage (within the  
recommended limit) of this medicine when  
fasting.
- Do not take other fever-reducing and pain-  
relieving medicines or cold medicines  
without consulting with a doctor or  
pharmacist - to avoid paracetamol  
overdose/toxicity.
- Do not take other paracetamol-containing  
preparations when using this medicine.
- Abstain from drinking alcohol or from  
taking medicines which contain alcohol  
when using this medicine.

### ☒ Before treatment with Supramol 500, inform the doctor if:

- you are pregnant or breastfeeding.
- you are suffering, or have suffered in the  
past, from:
  - impaired function of: the liver or the  
kidney/urinary system.
  - alcoholism.
  - jaundice.

**☒ If you are taking, or have recently taken,  
other medicines, including non-prescription  
medicines and nutritional supplements, tell  
the doctor or pharmacist.** It is particularly  
important to inform the doctor or pharmacist  
if you are taking:

- Anticoagulants, especially warfarin.
- Medicines against convulsions/  
epilepsy (carbamazepine, phenytoin,  
phenobarbital).
- Barbiturates.
- Rifampicin.
- Isoniazid, zidovudine (for AIDS patients).
- Non-steroidal anti-inflammatory  
preparations.
- Metoclopramide or domperidone (to treat  
nausea, vomiting and other digestive  
problems).
- Chloramphenicol (antibiotic).
- Probenacid (to treat gout).
- Cholestyramine (to reduce hyperlipidemia).
- Other analgesics or antipyretics.

### ☒ Use of paracetamol and consumption of alcohol:

Do not consume alcohol during the course  
of treatment with paracetamol, due to an  
increased risk of liver damage.

### ☒ Pregnancy and breastfeeding:

If you are pregnant or breastfeeding, consult  
the doctor or pharmacist before using the  
medicine.

### ☒ Use in children:

This medicine is intended for adults and  
children above 12 years of age.

### 3. HOW SHOULD YOU USE THE MEDICINE?

- Check with your doctor or pharmacist if  
you are uncertain.

### The usual dosage is generally:

For adults and children from 12 years of  
age and up:  
1-2 suppositories every 4-6 hours, as  
necessary, up to 8 suppositories per day.  
**Do not exceed the recommended dose.**

**Refer to the doctor if the fever persists  
for more than 3 days or if the symptoms  
do not pass within 5 days despite use of  
the medicine.**

- Do not swallow.
- For external use only.
- Do not halve the suppository.

### Instructions for use:

How to insert the suppository:

1. First, wash your hands thoroughly.
2. Remove the suppository wrapper and  
moisten with a bit of water.
3. Lie on your side. Push the suppository  
as deep as possible into the rectum, with  
the aid of your finger. If the suppository  
is too soft to allow insertion, chill it in  
the refrigerator for 30 minutes or place  
it under a stream of cold water before  
removing it from the wrapper.
4. Wash your hands after inserting the  
suppository.

### If you accidentally take too high a 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.

Do not induce vomiting unless explicitly  
instructed to do so by the doctor! Even if  
you feel well, immediate medical attention is  
essential, **due to risk of developing severe  
liver damage.** Side effects can be nausea  
and vomiting, diarrhea, loss of appetite,  
stomach pain, swelling, increased sweating,  
pain or tenderness in the upper abdomen  
and they may not reflect the severity of the  
liver damage.

### If you forget to take the medicine:

If you forget to take the medicine at the  
required time, take the next dose as soon  
as you remember. But if it is almost time for  
the next dose, do not take a double dose.  
Take the next dose at the regular time and  
consult 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.

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

### 4. SIDE EFFECTS:

As with any medicine, use of Supramol 500  
may cause side effects, such as rectal redness  
or burning/pain or dizziness in some users.

Do not be alarmed when reading the list of  
side effects. You may not suffer from any  
of them.

### Severe side effects

**Discontinue use of the medicine and refer  
to a doctor immediately if:**

- severe allergic reactions occur, such as  
rash and itching, swelling of the face, lips,  
tongue, throat and/or limbs that can cause  
breathing or swallowing difficulties.
- Paracetamol may, in rare cases, cause  
severe skin diseases, whose signs  
can include: redness, rash, blisters,  
widespread skin damage.
- Severe skin side effects may occur  
even if you have had no problem in the  
past taking preparations containing  
paracetamol as the active ingredient.
- If skin side effects occur, discontinue  
treatment and refer to the doctor  
immediately.
- nausea, vomiting, constipation, headache,  
restlessness, liver damage, lung damage  
have occurred (rare).
- signs of changes in the blood system  
appear, such as: bleeding, bruises,  
inflammations developing more easily.

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

### 5. HOW SHOULD THE MEDICINE BE STORED?

- Avoid poisoning! This medicine and any  
other medicine must be kept in a  
safe place out of the reach and sight of  
children and/or infants to avoid poisoning.  
Do not induce vomiting unless explicitly  
instructed to do so by a 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.
- Store below 25°C (room temperature).

### 6. FURTHER INFORMATION

In addition to the active ingredient, the  
medicine also contains: Wittepsol.

**What does the medicine look like and  
what are the contents of the package:**  
Oval milky-white suppository.

The suppositories are provided in aluminum  
trays in packs of 20 suppositories.

**Manufacturer and license holder and  
address:**

Sam-On Ltd., 25 Haavoda St., Bat-Yam.

**Registration number of the medicine in  
the National Drug Registry of the Ministry  
of Health:** 350325647

This leaflet was checked and approved by  
the Ministry of Health in November 2013.

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