

PATIENT PACKAGE INSERT IN
ACCORDANCE WITH THE PHARMACISTS'
REGULATIONS (PREPARATIONS) - 1998

The medicine is dispensed
without a doctor's prescription

Supramol "M" Pediatric Suppositories

Composition

Each suppository contains:
150 mg paracetamol

For the list of 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.**

**This medicine is dispensed without a
doctor's prescription and is intended for
children from 3 years to 6 years of age
for reduction of fever and relief of pain.
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.**

**Administer the medicine correctly.
Consult a pharmacist if you need further
information.**

1. WHAT IS THE MEDICINE INTENDED FOR?

The medicine is intended for the relief of pain
and reduction of fever.

Therapeutic group: Analgesic and
antipyretic.

2. BEFORE USING THE MEDICINE

☒ Do not use this medicine:

- if there is a known sensitivity to
paracetamol or to any of the other
ingredients of the medicine.

**Special warnings regarding use of the
medicine**

- If the child has developed skin side effects
in the past as a result of taking preparations
containing paracetamol, do not administer
preparations containing paracetamol, so
that severe skin effects will not recur.
- The preparation contains paracetamol
which may cause liver damage when:
 - given at a dosage higher than
recommended or for a prolonged
period.
 - consuming alcoholic beverages during
the course of treatment.
 - taking additional medicines which affect
liver function.
- Do not administer this medicine frequently
without consulting the doctor.

- Do not take additional fever reducers and
pain relievers or cold medicines without
consulting a doctor or pharmacist,
to prevent overdose or paracetamol
poisoning.
- Do not take other paracetamol-containing
preparations.
- Avoid taking a high dosage (within the
recommended limit) of this medicine when
fasting.
- If the child is sensitive to any food or
medicine, inform the doctor before
administering the medicine.

☒ Consult the doctor before commencing treatment if you are suffering, or have suffered in the past, from:

- liver disease or impaired liver function
- impaired kidney function
- alcoholism
- jaundice
- If you are pregnant or breastfeeding

**If you are taking, or have recently taken,
other medicines, including non-prescription
medicines and food supplements and
vitamins, tell the doctor or pharmacist.**
In particular, inform the doctor or pharmacist
if you are taking a medicine from the following
groups or if you have just finished treatment
with the medicine:

- Anticoagulants, especially warfarin.
- Preparations that stimulate liver
enzyme production (e.g., rifampicin,
barbiturates).
- Medicines for epilepsy - phenytoin,
carbamazepine.
- Non-steroidal anti-inflammatory
preparations.
- Metoclopramide or domperidone (to treat
nausea, vomiting and other digestion
problems).
- Chloramphenicol (antibiotic).
- Probenecid (to treat gout).
- Cholestyramine (to reduce excessive blood
fats).

☒ Use of paracetamol and alcohol consumption

During the course of treatment with
paracetamol, do not consume alcohol due
to increased risk of liver damage.

☒ Pregnancy and breastfeeding

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

☒ Use in children

Parents must inform the attending doctor
of any side effects as well as any other
medicine being given to the child.
Do not give the child alcohol or alcohol-
containing medicines during the course of
treatment with this medicine.

3. HOW SHOULD YOU USE THE MEDICINE?

Check with the doctor or pharmacist if you
are uncertain.

The usual dosage unless otherwise instructed
by the doctor:

Children up to 3 years of age: in accordance
with the doctor's instruction.

Children 3-4 years of age: 1 suppository, 4-5
times per day.

Children 4-6 years of age: 1-2 suppositories,
4-5 times per day.

This medicine is not usually intended for
children and infants below two years of age.
For them, use a liquid preparation.

Wait at least 4 hours before administering
another 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 exceed the recommended dosage.

If the child accidentally received a double
dose, consult the doctor immediately or
proceed to an emergency room.

Directions for use

Note: If the suppository is too soft to allow
insertion, it can be cooled by keeping it in
a refrigerator for about 30 minutes, or by
holding it under a stream of cold water before
removing the wrapper.

1. How to insert the suppository: First, wash
your hands thoroughly.
2. Separate one suppository from the strip
of suppositories. To remove the wrapper,
separate the tabs in the flat part of the
wrapper.
3. Lay the child on his side, and gently insert
the suppository deep into the anus with
your finger.
4. Wash your hands thoroughly after inserting
the suppository.

**If you have taken an overdose or if a child
has accidentally swallowed the medicine,**
immediately refer to a doctor or to a hospital
emergency room and bring the package of the
medicine with you. Do not induce vomiting
without explicit instruction from the doctor!
Even if you feel well, immediate treatment
is essential, **due to the risk of developing
severe liver damage.** Side effects can
be nausea and vomiting, diarrhea, loss
of appetite, abdominal pains, flatulence,
increased sweating, pain or tenderness in
the upper abdomen, and they may not reflect
the severity of the liver damage.

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 Supramol "M"
suppositories may cause side effects, such
as redness or soreness in the anal area,
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:

**Stop treatment and refer to the doctor
immediately:**

- If severe allergic reactions occur, such as
rash and itching, swelling of the face, lips,
tongue, throat and/or limbs which may
cause difficulty breathing or swallowing.
- Paracetamol may, in rare cases, cause
the appearance of severe skin diseases,
whose signs can be: redness, rash,
blisters, widespread skin damage.
Severe skin side effects may occur even
if you have had no problems in the past
taking preparations containing the active
ingredient paracetamol.
If skin side effects occur, stop treatment
and refer to the doctor immediately.
- If signs of changes in the blood system
occur, such as: bleeding, bruises,
development of inflammations more
easily.

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

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 without explicit instruction from
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.

Store below 25°C (room temperature).

6. FURTHER INFORMATION

In addition to the active ingredient, the
medicine also contains
Witepsol E76, Witepsol H15

What the medicine looks like and the
contents of the package:

Each package contains oval milky-white
suppositories.

Manufacturer and license holder:
Sam-On Ltd., 25 Haavoda St., Bat-Yam.

This leaflet was checked and approved by
the Ministry of Health in July 2014.

Registration number of the medicine in the
National Drug Registry of the Ministry of
Health: 425023368

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