Patient package insert according to Pharmacists' Regulations (Preparations) – 1986
This medicine can be sold without a physician's prescription

Paramol® Af night care, Caplets

Each caplet contains: Paracetamol 500mg, Pseudoephedrine hydrochloride 25mg, Chlorpheniramine maleate 2mg.

Inactive ingredients and allergens in the medicine – see section 6 "Additional information" and in section 2 "Important information about some of the ingredients of the medicine".

Read this entire leaflet carefully before using the medicine. This leaflet contains concise information about the medicine. If you have any further questions, ask the doctor or pharmacist.
This medicine is administered without a doctor's prescription and is intended for adults and children over 6 years. Take this medicine according to the instructions in section 3 "How to use the medicine?" in this leaflet. Consult the pharmacist if you need additional information.
Refer to a doctor if the fever persists for more than 3 days or if the symptoms worsen or do not improve after 5 days despite use of the medicine.

1. What is the medicine intended for?

The medicine is intended for the symptomatic relief of cold and nasal congestion accompanied by fever and pain – night care medicine.

Therapeutic group:
Paracetamol – analgesic and antipyretic.
Pseudoephedrine hydrochloride – relieves nasal congestion.
Chlorpheniramine maleate – antihistamine.

2. Before using the medicine:

Do not use the medicine if:

- You are hypersensitive (allergic) to the active ingredients (paracetamol, pseudoephedrine hydrochloride, chlorpheniramine maleate), to any of the other ingredients this medicine contains (see section 6), or to other antihistamine which is not chlorpheniramine.
- You suffer from heart disease or high blood pressure.
- You have diabetes.
- You suffer from Phaeochromocytoma (a rare tumor in the adrenal gland which affects blood pressure and heart rate).
- You suffer from overactive thyroid gland.
- You suffer from increased pressure in the eye (glaucoma).
- You suffer from severe kidney disease.
- You are taking additional cough and cold medicines or other preparations containing paracetamol.
- You are taking medicines from the beta-blockers group (used to treat heart problems, high blood pressure).
- You are taking or have taken in the last 14 days, medicines from the Monoamine Oxidase Inhibitors (MAOIs) group (to treat depression) or Reversible Inhibitors of Monoamine Oxidase (RIMAs).
- You are taking medicines that stimulate or suppress appetite or medicines to treat congestion and asthma (sympathomimetic medicines).
- You are pregnant or breastfeeding.

Special warnings regarding the 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 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.

  - Alcoholic beverages are consumed during the course of treatment.
  - Other medicines which affect liver function are taken.
- Do not use this medicine frequently without consulting a doctor.
- Do not take other antipyretics and analgesics or cold medicines without consulting a doctor or pharmacist to prevent paracetamol overdose or poisoning.
- Do not take other medicines from the **Paramol** family and/or other paracetamol containing preparations.
- Avoid taking a high dosage (within the recommended limit) of this medicine when fasting.
- If you are sensitive to any food or medicine, you must inform the doctor before taking this medicine.

Before the treatment with Paramol Af night care, tell the doctor if you suffer or have suffered in the past from:
- Impaired kidney or liver function
- Alcoholism
- Blocked arteries or veins
- Impaired thyroid function
- Difficulty passing urine or enlarged prostate (causes frequent urination)
- Jaundice
- Epilepsy
- Asthma, bronchitis, or any other lung problem
- Impaired prostate function

Drug interactions
If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist. Especially tell the doctor or pharmacist if you are taking a medicine from the following groups:
- Anticholinergics (to treat cramps and spasms such as atropine).
- Antihypertensives (to treat high blood pressure) such as: guanethidine, methyldopa, adrenergic neuron blockers, debrisoquine, bretylium and betanidine or other antihypertensives (e.g., beta-blockers – see in section 2, "Do not use the medicine if").
- Antidepressants (including MAOIs, RIMAs – see in section 2, "Do not use the medicine if") or if you have taken them within the last two weeks.
- Tricyclic antidepressants.
- Moclobemide – antidepressant.
- Cardiac glycosides (medicines used to treat heart rhythm disorders or heart failure such as digoxin).
- Ergot alkaloids – to treat migraine such as ergotamine or methysergide.
- Oxytocin (medicine to help contractions during childbirth).
- Cholestyramine (to reduce excessive blood fats).
- Metoclopramide or domperidone (for treatment of nausea, vomiting and other digestive problems).
- Anticoagulants (drugs used to thin the blood), such as warfarin.
- Oral contraceptives.
- Anticonvulsant medicines (for the treatment of epilepsy), such as: phenytoin, carbamazepine.
- Other antihistamines, including those in cough and cold medicines, that make you sleepy.
- Sleeping pills, medicines for anxiety and depression.
- Preparations which stimulate liver enzyme activity (e.g., rifampicin, barbiturates).
- Non-steroidal anti-inflammatory drugs.
- Chloramphenicol (antibiotic).
- Probenecid (for treatment of gout).

Inform the doctor or pharmacist if you are taking flucloxacillin (antibiotic), due to a serious risk of blood and fluid abnormality (high anion gap metabolic acidosis) that must have urgent treatment and which may occur particularly in case of severe renal impairment, sepsis (when bacteria and their toxins circulate in the blood leading to organ damage), malnutrition, chronic alcoholism, and if the maximum daily doses of paracetamol are used.

Use of the medicine and food
The medicine can be taken with or without food.

Use of the medicine and alcohol consumption
During treatment with this medicine, do not consume alcohol due to the increased risk of liver damage.

Pregnancy and breastfeeding
Do not use this medicine if you are pregnant or breastfeeding.

Driving and using machines
Do not drive or operate dangerous machinery while using this medicine because this medicine may impair alertness or cause blurred vision. As for children, they should be warned about riding a bicycle or playing near roads etc.

Use in children
This medicine is intended for adults and children over 6 years, see section 3.
Parents must inform the attending doctor of any side effects and any other medicine being given to the child.

Important information about some of the ingredients of the medicine
This medicine contains sunset yellow FCF aluminum lake (E110), which may cause allergic reactions.
This medicine contains less than 1 mmol sodium (23 mg) per caplet, that is to say essentially "sodium-free".

3. How to use the medicine?
Check with the doctor or pharmacist if you are not sure about the dosage and the manner of treatment with the medicine.
Unless otherwise instructed by the doctor, the usual recommended dosage is:
Adults and children over 12 years: 1-2 caplets before bedtime.
Children aged 10-12 years: 1 caplet before bedtime.
Children aged 6-9 years: ½ caplet before bedtime.
Patients over 60 years: consult the doctor before using this medicine, as they may be sensitive to preparations of this kind.
Upon concomitant use of **Paramol Af day care** do not exceed a total daily dosage of 8 caplets (upon concomitant use of **Paramol Af day care**, replace a dose of **Paramol Af day care** with a dose of **Paramol Af night care** and do not take it as a supplement to the maximum dosage recommended above for **Paramol Af night care**).
Do not exceed the recommended dose.
Refer to a doctor if the fever persists for more than 3 days or if the symptoms worsen or do not improve after 5 days despite use of the medicine.

Method of administration:
Swallow the caplet with water. The caplet can be halved. There is no information regarding chewing or crushing the caplet.

If you have accidentally taken a higher dosage
If you have taken an overdose or if a child has accidentally swallowed the medicine, proceed immediately to a doctor or 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 treatment is essential, **due to the risk of developing severe liver damage.**
Side effects could be: nausea and vomiting, diarrhea, loss of appetite, abdominal pain, flatulence, increased sweating, pain or tenderness in the upper abdomen and they may not reflect the severity of the liver damage.

If you forgot to take the medicine, take the next dose when needed, provided that the last dose was taken at least 4 hours before taking the current dose. Do not take a double dose.

Do not take medicines in the dark! Check the label and the dose <u>each time</u> you take a medicine. Wear glasses if you need them.
If you have further questions on the use of this medicine, consult the doctor or pharmacist.

4. <u>Side effects</u>

Like any medicine, the use of **Paramol Af night care** 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.
The elderly may be more likely to get side effects including confusion and may need to take a lower dose.

Serious side effects
Stop taking this medicine and refer to a doctor immediately with the occurrence of:

- Acute allergic reactions including skin rash such as hives (may include blistering and peeling of the skin) and itching, swelling of the face, lips, mouth, tongue, throat, which may cause difficulty in breathing or swallowing, swelling of the limbs.
- Paracetamol may, in rare cases, cause acute skin diseases whose signs can be: redness, rash, blisters, widespread skin damage. Acute skin side effects may occur even if you have taken preparations containing the active ingredient paracetamol in the past with no problem. If skin side effects occur, stop treatment and refer to the doctor immediately.
- Reduced blood flow to the heart which can cause angina (discomfort or pain in the chest, neck, back, jaw, shoulders, arms), or heart attack.
- Stroke (weakness of the face, arms or legs, or speech problems).
- A sudden onset of fever, reddening of the skin, or many small pustules (possible symptoms of Acute Generalised Exanthematous Pustulosis - AGEP) which may occur during the first two days of treatment with this medicine.
- Sudden onset of severe headache, nausea, vomiting, confusion, fits, visual disturbances.
- Hallucinations (seeing or hearing things that are not there, irrational thoughts or feelings).
- Sudden and severe abdominal pain or rectal bleeding due to inflammation of the colon as a result of insufficient blood supply (Ischaemic colitis).
- Signs of changes in the blood system such as: unexplained tiredness, anemia, bleeding, bruises, development of infections more easily.
- Liver problems including jaundice (yellowing of the skin and eyes).
- Sudden loss of vision.

Stop taking this medicine and refer to a doctor with the occurrence of:

- Difficulty passing urine (especially in men with prostate problems)

Additional side effects
Very common side effects (effects that occur in more than 1 in 10 users):

- Headache

Common side effects (effects that occur in 1-10 out of 100 users):

- Difficulty sleeping, nervousness, dizziness
- Dry mouth or nausea

Side effects with unknown frequency (effects for which a frequency has not yet been determined):

- Anxiety, restlessness, irritability, feeling jittery or feelings of extreme happiness
- Sleep disturbances
- A fast or irregular heartbeat or an increased awareness of the heartbeat (palpitations)
- Drowsiness
- High blood pressure
- Abdominal pain, diarrhea, vomiting
- Pain when passing urine
- Tingling or numbness of the hands or feet

- Tremor
- Reduced blood flow to the optic nerve which may cause loss of vision (Ischaemic optic neuropathy)
- Fatigue
- Inability to concentrate, blurred vision
- Dry mouth, loss of appetite, heartburn
- Confusion, ringing in the ears
- Sensitivity to light
- Low blood pressure, chest tightness, increased viscosity of sputum
- Muscle weakness, muscle twitching, lack of coordination
- Nightmares
- Confusion among the elderly
- Malaise
- Low blood count, hepatitis (severe abdominal pain, nausea, vomiting, loss of appetite)

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

Reporting side effects
Side effects can be reported to the Ministry of Health by clicking the link "דיווח על תופעות לוואי עקב טיפול תרופתי" found on the homepage of the Ministry of Health website (www.health.gov.il) directing to the online form for reporting side effects or via the link: https://sideeffects.health.gov.il

5. How to store the medicine?

- Avoid poisoning! This medicine and any other medicine must be stored in a closed 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 the doctor.
- Do not use the medicine after the expiry date (תאריך תפוגה) stated on the package. The expiry date refers to the last day of that month.
- **Storage conditions**: Store below 25°C.
- Do not throw away any medicines via wastewater or household waste. Ask the pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Additional information

In addition to the active ingredients, the medicine also contains:
Povidone, croscarmellose sodium, hypromellose, magnesium stearate, titanium dioxide (E171), macrogol 400, sunset yellow FCF aluminum lake (E110), quinoline yellow aluminum lake (E104), silica colloidal anhydrous, carnauba wax

What the medicine looks like and what the package contains:
An orange caplet with a score line on both sides.
Approved package sizes: 10, 20, 50 caplets. Not all package sizes may be marketed.
Revised in April 2023 according to MOH guidelines.
Drug registration number at the national drug registry of the Ministry of Health:
127-92-30768-00

Manufacturer and registration holder: Dexcel Ltd., 1 Dexcel St., Or Akiva 3060000, Israel