

**PATIENT PACKAGE INSERT WITH ACCORDING TO THE PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986**

The medicine is dispensed without a doctor's prescription

## Eximol Care Caplets

**Composition:** This medicine contains the active ingredient also contained in aspirin preparations.

**Each caplet contains:**  
**Acetylsalicylic acid 250 mg**  
**Paracetamol 250 mg**  
**Caffeine anhydrous 65 mg**

Inactive ingredients - 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.

This medicine is dispensed without a doctor's prescription and is not intended for children and adolescents below the age of 12. Below this age – contact the doctor.

Swallow this medicine properly. Consult a pharmacist if you need further information. Refer to the doctor if the signs (symptoms) of the ailment worsen or if the fever persists for more than 3 days or if there has been no pain relief within 5 days.

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

For temporary relief of headaches, mild to moderate headache associated with migraines, menstrual pains and pain accompanied by fever.

### Therapeutic group:

Acetylsalicylic acid – non-steroidal anti-inflammatory drug (NSAID).

Paracetamol – analgesic and antipyretic.

Caffeine – xanthine alkaloid, central nervous system stimulant.

### 2. BEFORE USING THE MEDICINE

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| <p><b>Do not use the medicine if:</b></p> <ul style="list-style-type: none"><li>• you are sensitive (allergic) to the active ingredients or to any of the other ingredients contained in the medicine.</li><li>• you are pregnant or breastfeeding.</li><li>• you are sensitive (allergic) to other NSAIDs.</li><li>• you are suffering from a bleeding peptic ulcer, hemorrhages, hemophilia, stomach problems (active peptic ulcer), asthma in combination with nasal polyps.</li><li>• you are under the age of 20 and are taking medicine to treat diseases accompanied by fever such as flu or chickenpox (due to fear of Reye's syndrome).</li><li>• you have ever suffered from the following effects, after taking an analgesic or fever-reducing medicine: urticaria (rash with swelling), swelling of the face, asthma, shock.</li><li>• you are concomitantly taking other preparations containing paracetamol (with or without a prescription). If you are not sure if a certain medicine contains paracetamol, consult the doctor or pharmacist.</li><li>• you are concomitantly taking other NSAIDs.</li><li>• you recently underwent, or are due to undergo, heart surgery.</li></ul> |
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### Special warnings regarding use of the medicine

- The medicine contains paracetamol - if you have previously developed skin side effects as a result of taking preparations containing paracetamol, do not take preparations containing paracetamol so that severe skin effects will not recur.
- Do not take additional antipyretics and analgesics or anti-cold medicines without consulting a doctor or pharmacist, to prevent paracetamol overdose or poisoning.
- Do not take additional preparations containing paracetamol.
- Do not use this medicine frequently or for a prolonged period without consulting the doctor.

- If you are sensitive to any food or medicine, inform the doctor before taking the medicine.
- Avoid taking a high dosage (at the recommended limit) of this medicine when fasting.
- This medicine may interfere with blood sugar test results.
- Do not take this medicine within the 7 days before any surgery.
- Taking this medicine at a dosage higher than recommended or for more than 10 days, may increase the risk of stroke or heart attack and gastric hemorrhage.

### Warnings relating to the liver:

- The medicine contains paracetamol, which may cause liver damage when:
- given at a dosage higher than recommended (more than 8 caplets within 24 hours).
  - given for a prolonged period.
  - alcoholic beverages are consumed during the course of treatment.
  - other medicines, which affect liver function, are taken, including other medicines containing paracetamol.

### Reye's syndrome:

Use of this medicine is prohibited in children and adolescents with or recovering from chickenpox or from flu-like symptoms. When using the medicine, if there are behavioral changes, together with nausea and vomiting, consult the doctor, as these symptoms may be early signs of Reye's syndrome - a rare but severe disease.

### Allergy warning:

This medicine may cause a severe allergic reaction that can include: urticaria (red, raised and itchy lesions), swelling of the face, asthma (wheezing) and shock.

### Gastric hemorrhage warning:

- Use of the medicine may cause gastric hemorrhage, particularly if:
- you are above the age of 60.
  - you are suffering from a peptic ulcer or from bleeding.
  - you are taking a higher dosage than recommended or for a longer time than recommended.
  - you are taking other NSAIDs, blood thinners or steroids.
  - you consume wine and alcoholic beverages.

### Before treatment with Eximol Care inform the doctor if:

- you are suffering from a severe headache; headache different from previous migraines; headache following a head injury, exertion, cough or bending down; migraine accompanied by vomiting.
- you had headache for the first time after the age of 50.
- you are suffering from fever and from a stiff neck.
- the migraines have never been diagnosed by a specialist.
- you are suffering, or have suffered in the past, from impaired function of: the respiratory system (e.g., asthma), the digestive system (e.g., ulcer, heartburn, persistent or recurrent abdominal pains), the blood system (e.g., coagulation).
- you are suffering, or have suffered in the past, from nasal polyps, gout, hypertension, heart and/or blood vessel diseases.
- you are suffering, or have suffered in the past, from a liver disease or impaired function of the liver (including jaundice and cirrhosis).
- you are suffering, or have suffered in the past, from impaired function of the kidney.
- you are suffering, or have suffered in the past, from alcoholism.
- you are taking diuretics.
- you are above the age of 60.
- taking a medicine from this group or any other analgesic, resulted in the past, in severe side effects.
- the warning regarding gastric hemorrhage applies to you.

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

- Additional NSAIDs with pain relieving and anti-inflammatory action.
- Additional medicines containing paracetamol, aspirin, an analgesic or antipyretic agent.

- Anticoagulants (warfarin, heparin) and blood thinners.
- Medicines to treat diabetes, gout (such as probenecid) or arthritis.
- Antiepileptics and anticonvulsants such as barbiturates, phenytoin, carbamazepine and valproate.
- Hepatic enzyme inducers (such as rifampicin, barbiturates).
- Metoclopramide or domperidone (for treatment of nausea, vomiting and other digestion problems).
- Chloramphenicol (antibiotic).
- Cholestyramine (to reduce excessive blood fats)
- Medicines to treat AIDS, such as zidovudine.
- Antacids.
- Medicines that affect urinary acidity.
- Antihypertensives (such as ACE inhibitors)
- Antidepressants or anxiolytics (such as SSRIs)
- Medicines to treat asthma (such as theophylline)
- Diuretics (such as furosemide)
- Methotrexate (chemotherapy)
- Corticosteroids.

### Use of the medicine and food

The recommended dosage of the medicine contains quantities of caffeine similar to those in a cup of coffee. During the course of treatment, limit caffeine consumption in medicines, foods and beverages, as excess caffeine may cause nervousness, irritability, insomnia and sometimes rapid heart rate.

Swallow the medicine whole with a full glass of water.

Take the medicine after a meal.

### Use of the medicine and alcohol consumption

During the course of treatment with this medicine, do not consume wines or alcoholic beverages, due to increased risk of liver damage and gastric hemorrhage.

### Pregnancy and breastfeeding

Do not use the medicine if you are pregnant or breastfeeding.

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

Check with the doctor or pharmacist if you are unsure.

Recommended dosage unless otherwise instructed by the doctor:

Adults and children over 12 years of age: 2 caplets every 6 hours.

Do not take more than 8 caplets in a 24-hour period.

When treating a migraine, do not take the medicine for more than 48 hours.

This medicine is not usually intended for adolescents and children under 12 years of age. Refer to a doctor if the fever persists for more than 3 days or if there has been no pain relief within 5 days.

### Do not exceed the recommended dose.

In the elderly, exercise caution in accordance with their medical condition, particularly among patients with low body weight.

Directions for use:

Do not crush/halve/chew the caplet. Swallow the medicine with a full glass of water.

Take this medicine after a meal.

Do not lie down for 15-30 minutes after taking the medicine.

**If you took an overdose or if a child 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 without explicit instruction from the doctor! Even if you feel well, immediate care is essential. **due to risk of developing severe liver damage.** Side effects can include nausea and vomiting, diarrhea, loss of appetite, abdominal pains, swelling, increased sweating, pain or sensitivity 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.

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

### 4. SIDE EFFECTS

As with any medicine, use of Eximol Care may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not experience any of them.

### Severe side effects:

#### Discontinue use and refer to the doctor immediately if:

- an allergic reaction occurs (rash, skin itching, redness, swelling of the face, lips, tongue, throat and/or limbs), shortness of breath or difficulties breathing or swallowing, tinnitus or hearing loss, redness and swelling in the painful area, severe abdominal pains.
- In rare cases, paracetamol may 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 a doctor immediately!
- signs of changes in the blood system occur, such as: bleeding, bruises, development of inflammations more easily.
- you feel increased weakness or tiredness.
- you feel faint, have bloody vomit, bloody or black stools, unrelenting abdominal pain. These are signs of gastric hemorrhage.
- the pain worsens or there has been no improvement in 5 days.
- the fever worsens or persists for more than 3 days.
- new symptoms develop.
- the following symptoms occur: Reye's syndrome, nervousness, insomnia, vomiting.

#### Additional side effects

- Nausea, stomach irritation, mild abdominal pain, heartburn.
- Dizziness

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

### Reporting side effects:

Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage ([www.health.gov.il](http://www.health.gov.il)) that directs you to the online form for reporting side effects, or by entering the link: <https://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffect/Medic@moh.gov.il>

In addition, you can report to Perrigo via the following address: [www.perrigo-pharma.co.il](http://www.perrigo-pharma.co.il)

### 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 and sight of children and/or infants to avoid poisoning. Do not induce vomiting without explicit instruction from 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 in the original package up to 25°C.
- Can be used for 9 months after first opening.

### 6. FURTHER INFORMATION

- In addition to the active ingredients, the medicine also contains: Carnauba wax, croscopovidone, blue No. 1 FD&C lake, hypromellose, microcrystalline cellulose, povidone, pregelatinized starch, propylene glycol, saccharin sodium, stearic acid, titanium dioxide.
- What the medicine looks like and the contents of the package: the medicine is provided in bottles containing 24, 50 or 100 white caplets with "L374" debossed on one side.
- Registration holder: Perrigo Israel Agencies Ltd., 29 Lehi Street, Bnei Brak 51200.
- Manufacturer: Perrigo Company, Allegan, Michigan, USA.
- This leaflet was checked and approved by the Ministry of Health in: January 2014.
- Registration number of the medicine in the National Drug Registry of the Ministry of Health: 15710.34987