

Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) – 1986

The medicine is dispensed without a doctor's prescription

## Efferamol

Effervescent tablet

### **:Name, dosage form and strength of the medicine (1**

**Name of the medicine:** Efferamol

**Dosage form:** Effervescent tablet

**Active substance in each tablet:** Each effervescent tablet contains paracetamol 500 mg

**Each tablet also contains:** sodium 332 mg

.For the list of inactive ingredients and allergens - see section 6

**Read the entire leaflet carefully before using the medicine.** Keep this leaflet. You may need to read it again

This leaflet contains concise information about the medicine. If you have further questions, ask the doctor or pharmacist

**This medicine is dispensed without a doctor's prescription and is intended for adults and children weighing more than 33 kg. You must take the medicine properly. Consult a pharmacist if you need further information**

**Contact a doctor if the fever persists for more than 3 days or if the disease signs (symptoms) do not resolve within 5 days despite using the medicine**

**What is the medicine intended for?** The medicine is intended for relief of pain and reduction of fever caused by various reasons, such as headaches, toothache, cold, influenza, rheumatic pain and menstrual pain

**.Therapeutic group:** Analgesic and antipyretic

### **:Before using this medicine (2**

**:Do not use the medicine**

the other ingredients If you are sensitive (allergic) to the active substance paracetamol or to any of the other ingredients and the other ingredients are specified of the medicine. The active substance is indicated in section 1 in section

**:Special warnings regarding use of the medicine**

If you have developed in the past skin side effects as a result of taking medicines containing paracetamol, do not take medicines containing paracetamol, so that severe skin effects are not caused again

.The medicine contains paracetamol which may cause liver damage when

• Given at a dosage higher than the recommended dosage or for a prolonged period →

• Alcoholic beverages are consumed during the treatment →

• Additional medicines which affect liver function are taken →

.Do not use this medicine often without consulting a doctor

• Do not take additional antipyretics and analgesics or medicines for cold without consulting a doctor or pharmacist - to prevent paracetamol overdose or poisoning

• Do not take additional medicines containing paracetamol

• Avoid taking a high dosage of this medicine (within the recommended dosage limits) when fasting

• If you are sensitive to any food or medicine, inform the doctor before taking the medicine

**:Consult a doctor before starting 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, 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 recently completed treatment with

the medicine

• (Anticoagulants (e.g. warfarin

• (Medicines stimulating the production of liver enzymes (e.g. rifampicin, barbiturates

• (Medicines for treatment of epilepsy (e.g. phenytoin, carbamazepine

• Medicines of the non-steroidal anti-inflammatory drugs (NSAID's) class such as: acetyl-salicylic acid (aspirin) or other salicylates

• Metoclopramide or domperidone (for treatment of nausea, vomiting and other gastrointestinal problems)

• (Chloramphenicol (an antibiotic

• (Probenecid (for treatment of gout

• (Cholestyramine (for reduction of excessive levels of blood lipids

**Use of paracetamol and alcohol consumption:** During the treatment with paracetamol, do not consume alcohol due to increased risk of liver damage

**Pregnancy and breastfeeding:** If you are pregnant or breastfeeding, consult a doctor before starting treatment with this medicine

**Use in children:** This medicine is intended for adults and children above the age of 6 years, see section "3 "How should you use the medicine

Parents must report to the attending doctor of any side effects as well as any additional medicine given to the child

**Important information about some of the ingredients of the medicine:** Each tablet contains 332 mg of sodium (present in table salt). This quantity is about 22% of the maximal daily intake recommended for adults

### **?How should you use the medicine (3**

.Check with the doctor or pharmacist if you are not sure

**:The standard dosage unless instructed otherwise by the doctor**

**Adults and children aged 12 years and older:** 1-2 effervescent tablets dissolved in a glass of water every 4-6 hours as required

.Do not exceed the dose of 8 effervescent tablets per 24 hours

**Children below the age of 12 years, weighing more than 33 kg:** One effervescent tablet dissolved in a glass of water every 4-6 hours as required

.Do not exceed the dose of 4 effervescent tablets per 24 hours

**Do not exceed the recommended dose.** Ensure dissolving the effervescent tablet in water prior to (drinking the solution (see "Instructions for use" below

**Contact a doctor if the fever persists for more than 3 days or if the disease signs (symptoms) do not resolve within 5 days despite using the medicine**

**Instructions for use:** Do not swallow the effervescent tablet in its dry and solid state. Prior to taking the medicine, dissolve the effervescent tablet in a glass containing a small quantity of water and mix with a teaspoon, as required

The medicine dissolved in water has an orange flavor. Drink the solution directly from the glass immediately after preparing it

.Take the medicine after a meal, on a full stomach

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

Do not take medicines in the dark! Check the label and the dose each time you take a medicine. Wear glasses if you need them

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

### **:Side effects (4**

As with any medicine, use of this medicine may cause side effects such as dizziness in some users. Do not be alarmed by the list of side effects. You may not suffer from any of them

**- Severe side effects: Discontinue the treatment and contact a doctor immediately**

• If acute allergic reactions occur, such as: rash and itching, swelling of the face, lips, tongue, throat and/or extremities, which may cause difficulties breathing or swallowing

• Paracetamol may, in rare cases, cause the appearance of severe skin diseases, the signs of which may be: redness, rash, blisters, extensive skin damage

• Acute skin side effects may appear even if you have previously taken medicines containing the active ingredient paracetamol without any problem. If skin side effects appear, discontinue the treatment and contact a doctor immediately

• If signs of changes in the blood system occur, such as: bleeding, bruises, development of inflammations more easily

**If a side effect appeared, if any of the side effects is worsening or if you experience any side effect not mentioned in the leaflet, consult the doctor immediately**

Side effects can be reported to the Ministry of Health by using the link "Reporting side effects due to medication therapy" located on the Ministry of Health home page ([www.health.gov.il](http://www.health.gov.il)) directing to the online form for side effects reporting, or by entering the link: <https://sideeffects.health.gov.il>

### **?How to store the medicine (5**

Avoid poisoning! This medicine and any other medicine should be kept in a closed place out of the reach of children and/or infants in order to avoid poisoning. Do not induce vomiting without an explicit instruction of the doctor

.Do not use the medicine after the expiry date (exp. date) appearing on the cylinder package

.The expiry date refers to the last day of that month

**Storage conditions:** Store at a temperature below 25°C. Keep the cylinder with the effervescent tablets tightly closed

**.Shelf life after first opening:** After first cylinder opening, the medicine can be used for a period of 6 months

### **:Additional information (6**

**:In addition to the active substance, the medicine also contains the following inactive ingredients**

Sodium Hydrogen Carbonate, Citric Acid Anhydrous, Sorbitol, Saccharin Sodium, Orange Flavor,

Sucrose Monopalmitate, Povidone K30

**What does the medicine look like and contents of the pack:** the medicine looks like a white, round and flat tablet

The effervescent tablets are packed in a plastic cylinder with a stopper. Each plastic cylinder contains

10 effervescent tablets

**:Pack size:** The medicine is supplied in a pack, as detailed below

plastic cylinders. The number of cylinders in each carton pack may vary. Carton packs containing 10 tablets may change according to the pack size. The number of effervescent tablets in each pack is indicated on the carton pack

• Occasionally not all the packs are marketed

**Marketing Authorization Holder:** Tree of Life Pharma Ltd., company number 513071621, P.O.B. 799, Lod 7110604

**.Manufacturer:** E-Pharma Trento, Trento, Italy

Registration number of the medicine in the National Drug Registry of the Ministry of Health: 158.67.34469.00

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