

**Patient package insert in accordance with the Pharmacists' Regulations (Medical Preparations) 1986**

The medicine is dispensed without a doctor's prescription

## **Strepsils® Plus**

Lozenges

### **Active ingredients and their concentration:**

#### **Each Strepsils® Plus lozenge contains**

2,4 Dichlorobenzyl Alcohol 1.2 mg

Amylmetacresol 0.6 mg

Lidocaine Hydrochloride 10.0 mg

For the list of inactive ingredients, see section 6. See also section "Important information about some of the ingredients of the medicine".

**Carefully read the leaflet to the end before using the medicine.** This leaflet contains concise information about the medicine. If you have any further questions, ask your doctor or pharmacist. Take the product according to the instructions in the dosage section of this leaflet.

The medicine is intended for adults and children over 12 years of age. Use the medicine correctly. Consult a pharmacist if you need further information. You should contact the doctor if the signs of the disease (symptoms) worsen or do not improve after a few days.

### **1. What is the medicine intended for?**

For the rapid relief of a severe sore throat and as an antiseptic for the throat.

**Therapeutic group:** Antiseptic.

The product contains two active substances (2,4 dichlorobenzyl alcohol and amylmetacresol) with antiseptic action, which kill bacteria involved in mouth and throat infections. In addition, the product contains lidocaine - a local anesthetic - which rapidly relieves sore throats.

### **2. Before using the medicine**

#### **Do not use the medicine if:**

- You are sensitive (allergic) to the active substances or to any of the other components of the medicine (see section 6).
- You have previously suffered from an allergy to local anesthetics from the amide group.
- You have suffered in the past or suspect that you suffer from methemoglobinemia (cyanosis).

#### **Special warnings about the use of the medicine**

Before treatment with Strepsils Plus tell your doctor if:

- You are pregnant or breastfeeding.
- You have been told by the doctor that you suffer from an intolerance to certain sugars (see section "Important information about some of the ingredients of the medicine")
- You suffer from asthma.
- The signs of the disease (symptoms) do not improve or are accompanied by high fever, headache or any other unusual sign.

#### **Children and adolescents:**

This medicine is not intended for children under 12 years of age.

**If you are taking, or have recently taken, any other medicines including over-the-counter medicines and dietary supplements, tell your doctor or pharmacist.**

### **Pregnancy and breastfeeding**

The use of the medicine is not recommended if you are pregnant or breastfeeding except if you are under medical supervision.

### **Important information about some of the ingredients of the medicine**

Each lozenge contains:

- 1.52 grams sucrose and 0.98 grams glucose. Consult your doctor before using the medicine if you have been told that you suffer from an intolerance to certain sugars (see section "**Special warnings regarding the use of the medicine**") or if you are diabetic.  
Avoid using the medicine if you suffer from an intolerance to certain sugars such as fructose, glucose-galactose malabsorption and a sucrose-isomaltose insufficiency.
- Less than 1 millimol (23 mg) of sodium, which is considered "sodium-free".
- The product contains very low levels of gluten (from wheat starch). The product is considered 'gluten-free'. It is unlikely that this product will cause any problems in celiac patients. One lozenge contains no more than 19.60 micrograms of gluten. **Do not take this product if you suffer from gluten allergy** (a condition different from celiac disease).
- The product contains Star Anise Oil and peppermint oil flavorings that include d-limonene, Anisyl alcohol, and linalool that may cause allergic reactions.
- It also contains sulfite - sulfur dioxide (E220) (found in liquid glucose) which may rarely cause severe allergic reactions or bronchospasm.

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

Check with the doctor or pharmacist if you are not sure about the dosage and manner of treatment with the product.

The usual recommended dose for adults and children over 12 years old is:

Suck on one lozenge slowly every 2-3 hours as needed.

Do not use more than 8 lozenges a day.

**Do not exceed the recommended dose.**

This medicine is not intended for children under 12 years of age.

If there is no improvement in your condition within 3 days, refer to a doctor.

#### **Treatment duration:**

For short term use only.

The lowest dose should be taken for the shortest time in order to relieve the symptoms.

**If you have taken an overdose or if a child has accidentally swallowed the medicine**, proceed to a hospital emergency room immediately, and bring the medicine package with you.

**If you forgot to take the medicine** at the designated time, do not take a double dose. Take the next dose at the usual time and do not exceed the recommended dose.

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

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

### **4. Side effects**

Like any medicine, the use of Strepsils Plus 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.

**Stop use and refer to a doctor** if an allergic reaction occurs such as rash, swelling under the skin, nausea, discomfort in the oral cavity. Frequency is unknown (it is not possible to determine their frequency from the available information).

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

You can report side effects to the Ministry of Health by clicking on the link "Reporting side effects due to medication" found on the home page of the Ministry of Health website ([www.health.gov.il](http://www.health.gov.il)) which refers to the online form for reporting side effects, or by entering the link <http://sideeffects.health.gov.il>

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

- Prevent 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 unless explicitly instructed to do so by the doctor.
- Do not use the medicine after the expiration date (exp. date) that appears on the carton. The expiration date refers to the last day of that month.
- Storage conditions: Store at a temperature below 25°C.
- Ask the pharmacist how to dispose of medicines that are no longer in use. These steps will help you protect the environment.

## **6. Additional information**

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

Liquid Sucrose, Liquid Glucose, Tartaric Acid, Sodium Saccharin, Levomenthol, Peppermint Oil, Star Anise Oil, Indigo Carmine, Quinoline Yellow.

**What the medicine looks like and the contents of the pack:** The carton package contains 24 lozenges. The lozenges are round, light blue in color.

**Manufacturer and address:** Reckitt Benckiser Healthcare International Ltd., Nottingham, England

**Registration holder and address:** Reckitt Benckiser (Near East) Ltd., 6 Hangar St., Hod Hasharon.

**Drug registration number at the national drug registry of the Ministry of Health:**

106.86.28928.00

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