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Pharmaceutical Laboratories S.A.

PATIENT INFORMATION LEAFLET

TREBON-N ®

Powder for oral suspension 200 mg/5ml

1. MEDICINAL PRODUCT SPECIFICATIONS

1.1 **Name: TREBON-N® Pd.or.sus. 200 mg/5ml**

1.2 **Composition:**

Active ingredient: ACETYLCYSTEINE

Excipients:

Saccharin sodium, Glycine, Sodium citrate, Methyl-p-hydroxybenzoate sodium salt E 215, Glucose anhydrous, Orange flavour in powder, B. Carotene 1% cws, Water.

1.3 **Pharmaceutical form:**

Powder for oral suspension.

1.4 **Concentration in Active Substance**:

Each teaspoon (5 ml) of the suspension of 200mg/5ml that has been diluted according to the instructions contains 200mg of ACETYLCYSTEINE.

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1.5 **Presentation-Packaging:**

Cardboard box that contains a colourless flacon of 150 ml, with a plastic screw cap, which contains 30.0 g orange powder, and a Patient Information Leaflet.

The powder after the addition of 120 ml of water constitutes an oral suspension (FL x 120ml).

1.6 **Therapeutic Category:**

Mucolytic - expectorant.

1.7 **Marketing Authorization Holder:**

UNI-PHARMA KLEON TSETIS PHARMACEUTICAL LABORATORIES S.A.
14th km National Road 1, GR-145 64 Kifissia, Greece
Tel.: +30 2108072512
Fax: +30 2108078907
e-mail: unipharma@uni-pharma.gr

1.8 **Manufacturer:**

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2. WHAT YOU SHOULD KNOW ABOUT THE MEDICINAL PRODUCT

2.1 General information:

The active ingredient of the medicinal product is ACETYLCYSTEINE, which is produced through the acetylation of CYSTEINE, which is a natural amino acid. ACETYLCYSTEINE is used as a mucolytic agent.

2.2 Indications:

For the liquefaction of bronchial excretions in acute and chronic broncho-pulminary, conditions (bronchitis, emphysema, tracheobronchitis, chronic asthmatic bronchitis).

When deemed necessary, during acute outbreaks of bronchitis, an appropriate antibiotic should be co-administered.

2.3 Contra-Indications:

You should not take the medicine, in case you had any allergic reaction to the medicine in the past or in case you have an active gastro-duodenal ulcer.

2.4 Special Precautions & warnings prior to use:

2.4.1 *Generally*

❖ During the usage of this medicine, an increase in liquefied bronchial excretions may be presented and there will have to be an effort from the patient to remove the excess quantity by coughing. If this is not effective, special support may be required in order to keep the airways open.

❖ The medicine should be administered with caution to asthmatic patients, due to the risk of bronchospasm. In the event of bronchospasm the treatment should stop immediately.

❖ The administration of the medicine to patients with hepatic and renal impairment should be avoided.

2.4.2 *Use in pregnancy*

ACETYLCYSTEINE should be administered to women in pregnancy, only when it is deemed necessary.

2.4.3 *Use during lactation*

ACETYLCYSTEINE should be administered with caution to breastfeeding women.

2.4.4 *Effect on the ability to drive or use machinery*

There are no indications showing that ACETYLCYSTEINE has any effect on the ability to drive or use machinery.

2.4.5 *Special Precautions & warnings prior to use, concerning the excipients contained in the formulations:*

Diabetic patients should be informed that the powder for oral suspension contains sugar.

2.5 **Drug Interactions:**

- ACETYLCYSTEINE should not be co administered with cough suppressants or medicines with an atropine effect.
- Always inform your attending physician or pharmacist concerning any other medicine you take, even if this medicine was not given to you with a medical prescription.

2.6 **Dosage:**

Dosing must be individualized by your doctor, depending on your special needs. Do not change by yourself the dosage regimen set by your attending physician. The following dosage regimen is usually applied:

- *Infants up to the age of 2*

100mg two times per day.

- *Children in the ages of 2-6*

200mg two times per day

- *Adults and Children in the ages of 7 years and above*

200mg three times per day

It is preferable that the medicine is administered before meals.

The dosage may be increased according to the instructions of the attending physician based on the assessment of treatment outcomes.

Duration of treatment: The duration of treatment should not exceed 8-10 days without medical advice.

2.7 Overdosage:

If you accidentally take a high dose of ACETYLCYSTEINE, immediately inform your doctor.

The intake of high oral doses of ACETYLCYSTEINE is usually followed by general gastrointestinal symptoms (like nausea, vomiting).

2.8 Adverse Reactions - Side Effects:

- Hypersensitivity reactions have rarely been reported. Some gastrointestinal symptoms (stomatitis, nausea, vomiting, activation of gastro-duodenum ulcer), fever, rhinorrhea, sluggishness, dizziness, headache, vertigo, rash and chills may appear.
- Clinically diagnosed bronchospasm occurs rarely and unpredictably in patients with asthmatic bronchitis.
- Cases of acquired sensitivity to ACETYLCYSTEINE have rarely been reported.

Do not neglect to immediately inform your physician in the event of any unusual symptom occurring throughout the duration of the treatment.

2.9 What you should know in case you miss a dose:

If you miss a dose take it as soon as possible. However, if it is time for your next dose, skip the one you missed and continue with your known dosage regimen. **Do not double the dosages.**

2.10 **Expiration date:**

TREBON-N®, when stored at room temperature, in its original packaging, remains stable up to the expiration date printed on the packaging.

Do not use the product after the expiration date printed on the packaging.

2.11 **Special precautions for storage:**

Do not store above 25°C. After the reconstitution the product should be stored in the refrigerator for 20 days or at temperature not above 25°C for 12 days.

2.12 **Date of last revision:**

2.13 **Prescribing Information:**

Medicinal product subject to medical prescription.