

## PATIENT INFORMATION LEAFLET

### Oledro Hot Effervescent Granules

**It's taken orally.**

**Active Ingredients:** Each effervescent Granules contains Paracetamol 500 mg, Phenylephrine HCl 10 mg, Chlorphenyramine maleat 2 mg, Oxolamine citrate 100 mg.

**Excipients:** Tartaric acid, Citric acid, Sodium bicarbonate, Sodium carbonate, Quinoline yellow, Lemon flavor, Collidone K-30, Saccharine, Sugar

**Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor.
- This medicine has been prescribed for you only. Do not pass it on to others.
- If you go to hospital or doctor when using this medicine, tell your doctor that you are using this medicine.
- We are asleep to those who write this instruction. Do not use high or low doses other than the recommended dose for the medication.

#### **What is in this leaflet;**

1. What OLEDRO HOT® is and what it is used for?
2. What you need to know before you take OLEDRO HOT®?
3. How to take OLEDRO HOT®?
4. Possible side effects
5. How to store OLEDRO HOT®?

## **1. What OLEDRO HOT® is and what it is used for?**

OLEDRO HOT® is contain active ingredient like Paracetamol, phenylephrine, chlorpheniramine maleate and oxolamine citrate and its White-light yellow colored, homogeneous granules in lemon flavor and smell Single Dose Effervescent Granule Sachet.

OLEDRO HOT® is available in packages containing 6 and 12 Sachet, in the original box.

OLEDRO HOT® is combination medicine of four active ingredients. OLEDRO HOT® is decrease the symptom like fever and flu, pain due to colds and flu.

## **2. What you need to know before you take OLEDRO HOT®**

### **Do not use OLEDRO HOT® in the following situations**

- If you are allergic to OLEDRO HOT® or to any of the other ingredients of this medicine (listed in section 6),
- If you have severe cardiovascular, liver (Child-Pugh category 9) or kidney disease,
- If you have a disease accompanied by severe high blood pressure or rapid heartbeat,
- If you have some urine remaining in the bladder after the procedure, such as prostate adenoma,
- If you have blockage in your bladder or intestines,
- If you have a peptic ulcer that causes constriction,
- If you have any lung disease, including asthma,
- If you have eye strain (glaucoma)
- If you have deficiency of glucose 6-phosphate dehydrogenase enzyme (lack of protein that protects red blood cells from the damaging condition called oxidation reactions)
- If you are suffering from Sara (epilepsy)
- If you are using other medications that contain paracetamol,
- If you are pregnant or breast-feeding your baby,
- If you are younger than 12,

**Use OLEDRO HOT® with caution in the following situations.**

- If you are using alcohol,
  - If you have liver trouble next to your continuous alcohol use,
  - If a Torsades de Pointes or QT extension has been seen in the past due to impairment of heart rate (arrhythmia)
  - If you have cardiovascular system diseases,
  - If you are suffering from cerebral atherosclerosis,
  - If your tension drops for an unspecified reason (idiopathic orthostatic hypotension)
  - If you are suffering from pheochromocytoma (a tumor of the adrenal glands that causes an increase in the amount of adrenaline)
  - If you have a thyroid dysfunction,
  - If you are growing prostate,
  - If you have bronchial asthma,
  - If you have diabetes (diabetes mellitus)
  - If you have Gilbert syndrome, a hereditary disease characterized by elevation of liver enzymes (e.g. alanine aminotransferase (ALT) level) and transient jaundice,
  - If you have surgery,
  - If you have been using a monoamine oxidase inhibitor (MAOI) for depression, psychiatric or emotional disorders or Parkinson's treatment, or have used it in the last 2 weeks.
  - Do not use OLEDRO HOT® longer or shorter than recommended. OLEDRO HOT® contains recommended doses and paracetamol, which can cause liver damage when used on saline.
  - Paracetamol may cause severe liver poisoning at high doses.
  - It should be used with caution under the control of a doctor in patients with anemia, lung patients, liver and kidney dysfunction.
  - If you are using a paracetamol-containing product for the first time or if you have used it before, redness, rash or a skin reaction may occur in the first dose or repeated doses. In this case, contact the doctor. You need to leave an alternative and go to an alternative treatment. You should not use this medication or another medication that contains paracetamol in the formation of such a skin reaction. This can lead to serious and fatal skin reactions.
- May cause liver damage in adults at long-term (chronic) daily doses. It should be used with caution in patients with alcoholic liver disease.

Please consult your doctor if these warnings apply to you at any time in the past.

### **Used OLEDRO HOT® with food and drink**

OLEDRO HOT® should not be used with alcohol as it may cause liver damage.

Due to the risk of liver poisoning (hepatotoxicity) in people who drink alcohol, the daily dose of paracetamol should not exceed 2000 mg.

### **Pregnancy**

*You will consult your pharmacist or doctor before taking OLEDRO HOT®.*

Do not take this medicine if you are pregnant or plan to become pregnant.

If you notice that you are pregnant during your treatment, consult your doctor or pharmacist immediately.

### **Breast-Feeding**

*You will consult your pharmacist or doctor before use it.*

If you are breastfeeding your baby, consult your doctor before taking OLEDRO HOT®

### **Driving and using machines**

OLEDRO HOT® may cause drowsiness. Therefore, please be careful when using tools and machines.

### **Important information about some of the auxiliary substances contained in OLEDRO HOT®**

#### Sodium Warning

OLEDRO HOT® contains 4,40 mmol (108,6 mg) sodium per dose. To be taken into consideration by patients on a controlled sodium diet.

#### Sugar (sucrose) Warning

OLEDRO HOT® contains 7,918 g of sugar (sucrose) per dose. This should be considered in patients with diabetes mellitus.

### **Use with other medicines**

Do not use OLEDRO HOT® if you are taking other medicines containing monoamine oxidase inhibitors (including moclobemide) or paracetamol.

The effect of OLEDRO HOT® may change when used in combination with certain medicines. Please inform your doctor or pharmacist if you are using or have recently used any medicine with or without a prescription.

### **3. How to use OLEDRO HOT<sup>®</sup>**

Children who is bigger than 12 years old and Adults:

It can be taken in per 6 hours. It should not be used more than 4 doses in a day and more than 5 days.

Due to the risk of liver poisoning (hepatotoxicity) in people who drink alcohol, the daily dose of paracetamol should not exceed 2000 mg.

#### **Application Method:**

OLEDRO HOT<sup>®</sup> is taken orally and is used as follows:

Each sachet should be dissolved in 2/3 of a glass hot water and should be drunk hot. You can use it before or after meals.

#### **Use in children and adolescents**

##### Children

OLEDRO HOT<sup>®</sup> should not be used in children under the age of 12 years.

#### **Geriatric population:**

There isn't a special situation for geriatric population

#### **Specific use cases**

OLEDRO HOT<sup>®</sup> should be used with caution when used in patients with liver or renal insufficiency.

OLEDRO HOT<sup>®</sup> should not be used when patients have severe liver or renal insufficiency

If you have an idea like medicine's effect high or low, please inform your doctor or pharmacist.

#### **If you take more OLEDRO HOT<sup>®</sup> than you should;**

Palpitations, nausea and vomiting are frequent early signs of overdose. In some cases, however, the symptoms may not occur for several hours. For this reason, immediately inform your doctor or consult the hospital for overdose or accidental medication. Acute (short-term) high doses can lead to liver poisoning. Overdose damage is higher in alcoholic liver patients.

Paracetamol overdose should be treated immediately. The effects of overdose are similar to the effects listed in the possible side effects section. In serious cases, mental confusion, hallucinations (vision), seizures, and cardiac rhythm disturbances may occur.

In the event of overdose, dizziness, color puffiness, vomiting and excitement may occur. If you accidentally take too much OLEDRO HOT<sup>®</sup>, contact your doctor immediately.

## **If you forget to take OLEDRO HOT®**

If you accidentally miss a daily dose, just take the next dose as normal. If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

Do not take a double dose to make up for a forgotten dose.

## **4. Possible Side Effects**

Like all medicines, this medicine can cause side effects, although not everybody gets them. If happen following situation when you used OLEDRO HOT, stop using it and contact your doctor immediately:

Allergic skin reactions such as redness and itching on the skin

- Anemia when taken in large quantities, a decrease in the number of blood cells (thrombocytopenia, thrombocytopenic purpura, leukopenia, neutropenia, pancytopenia)
- Reduction in the number of white blood cells (agranulocytosis)
- Lyell syndrome (toxic epidermal necrolysis including fatal outcomes, a skin disease that can develop due to drugs and various infections)
- Stevens-Johnson syndrome (infiltration of blood around the skin and the eye, swelling and redness)
- Acute generalized exanthematous pustulosis (acute diffuse rash accompanied by high fever, small bubbles filled with pus)
- Asthma and shortness of breath
- Disorder in the liver when taken in too much

These are all very serious side effects. If any of these are present in you, you have a serious allergy to OLEDRO HOT®. You may need to be admitted to an emergency medical intervention or hospital.

All of these very serious side effects are very rare.

The side effects are listed below according to their frequency of occurrence. Very common: it can be seen in at least one of 10 patients.

Common: less than one in 10, but more than 100 in one.,

Uncommon: less than one in 100 patients, but more than 1000 in one. Rare: less than one in 1000 patients, but more than one in 10000 patients.

Very rare: less than one in 10,000 patients. Unknown: Not predicted by available data.

## **Common**

- Headache, dizziness, sleepiness
- Upper respiratory tract disease indications
- Nausea, vomiting, gastrointestinal stomach-intestinal swelling, abdominal pain, constipation

## **Uncommon**

- Gastrointestinal bleeding
- Harmful effect on the kidney for prolonged use in treatment doses

## **Rare**

- Blood count changes such as decrease in blood pressure (thrombocytopenia), decrease in white blood cell count (leucopenia), decrease in blood cells (pancytopenia), anemia (anemia), hemolytic anemia
- Allergic reactions, anaphylactic shock (swelling of hands, feet, face and lips, or swelling especially in the throat, resulting in shortness of breath)
- Erythema multiform, which produces red rash, itching, allergic edema, swelling on the face, on the stomach and in the throat (angioedema), widespread chills (acute generalized exanthematous pustulosis)
- Asthma-like symptoms (bronchospasm) that lead to shortness of breath in the lung, thickening of the bronchial secretions
- Diarrhea, indigestion
- Liver disorder, hepatitis including jaundice (liver inflammation)
- Fatigue, chest compression
- Loss of appetite
- Depression, nightmares
- Irritability, inability to concentrate
- Blurred vision
- Tinnitus
- Acceleration of heart beat (tachycardia), palpitations, impaired rhythm in heart (arrhythmia)
- Low blood pressure

- Eye illusion in children
- Nausea, vomiting, burning of the stomach, increased intestinal motility, decreased transient feeling in the oral mucosa

### **Very rare**

- Lyell syndrome (an emerging skin disease due to drug and various infections)
- Reduction in the number of white blood cells

### **Unknown**

- Central nervous system arousal, brain inflammation (encephalopathy), trembling in the hands (tremor)
- Irritability, irritability (hypersensitivity to stimulants), restlessness, excitability
- Insomnia

Muscle diversion and incoordination (deterioration of coordination)

- Urinary retention (unable to urinate)
- Allergic reactions including exfoliative dermatitis (skin rash and scaling), light sensitivity, skin reactions
- Urticaria (hives)
- Sedation, headache, paradoxical excitation (induction of the body / organs) in children, confusional psychosis in the elderly (nervous disorder with consciousness blurring) ranging from mild dizziness to deep sleep,
- Oral establishment

*If you experience any side effects not mentioned in these instructions for use, please inform your doctor or pharmacist.*



## **5. How to store OLEDRO HOT®**

Keep this medicine out of the sight and reach of children.

Keep in original package, Store at room temperature below 25°C and a dry place. Do not use this medicine after the expiry date which is stated on the carton or the bottle label.

### **Marketing Authorization Holder:**

Drogsan İlaçları San. ve Tic. A.Ş.

Oğuzlar Mah. 1370. Sok. 7/3

Balgat – Ankara / TURKEY

### **Manufacturer:**

Drogsan İlaçları San. ve Tic. A.Ş.

Esenboğa Merkez Mah. Çubuk Cad.

No:31 Çubuk – Ankara / TURKEY

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