

## PATIENT INFORMATION LEAFLET

### OLEDRO® PEDIATRIC SYRUP

For oral administration only.

- **Active pharmaceutical ingredient:** Each 5 ml syrup contains 5.00 mg Phenylephrine hydrochloride and 1.00 mg Chlorpheniramine maleate
- **Excipients:** Ethanol, propylene glycol, raspberry essence, sugar (sucrose), glycerol, sodium methyl hydroxybenzoate, Sodium propylhydroxybenzoate, citric acid, deionized water.

**Read this entire 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 further questions, please ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others.
- Tell your doctor if you go to a doctor or the hospital when you use this medicine.
- Follow strictly to what is written in these instructions. Do not use **high or low** doses other than the recommended dose for the medication.

**What is in this leaflet:**

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

**Titles are included.**

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

- OLEDRO is a medicine with raspberry taste, clear and colorless in syrup form.
- OLEDRO, is a combined medicine, consist of one analgesic, one antipyretic (paracetamol) and one antihistaminic (chlorpheniramine maleate) and one decongestant (phenylephrine hydrochloride) which is formulated to be used in the

symptomatic treatment of non-specific upper respiratory system infections such as cold and flu.

- OLEDO is presented in 100 mL coloured glass bottles having with ½ scaled 5 ml spoon in cartoon box.
- OLEDO, is used for symptomatic treatment of common cold and flu, such as high temperature, chill, body pain, headache, nasal congestion, sneezing, runny nose.
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## **2. What you need to know before you take OLEDO?**

### **DO NOT TAKE OLEDO in the following situations**

- If you are allergic to OLEDO or to any of the other ingredients of this medicine (listed in section 6),
- If you have severe kidney or liver disease (Child-Pugh category >9)
- If you have severe hypertension or fast heart rate accompanied illness
- If you have coronary artery disease
- If you use MAO Inhibitors or you have used last dose of this type of medicine less than 2 weeks ago.
- If you have bladder or bowel outlet obstruction
- If you have narrowed stomach caused by peptic ulcer
- If you have diabetes (diabetes mellitus)
- If you have hyperthyroidism
- If you have any lung disease including asthma
- If you have epilepsy
- If you have glaucoma
- If you have pheochromocytoma
- It should not be used in children under 6 years of age

### **TAKE OLEDO CAREFULLY in the following situations**

- If you have cardiac arrhythmia, coronary artery disease, heart failure
- If you have high blood pressure
- If you have prostate enlargement
- If you have kidney impairment
- If you have thyroid dysfunction
- If you have congenital heart failure (QT syndrome or Torsades de Pointes)

- If you are older than 60
- If you use MAO Inhibitors which can be used for treatment of depression, psychiatric or emotional disorders, or Parkinson's disease or you have used last dose of this type of medicine less than 2 weeks ago.
- If you have stiffness in brain vessels
- If you have Idiopathic orthostatic hypotension
- OLEDO usage should be avoided in case of surgery
- OLEDO should be used cautiously under doctor supervision in the patients with anemia, lung diseases, impaired liver and kidney function
- If paracetamol would be used for the first time or there is any history of usage, redness in skin, rash or skin reaction could be seen with the first dose or repetitive doses. If this occurs contact with doctor to discuss discontinuation of treatment and changing alternative therapy. A person who had skin reactions following paracetamol therapy should not use this medicine or any other medicine that contains paracetamol. This could lead skin reactions including Steven-Johnson syndrome (blood blister on skin and eyes, and inflammation accompanied with swelling and skin rash) which is severe and could lead to death and acute generalized exanthematous pustulosis (It is characterised by the rapid appearance of areas of red skin studded with small sterile pustules accompanied with fever)
- Usage of other drugs which contains paracetamol, chlorpheniramine maleate and phenylephrine HCl together with OLEDO should be avoided.
- If you have Gilbert syndrome which is characterized with high liver enzymes and impermanent hepatitis.
- If you have deficiency of glucose-6-phosphate dehydrogenase enzyme (G6PD), which is deficiency of protein which protects red blood cells from destructive situation called oxidation reaction.
- If you have functional problems with bone marrow
- Paracetamol, which is one of the active ingredients of OLEDO has serious toxic effect on liver at acute high doses.
- It should be used cautiously with alcoholic liver patients. Maximum daily dose should not exceed 2 grams.
- If palpitation and increase in heartbeat is observed, treatment should be stopped.

- Do not use OLEDRO high doses other than recommended dose or longer than recommended time. Usage of high doses of OLEDRO other than recommended dose and time could lead liver damage and kidney failure which is caused by paracetamol.
- If you have new complaints or your fever and/or pain would not decrease in 3-5 days stop using OLEDRO and consult to your doctor.
- It is reported that sympathicomimetik medicines including phenylephrine rarely could cause encephalopathy/impermanent narrowing of blood vessels in brain. If you experience sudden onset of headache, nausea, vomiting and visual impairment stop using OLEDRO immediately.
- If haemorrhoid develops with stomach ache, rectal bleeding stop using OLEDRO immediately.
- OLEDRO should not be used children under 6 years of age unless there is necessary medical reason.

If you notice any of followings contact with your doctor.

- If you have breathing problems such as constant cough, asthma and chronic bronchitis
- If you expectorate excessively

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

### **Taking OLEDRO with food and drink**

As it may cause liver damage if taken with alcohol, alcoholic drinks should not be used while taking this medicine.

### **Pregnancy**

*Consult your doctor or pharmacist before taking this medicine,*

If you are pregnant or planning to get pregnant, contact your doctor before using OLEDRO.

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

### **Breast-feeding**

*Consult your doctor or pharmacist before taking this medicine,*

If you are breast-feeding, consult your doctor before taking OLEDRO

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

OLEDRO contains sugar (sucrose). If you have previously been told by your doctor that you have intolerance to some sugars, you should consult your doctor before taking this medicinal product.

This medicine contains 10.4% alcohol (w/v) by volume. Each 5 ml dose contains 520 mg ethanol. In other words, it contains ethanol which equals to 12.8 ml beer or 5.34 ml wine. It may be harmful for people with alcohol addiction. It should be used cautiously with pregnant and breastfeeding woman, children or patients who has high risk diseases such as liver disease or epilepsy.

Due to presence of propylene glycol, it may cause alcohol like symptoms.

Due to presence of Methyl and propyl hydroxybenzoates, it may cause allergic reactions (probably delayed)

This medicinal product contains less than 1 mmol (23 mg) Sodium for each 5 ml i.e. essentially 'sodium- free'.

### **Other medicines and OLEDRO**

When used with some medications the effect of OLEDRO may change.

Tell your doctor if your child is taking the following medicines.

If your child,

- is taking other medicines which contain Monoamine oxidase inhibitors or paracetamol  
Oledro should not be used.
- Sedatives, tranquilising medicines
- Medicines that cause delay in gastric emptying (i.e. propanthelin)
- Antidepressants (Some drugs used in the treatment of mental depression)
- Use of Chloramphenicol as an antibiotic
- Medicines that stimulate liver enzymes (i.e. rifampicin)
- Some sleeping pills like phenobarbital
- Some drugs used in epilepsy, such as phenytoin, carbamazepine
- Anti-clotting medicines such as derivatives of warfarin and coumarin
- Zidovudine (a medicine which is used HIV treatment)
- Domperidone (treatment of nausea-vomiting)
- Alcohol
- Medicines which is used of treatment of nausea and vomiting (tropisetron, granisetron)

- The use of OLEDRO with nasal decongestants, tricyclic antidepressants (used to treat psychiatric disorders), appetite suppressants and certain nerve stimulating drugs or monoamine oxidase inhibitors (MAOI) (used in the treatment of psychiatric disorders, eg, moclobemide) sometimes leads to elevated blood pressure.
- St. John's Wort-Hypericum perforatum, used in the treatment of mild to moderate depression
- The use of OLEDRO with cardiac glycosides (used in heart failure) increases the risk of heart rhythm disturbances.
- The use of ergot alkaloids (used in the treatment of migraine) increases the risk of side effects.
- OLEDRO inhibits the metabolism of phenytoin, which is used in epilepsy, and may cause phenytoin poisoning.

*Tell your doctor or pharmacist if your child is taking, have recently taken or might take any other prescribed or non-prescribed medicines.*

### **3. How to take OLEDRO?**

#### **Instructions for appropriate using and dose/application frequency:**

If not advised otherwise by the doctor, use at the following doses:

Children between 6 and 12 years of age (22-43 kg):

2 measuring spoon (10 ml) every 6 hours

It should not be used in children under 6 years of age.

Do not use more than 4 doses per day.

Do not use OLEDRO more than 5 days.

#### **Method of administration**

OLEDRO is for oral administration only

You can use OLEDRO before or after meals.

#### **Various age groups:**

Use in adults:

Children and adults over 12 years

20 ml (4 measuring spoons) every 6 hours

**Use in the elderly:**

OLEDRO should not be used in patients over 60 years of age.

**Special uses:**

OLEDRO should be used with caution when used in patients with liver or renal insufficiency.

OLEDRO should not be used in patients with severe liver or renal insufficiency.

*If you have an impression that the effect of ZIOKIM is too strong or weak, talk to your doctor or pharmacist.*

**If you take more OLEDRO than you should**

Palpitations, nausea and vomiting are frequent early signs of overdose. In some cases, 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.

Anticholinergic effects (blurred vision, mental retardation, urinary retention), convulsions (involuntary contraction of muscles that work voluntarily), paroxetine stimulation of the central nervous system, toxic psychosis, seizure, apnea (temporary respiratory depression) Cardiovascular collapse, including constipation), dystonic reactions (involuntary, strong muscle contractions and postural disturbances), and arrhythmia (abnormal heartbeats) can occur.

Tightness, restlessness, tremors, convulsions, palpitation and high blood pressure can be seen with side effects seen at recommended doses.

*If you take more OLEDRO than you should, talk to your doctor or pharmacist.*

**If you forget to take OLEDRO**

If you forget to give a dose of OLEDRO to your child, give missed dose as soon as you remember and repeat after 6 hours if necessary (in accordance with your doctor's recommendation).

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

#### **4. Possible side effects**

Like all medicines, OLEDRO can cause side effects in people sensitive to substances in the content of OLEDRO

**If any of the following happens, stop taking ZIOKIM and report to your doctor IMMEDIATELY or contact the emergency department of your nearest hospital:**

- Redness, itching, hives (urticaria)
- Allergic skin reactions such as skin rashes
- Allergic edema and angioedema (allergy related face and throat swelling)
- Acute generalized exanthematous pustulosis (acute diffuse rash accompanied by high fever, small bubbles filled with pus)
- Erythema multiform (hypersensitivity, usually redness, which is similar to spontaneous hand, face and leg lace)
- Stevens-Johnson syndrome (blood blister around the skin and the eye, swelling and redness)
- Lyell's syndrome (toxic epidermal necrolysis including fatal outcomes, a skin disease that can develop due to drugs and various infections)
- Heart rate irregularity (arrhythmia) or acceleration, palpitations
- Blockage of heart-feeding vessels (ischemic heart disease)
- Liver dysfunctions
- Anemia when taken in large quantities, a decrease in the number of blood cells after long period of usage (thrombocytopenia, thrombocytopenic purpura, leukopenia, neutropenia, pancytopenia)
- Reduction in the number of white blood cells (agranulocytosis)
- Asthma and shortness of breath
- Disorder in the liver when taken in too much



These are very serious side effects. If these side effects are applied to your child, it means your child is allergic to OLEDRO seriously.

This very serious side effect is observed quite rare.

Side effects are categorized as follows:

Very common: more than 1 in 10 people are affected

Common: between 1 in 10 and 1 in 100 people are affected

Uncommon: between 1 in 100 and 1 in 1,000 people are affected

Rare: between 1 in 1,000 and 1 in 10,000 people are affected

Very rare: fewer than 1 in 10,000 people are affected

Frequency not known (cannot be estimated from the available data)

### **Common**

- Headache, dizziness, sleepiness
- Upper respiratory tract disease indications
- Nausea, vomiting, stomach-intestinal swelling due to gall bladder, abdominal pain, constipation, diarrhea, mouth instability
- Nervousness, insomnia
- Muscle weakness and dizziness

### **Uncommon**

- Gastrointestinal bleeding, gastrointestinal disorders
- Drowsiness, dizziness
- Fatigue, agitation, restlessness
- Kidney damage that can lead to kidney failure
- Difficulty in urinating
- Inability to urinate in male patients (a pre-existing prostatic growth may be the predisposing factor).

### **Rare**

- Blood count changes such as decrease in blood pressure (thrombocytopenia), decrease in white blood cell count (leucopenia), decrease in blood cells (pancytopenia), anemia, hemolytic anemia

- Erythema multiforme, which produces red rash, itching, allergic edema, redness on the face, on the dorsal and throat swellings (angioedema), widespread chest pains (acute generalized axanthematous pustulosis)
- Allergic reactions, anaphylactic shock (swelling of hands, feet, face and lips, or swelling especially in the throat, resulting in shortness of breath)
- Asthma-like symptoms (bronchospasm) that lead to shortness of breath in the lung, thickening of the bronchial secretions
- Loss of appetite
- Depression, nightmare
- Dizziness, irritability (hypersensitivity to stimulants), not being able to concentrate
- Central nervous system stimulation indications, including imagery (especially in children)
- Blurred vision
- Tinnitus
- Fatigue, chest compression
- Blood pressure increase
- Hepatitis including jaundice
- Anxiety (anxiety)

### **Unknown**

- Central nervous system arousal, brain inflammation (encephalopathy), insomnia, tremor
- Headache
- Depressed state ranging from mild drowsiness to deep sleep, paradoxical excitation (induction of body / organs) in children, confusional psychosis in the elderly (nervous disorder with consciousness blurring)
- Allergic reactions including exfoliative dermatitis (skin rash and scaling), light sensitivity, skin reactions, urticaria
- Muscle diversion and incoordination (deterioration of coordination)
- Urinary retention (incontinence)
- The effects of metabolic function on endocrine and other regulators
- Irritability, irritability (hypersensitivity to stimulants), restlessness and excitement
- Insomnia

- Elevation of blood pressure (especially in hypertensive diseases), reflex bradycardia (slowing of heart rate to prevent abnormal elevation of blood pressure)
- Nausea, vomiting
- Difficulty at beginning of micturation (urination) and painful urination.
- It is more likely to be seen in people with mydriasis (extreme dilation of the eye baby), acute angle glaucoma (closed angle eyedrops).
- Hypersensitivity reactions include allergic reactions (eg, rash, urticaria, allergic dermatitis), and cross sensitivity caused by other sympathomimetics (drugs that cause similar effects to that of the sympathetic nervous system).
- difficul or painful urination, urinary retention (incontinence), this can be caused by obstruction of the bladder outlet obstruction, slight increase in heart rate, such as prostatic hypertrophy (prostate enlargement) and phenylephrine. Rarely, dizziness, headache, hypertension (high blood pressure, blood pressure above normal values) and restlessness have been reported.

*If you get any side effects, which is not included in this leaflet, report to your doctor or pharmacist.*

## **5. How to store OLEDRO?**

It should be stored in a dry place and in room temperature below 25 °C.

**KEEP AWAY FROM SIGHT AND REACH OF CHILDREN AND IN ITS PACKAGE.**

*Do not take ZIOKIM after the expiry date that is stated on the package.*

### ***Marketing Authorization Holder:***

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Oğuzlar Mah. 1370. sok. 7/3  
06520 Balgat-ANKARA

### ***Manufacturing Place:***

Drogsan İlaçları San. ve Tic. A.Ş.  
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