## 1.3.1 Summary of Product Characteristics (SPC)



AMRIYA - ALEXANDRIA - CAIRO , DESERT ROAD , KM . 25
P.O.BOX 111 EL-MANSHIA - ALEXANDRIA - ZIP CODE : 21111 - TEL : +2 - 03 - 4701003
SCIENTIFIC OFFICE : 3 MOHAMED BAHAA EL-DIN GHATWARY ST , SMOUHA - ALEX
TEL: +2- 03- 4206920/1 - FAX : +2- 03 - 4206922

### 1.3.1.1 Name of the Medicinal Product

**OPLEX Syrup**.

### 1.3.1.2 Qualitative and Quantitative Composition

#### 1.3.1.2.1 Qualitative Declaration:

**International Non-Proprietary Name (INN):**

Oxomemazine.

Guaifenesin.

Sodium Benzoate.

#### 1.3.1.2.2 Quantitative Composition:

| Name of the Ingredient | Quantity (unit/5 ml) | Function | Reference to Standard |
|---|---|---|---|
| **Active Pharmaceutical Ingredients (APIs) (Drug Substances):** | | | |
| Oxomemazine | 1.65 mg | Active Ingredient | In-house |
| Guaifenesin | 33.3 mg | Active Ingredient | USP |
| Sodium Benzoate | 33.3 mg | Active Ingredient | Eur.Ph. |
| **Inactive Ingredients (Excipients):** | | | |
| Sodium Citrate Dihydrate | 25 mg | Buffering agent | Eur.Ph. |
| Citric Acid Anhydrous | 6.856 mg | Acidifying agent | Eur.Ph. |
| Sucrose | 3500 mg | Sweetening agent | USP |
| Caramel color | 15 mg | Coloring agent | USP |
| Glycerol | 250 mg | Sweetening agent | Eur.Ph. |
| Caramel flavor | 10 mg | Flavoring agent | In-house |
| Purified Water to | 5 ml | Vehicle | Eur.Ph. |



AMRIYA - ALEXANDRIA - CAIRO , DESERT ROAD , KM . 25
P.O.BOX 111 EL-MANSHIA - ALEXANDRIA - ZIP CODE : 21111 - TEL : +2 - 03 - 4701003
SCIENTIFIC OFFICE : 3 MOHAMED BAHAA EL-DIN GHATWARY ST , SMOUHA - ALEX
TEL: +2- 03- 4206920/1 - FAX : +2- 03 - 4206922

### 1.3.1.3 Pharmaceutical Form

**The Syrup**

**Description** : Brown syrup with caramel odor and taste.

### 1.3.1.4 Clinical Particulars

#### 1.3.1.4.1 Therapeutic Indications

OPLEX Syrup is used in the treatment of dry and wet cough, including allergies and irritants.

#### 1.3.1.4.2 Posology and Method of Administration

Treatment should not exceed a few days.

The use of this medication must be distributed

during the day.

Adults:

1 or 2 teaspoons of syrup, 2 or 3 times a day. In the

elderly, starting with the lowest dose.

Children To 30:months : 1 to 3 teaspoons of syrup per

day, in 2 or 3 divided doses

• Above 30 months : 3 to 5 teaspoons of syrup per

day, in 2 or 3 divided doses



AMRIYA - ALEXANDRIA - CAIRO , DESERT ROAD , KM . 25
P.O.BOX 111 EL-MANSHIA - ALEXANDRIA - ZIP CODE : 21111 - TEL : +2 - 03 - 4701003
SCIENTIFIC OFFICE : 3 MOHAMED BAHAA EL-DIN GHATWARY ST , SMOUHA - ALEX
TEL: +2- 03- 4206920/1 - FAX : +2- 03 - 4206922

### 1.3.1.4.3 Contraindications

This medicine should not be used in cases of respiratory or hepatic insufficiencies.

### 1.3.1.4.4 Special Warning and Precautions for Use

Don't use this medicine in children under 6 years without medical advice.

Don't use this medicine in children under 2 years.

Cough is a symptom that can reveal many diseases:

Consult your physician if it persists more than a few days.

This syrup contains sugar (sucrose) in significant quantity, so not to be used in patients with diabetes mellitus.

Avoid alcoholic beverages: increased risk of drowsiness. Driver: This medication may be responsible for drowsiness or impaired alertness.

### 1.3.1.4.5 Interaction with other Medicinal Product and Other Forms of Interaction

This medication may interact with other sedatives or atropine. Report your doctor or pharmacist for any other treatment course



AMRIYA - ALEXANDRIA - CAIRO , DESERT ROAD , KM . 25
P.O.BOX 111 EL-MANSHIA - ALEXANDRIA - ZIP CODE : 21111 - TEL : +2 - 03 - 4701003
SCIENTIFIC OFFICE : 3 MOHAMED BAHAA EL-DIN GHATWARY ST , SMOUHA - ALEX
TEL: +2- 03- 4206920/1 - FAX : +2- 03 - 4206922

### 1.3.1.4.6 Fertility, Pregnancy and Lactation

**Pregnancy and Lactation:**

The effect of this medicine during pregnancy or lactation is poorly understood. The evaluation of possible risks associated with its use is individual. Ask your pharmacist or doctor.

### 1.3.1.4.7 Effects on Ability to Drive and Use Machines

Driver: This medication may be responsible for drowsiness or impaired alertness.

### 1.3.1.4.8 Undesirable Effects

Sleepiness, digestive disorders, thickening of the bronchial secretions, dry mouth, blurred vision, constipation, urine retention, mental confusion in the elderly and more rarely agitation in children.

### 1.3.1.4.9 Overdose

Signs of oxomemazine overdose are convulsion (specially for babies and children, disorientation, coma, symptomatic treatment will be set up in specific settings.



AMRIYA - ALEXANDRIA - CAIRO , DESERT ROAD , KM . 25
P.O.BOX 111 EL-MANSHIA - ALEXANDRIA - ZIP CODE : 21111 - TEL : +2 - 03 - 4701003
SCIENTIFIC OFFICE : 3 MOHAMED BAHAA EL-DIN GHATWARY ST , SMOUHA - ALEX
TEL: +2- 03- 4206920/1 - FAX : +2- 03 - 4206922

## 1.3.1.5 Pharmacological Properties

### 1.3.1.5.1 Pharmacodynamic Properties

Pharmacological Action:

This medicine is a combination of substances which contains an antihistamine, antitussive and sedative (Oxomemazine), two expectorants (Guaifenesin and Sodium benzoate)

Pharmacokinetics:

Guaifenesin is absorbed from the gastrointestinal tract. It is metabolised and then excreted in the urine.

Sodium benzoate is absorbed from the gastrointestinal tract and conjugated with glycine in the liver to form hippuric acid, which is rapidly excreted in the urine.

## 1.3.1.6 Pharmaceutical Particulars

### 1.3.1.6.1 List of Excipients

Sucrose

Glycerol

Caramel color.

Caramel flavor.

Sodium Citrate Dihydrate.

Citric Acid Anhydrous.

Purified Water.



AMRIYA - ALEXANDRIA - CAIRO , DESERT ROAD , KM . 25
P.O.BOX 111 EL-MANSHIA - ALEXANDRIA - ZIP CODE : 21111 - TEL : +2 - 03 - 4701003
SCIENTIFIC OFFICE : 3 MOHAMED BAHAA EL-DIN GHATWARY ST , SMOUHA - ALEX
TEL: +2- 03- 4206920/1 - FAX : +2- 03 - 4206922

### 1.3.1.6.2 Incompatibilities

None.

A mixture of both Drug Substance and Excipients of **OPLEX Syrup** are compatible and this compatibility is not lost on storage under accelerated or shelf-life stability study conditions.

### 1.3.1.6.3 Shelf Life

Three years.

### 1.3.1.6.4 Special Precaution for Storage

Store at temperature not exceeding 30°C.

Keep out of the reach of children.

### 1.3.1.6.5 Nature and Contents of Container

A chromo-duplex carton box containing one amber glass bottle (of 125 ml syrup) and a pamphlet. The bottle is made of amber polyethylene terephthalate plastic (PET), and closed with plastic polyethylene cap with low density expanded polyethylene (LDEPE) liner.

## 1.3.1.7 Marketing Authorization Holder

**Name** : AMRIYA Pharm. Ind.

**Address** : Km 25, Alexandria-Cairo Desert Road, Amriya, Alexandria, Egypt.

**Tel.** : (+203) 4701001.

**Fax** : (+203) 4701002.

### 1.3.1.8 Marketing Authorization Number(s)

22353/2019.

### 1.3.1.9 Date of First Authorization / Renewal of the Authorization

2019.

### 1.3.1.10 Date of Revision of the Text

September 2019.



AMRIYA - ALEXANDRIA - CAIRO , DESERT ROAD , KM . 25
P.O.BOX 111 EL-MANSHIA - ALEXANDRIA - ZIP CODE : 21111 - TEL : +2 - 03 - 4701003
SCIENTIFIC OFFICE : 3 MOHAMED BAHAA EL-DIN GHATWARY ST , SMOUHA - ALEX
TEL: +2- 03- 4206920/1 - FAX : +2- 03 - 4206922