## 1. NAME OF THE MEDICINAL PRODUCT

Vistulent® Eye drops
Potassium Iodide 0.3$^{w}/_{v}$ + Sodium Iodide 0.3$^{w}/_{v}$

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml of Vistulent® Eye drops contains Potassium Iodide 3mg + Sodium Iodide 3mg

Excipients:

For full list of excipients, see section 6.1

## 3. PHARMACEUTICAL FORM

Ophthalmic Liquid (Drops)

## 4. CLINICAL PARTICULARS

### 4.1 Therapeutic indications

Vistulent® eyedrops is used in treatment of Clouding and haemorrhage of the vitreous body due to any cause (age, myopia, hypertonia, diabetes, periphlebitis), clouding of the lens as a first sign of cataracta senilis.

### 4.2 Posology and Method of Administration

Posology

Adults including the elderly: One drop is applied into the conjunctival sac, 1-3 times a day
Mode of Administration(s): Ophthalmic.

### 4.3 Contraindications

People allergic to any ingredient in this product should not use it. This product is contraindicated with functional disturbances of the thyroid or a bland nodular struma

### 4.4 Special warnings and precautions for use

Carriers of contact lenses should apply the product during the time when the lenses are not worn. Wait at least 30 minutes after the administration of the preparation before placing the lenses back into the eye. In order to minimize systemic resorption, the patient should gently compress the lacrimal sac with his finger for 1-2 minutes after the instillation of the eye drops.

### 4.5 Interaction with other medicinal products and other forms of interaction

No interactions with systemically applied drugs have been reported. In cases of concomitant ophthalmic medication with other drugs, an interval of at least 5 minutes should be observed between the two medications.

### 4.6 Pregnancy and lactation

As there is no controlled studies in animals or in pregnant women are available, this product should only be prescribed in those cases where the potential benefit exceeds the risk for the fetus. The use of this product during lactation has not been investigated (Pregnancy category C).

### 4.7 Effects on ability to drive and use machines

No Reported case

### 4.8 Undesirable effects

1) Systemic effects: This product contains iodides which can cause hyperthyroidism and acne-type effects in predisposed individuals.

2) Local effects on the eye: This product may cause slight burning or pricking sensation for short time after application. Occasionally increased tear flow may happen.

### 4.9 Overdose

The risk of adverse effects due to topical overdosage or accidental oral ingestion is very limited due to the relatively low total content of iodides per dropper bottle

## 5. PHARMACOLOGICAL PROPERTIES

### 5.1 Pharmacodynamic properties

Pharmacotherapeutic group: {Ophthalmic Agents}, ATC code: {Potassium iodide: S01XA04 Sodium iodide: V09FX03}
Systemic as well as topical application of iodides can activate the metabolism and occasionally counteract the cloudiness of the vitreous body. The effect of iodine on early senile cataracts has not yet been established. Occasionally it is possible to slow down the progression of cloudiness and the degradation of visual acuity.

### 5.2 Pharmacokinetic properties

a) Local administration into the eye: Potassium iodide diffuses rapidly into the vitreous humour of the isolated rabbit's eye. Within 60 minutes 0.25 µmoles of potassium iodide accumulate in 1 ml of aqueous humor. 6.4% of the iodide present in the treated eye was found in the lens and 3.7% in the vitreous body.
b) Systemic administration: The degree of systemic resorption after local administration into the eye has not been investigated.

### 5.3 Preclinical safety data

Not applicable

## 6. PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Sodium chloride
Boric acid
Sodium borate
Disodium edetate
Chlorhexidine acetate
Hypromellose E4m premium
Water for injection

### 6.2 Incompatibilities

None known

### 6.3 Shelf life

36 months

### 6.4 Special precautions for storage

Store below $30^0$C, and protect from light and moisture. Replace the cap immediately after use. Discard after 28 days of opening the bottle

### 6.5 Nature and contents of container <and special equipment for use, administration or implantation>

Vistulent® Eye Drops is available in available in opaque white sterile lupolen bottle containing 10 ml of the ophthalmic solution in hardboard carton with leaflet enclosed.

### 6.6 Special precautions for disposal <and other handling>

No special requirements

## 7. SUPPLIER

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## 8. DATE OF REVISION OF THE TEXT

06/2023