Catarest™

1. Generic Composition

Potassium Iodide IP

Sodium Chloride IP

Calcium Chloride IP

2. Composition

Potassium Iodide IP	3.3 % W/V
Sodium Chloride IP	0.83 % W/V
Calcium Chloride IP	1.0 % W/V

3. Dosage form and strength

Topical ophthalmic solution containing Potassium Iodide IP 3.3 % , SodiumChloride IP 0.83 % (0.83mg/100ml) and Calcium Chloride IP 1.0 %.

4. Clinical particulars

4.1 Therapeutic indication

- Catarest Eye Drops can be used for prevention of lenticular opacity pre-operatively and for prevention of Posterior Capsular Opacity (PCO), post-operatively, in patients with cataract. Especially, when the decision is to postpone to cataract surgery in patients with uncontrolled hypertension, diabetes mellitus, severe bleeding disorders and severe respiratory disorders.
- Catarest eye drops delays cataractogenesis, maintains normal nutrition of lens, assists visual improvement in early cataract and prevents posterior capsular opacification.

4.2 Posology and method of administration

As directed by physician.

4.3 Contraindication

Catarest is not advocated in those with known history of hypersensitivity to its ingredients

4.4 Special warnings and precautions for use

Not any.

4.5 Drug interactions

None are reported.

4.6 Use in special population

- Paediatric: No data available.
- Geriatric: No data available.
- Liver impairment: No data available.
- Renal failure: No data available.
- Pregnancy and lactation: Doctor advice is recommended.

4.7 Effects on ability to drive and use machine

Patients should be cautioned against engaging in activities requiring complete mental alertness, and motor coordination such as operating machinery until their response to Catarest is known.

4.8 Undesirable effects

None are reported.

4.9 Overdose

There is limited experience of overdose with Catarest. Initiate general symptomatic and supportive measures in all cases of overdosages where necessary.

5. Pharmacological properties

5.1 Mechanism of action

Normally to maintain lens membrane permeability, water electrolyte balance must be maintained intracellularly as well as extracellularly. Membrane permeability is shown to be responsible for maintenance of lens transparency. Sodium is major serum extracellularcation while potassium is major intracellular cation. In lens, concentration of sodium is less than potassium while in serum it is vice versa. This cation balance maintains osmotic pressure and thus water balance across the lens membrane with the action of NaKATPase. Changes in serum electrolytes levels can induce changes in aqueous humor electrolytes levels of lens and probably cataract formation.
Catarest helps to maintain the electrolyte balance.

5.2 Pharmacodynamic properties

No data available.

5.3 Pharmacokinetic properties

No data available.

6. Nonclinical properties

6.1 Animal Toxicology or Pharmacology

NA.

7. Description

Sodium Chloride is a metal halide composed of sodium and chloride with sodium and chloride replacement capabilities. Its empirical formula is NaCl and molecular weight is 58.44 g/mol.

Potassium Iodide is a metal halide composed of potassium and iodide with thyroid protecting and expectorant properties. Its empirical formula KI is and molecular weight is 166.003 g/mol.

Calcium Chloride: Its empirical formula $CaCl_2$ is and molecular weight is 147.01 g/mol.

8. Pharmaceutical particulars

8.1 Incompatibilities

There are no known incompatibilities.

8.2 Shelf-life

36 months.

8.3 Packaging Information

Catarest eye drops is available in 10ml lupolen vial.

8.4 Storage and handling instructions

Store in cool and dry place.

9. Patient Counselling Information

9.1 Adverse Reactions

Refer part 4.8

9.2 Drug Interactions

Refer part 4.5

9.3 Dosage

Refer part 4.2

9.4 Storage

Refer part 8.4

9.5 Risk Factors

Refer part 4.4

9.6 Self-monitoring information

NA

9.7 Information on when to contact a health care provider or seek emergency help

Patient is advised to be alert for the emergence or worsening of the adverse reactions and contact the prescribing physician.

9.8 Contraindications

Refer part 4.3

10. Manufactured by CENTAUR PHARMACEUTICALS PVT. LTD. and DCI Pharmaceuticals

11. Details of permission or license number with date

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