

# Instasia Gel

Benzocaine 14%, Butamben 2% & Tetracaine Hydrochloride 2%

## Composition:

Each gram **Instasia** Gel contains Benzocaine BP 140 mg, Butamben USP 20 mg, Tetracaine Hydrochloride BP 20 mg.

## Pharmacology:

The onset of **Instasia**-produced anesthesia is rapid (approximately 30 seconds) and the duration of anesthesia is typically 30-60 minutes, when used as directed. This effect is due to the rapid onset, but short duration of action of Benzocaine coupled with the slow onset, but extended duration of Tetracaine HCl and bridged by the intermediate action of Butamben. It is believed that all of these agents act by reversibly blocking nerve conduction. Speed and duration of action is determined by the ability of the agent to be absorbed by the mucous membrane. It will be excreted in the urine after metabolism.

## Indications:

**Instasia** is a topical anesthetic indicated for the production of anesthesia of all accessible mucous membrane except the eyes. **Instasia** is indicated to control pain and for use for surgical or endoscopic or other procedures in the ear, nose, mouth, pharynx, larynx, trachea, bronchi and esophagus. It may also be used for vaginal or rectal procedures when feasible.

## Dosage and Administration:

Dispense and apply 200 mg of gel (a bead approximately 1/4 to 1/2 inches long) by gently squeezing the tube. Application of gel in excess of 400 mg is contraindicated. Spread thinly and evenly over the desired area using a cotton swab. An appropriate pediatric dosage has not been established for **Instasia**. Dosages should be reduced in the debilitated elderly, acutely ill, and very young patients. Tissue need not be dried prior to application of **Instasia**. It should be applied directly to the site where pain control is required. Anesthesia is produced within one minute with an approximate duration of thirty minutes. Each 200 mg dose of **Instasia** contains 28 mg of benzocaine, 4 mg of butamben and 4 mg of tetracaine HCl.

## Contraindications:

**Instasia** is not suitable and should never be used for injection. Do not use on the eyes. To avoid excessive systemic absorption, **Instasia** should not be applied to large areas of denuded or inflamed tissue. **Instasia** should not be administered to patients who are hypersensitive to any of its ingredients or to patients known to have cholinesterase deficiencies. Tolerance may vary with the status of the patient. **Instasia** should not be used under dentures or cotton rolls, as retention of the active ingredients under a denture or cotton roll could possibly cause an escharotic effect. Routine precaution for the use of any topical anesthetic should be observed when using **Instasia**.

## Precaution:

On rare occasions, methemoglobinemia has been reported in connection with the use of benzocaine-containing products. Care should be used not to exceed the maximum recommended dosage (see Dosage and Administration). If a patient becomes cyanotic, treat appropriately to counteract (such as with methylene blue, if medically indicated).

## Side effects:

Hypersensitivity Reactions: Unpredictable adverse reactions (i.e. hypersensitivity, including anaphylaxis) are extremely rare. Localized allergic reactions may occur after prolonged or repeated use of any aminobenzoate anesthetic. The most common adverse reaction caused by local anesthetics is contact dermatitis characterized by erythema and pruritus that may progress to vesiculation and oozing. This occurs most commonly in patients following prolonged self-medication, which is contraindicated. If rash, urticaria, edema, or other manifestations of allergy develop during use, the drug should be discontinued. To minimize the possibility of a serious allergic reaction, **Instasia** preparations should not be applied for prolonged periods except under continual supervision. Dehydration of the epithelium or an escharotic effect may also result from prolonged contact.

## Use in Pregnancy:

Safe use of **Instasia** has not been established with respect to possible adverse effects upon fetal development. Therefore, **Instasia** should not be used during early pregnancy, unless in the judgement of a physician, the potential benefits outweigh the unknown hazards. Routine precaution for the use of any topical anesthetic should be observed when **Instasia** is used.

## Pediatric Use:

Safety and effectiveness of **Instasia** Gel in pediatric patients have not been established.

## Storage:

Store in a cool and dry place, protect from light. Keep out of reach of children.

## Packaging:

Each carton contains a tube of 30 gm gel & an insert.

Manufactured by



**Ziska Pharmaceuticals Ltd.**

Kaliakoir, Gazipur, Bangladesh