Composition

Oralube is a viscous clear pink solution that has an artificial lemon flavour and fragrance for topical oral and buccal spray application.

Oralube contains electrolytes; sodium, potassium, chloride, calcium, phosphate, magnesium, and fluoride. All in proportions less than 10% w/v.

Other excipients are: Methyl Hydroxybenzoate, Sorbitol, Thickener (Carboxymethylcellulose), Colour, and Flavour all at proportions less than 10% w/v, with Purified Water to 100%

Use

Oralube is recommended for the treatment of the symptoms of xerostomia (dry mouth) and salivary gland hypofunction.

It can be used to relieve any of the following symptoms:

- Less saliva, no pooling in the floor of the mouth.
- Dry and sticky oral mucosa that may sometimes be red and painful.
- Frothy, foamy saliva that comes from the corner of the mouth.
- Difficulty swallowing, tasting and eating food.
- Smacking noise when speaking.
- Sticking of the tongue and/or cheek to the palate.
- Increased teeth discoloration and dental caries initially appearing on the surface of the teeth at the gum level, and then progressing to surrounding the tooth. Decay then appears on incisal edges and if not treated loss of many teeth can occur in a few years.
- Infections of the oral mucosa.

Oralube is also indicated for use if saliva production is not present or reduced and when the following can occur:

- Reduced moistening and lubrication of the oral mucosa for mastication.
- Less food is changed into a semisolid mass so that tasting and eating food becomes difficult.
- Swallowing becomes more difficult.
- Speech can be impaired
- Decreased remineralization of teeth by calcium and phosphate ions.
- Salivary pH changes due to less effect of carbonate and phosphate buffers leading to less protection of tooth dentine from acid damage (demineralization) leading to an aggressive progression of dental caries and loss of teeth.
- Reduced ability of the body to maintain water balance because of a diminished stimulation of thirst.
- Diminished protection of mucous membranes in the mouth, throat, and oesophagus from physical damage.
- Reduced oral antimicrobial activity of enzymes and IgA.
- Increased risk of oral thrush.
**Actions**

Oralube is manufactured to mimic the composition and action of saliva. Studies show that there are three important characteristics a saliva substitute should have, to give the best results in treating the detrimental symptomatic effects of salivary gland hypofunction (hyposalivation) and xerostomia (dry mouth). These three characteristics are:

- To contain similar electrolytes to those main salivary electrolytes such as sodium, potassium, chloride, calcium, bicarbonate and phosphate.
- A pH similar to that of saliva, which is generally slightly acidic tending towards a neutral pH (pH 6.75 to 7.00).
- A viscosity that is low enough to allow electrolytes, especially calcium, to travel through the matrix of the saliva substitute quickly enough to be useful in the remineralization process.

**Pharmacokinetic properties**

Oralube has a composition very similar to naturally occurring saliva therefore its pharmacokinetics are similar to those of normal electrolytes in the body.

**Absorption:** Some absorption of electrolytes will readily occur through the oral mucosa and also from the gastrointestinal tract when Oralube is swallowed. However as the dose is small, absorption is small and causes no effect to overall plasma electrolyte levels and acid-base balance of the blood.

**Distribution:** Oralube is highly water-soluble. It is mostly contained in the oral cavity and dispersed over the oral mucosa and teeth. As it provides a super saturated solution, like saliva, of phosphate, calcium and fluoride to the oral cavity some of the calcium, phosphate and fluoride ions are incorporated in to new dentine part of tooth enamel when remineralization occurs. Fluoride diffuses across the placenta and is present in faeces, sweat, saliva, teeth, bone, milk, tears and hair. However the amounts in Oralube are very low and are unlikely to cause any untoward effects from a fluoride build up or intoxication.

**Metabolism:** Any excess Oralube not used in the oral cavity is metabolised as normal electrolytes are. They are used in the body and become components of soft tissue or body fluids.

**Elimination:** If the electrolytes in Oralube are not required for use by the body they are excreted in the urine to maintain electrolyte equilibrium.

**Contraindications**

Known hypersensitivity to any of the ingredients of the product

**Directions for use**

Oralube is to be sprayed into the oral cavity. As it is viscous a mist as such will not be produced from the spray but a more liquid application will be. Care should be taken to not accidentally spray solution into eyes or nose. Wash any area with water where spray may deposit unintentionally or not be wanted. If the eyes are involved, remove contact lens if worn. Hold eyes open and flush with gently running water for 15 minutes.

**Children:** 1 spray directed into the back of the mouth and tongue, when required for relief of symptoms associated with dry mouth.

**Adults:** 1-2 sprays directed into the back of the mouth and tongue, when required for relief of symptoms associated with dry mouth.
Precautions

For topical oral administration only.

When Oralube is commenced and if it is going to be used for some time a medical assessment and investigation of the causes of the hyposalivation or xerostomia should be performed by a health care professional.

Causes of reduced saliva production or xerostomia (dry mouth) are:

- Certain diseases, such as diabetes, Sjogren's syndrome, HIV, and sarcoidosis.
- Radiation therapy of the head and neck.
- Some prescription medications such as amitriptyline or over the counter medications, like pseudoephedrine.
- Old age.
- Smoking.

If the need for Oralube continues an oral health management program needs to be undertaken. This entails regular use of Oralube as a saliva substitute, as this is one way of relieving the difficulties and damage that can occur if saliva production is decreased or not present. Other management must include: ongoing dental caries prevention and treatment, regular checking and treatment of oral candidiasis, review and possible modification/cessation of concomitant medication use.

The low concentration of fluoride is unlikely to lead to intoxication or overdoses even when high amounts of Oralube are administered clinically.

Pregnancy and Lactation:

- Oralube is not contraindicated in pregnancy or during lactation.
- Oralube is similar to natural saliva. It contains fluoride, which is a normal component of body fluids and soft tissues. Fluoride crosses the placenta and occurs naturally in faeces, sweat, saliva, teeth, bone, milk, tears and hair. The amount of fluoride in Oralube is low (approximately 0.23mg fluoride in 100mL Oralube). This amount is approximately 200 times less than fluoride concentrations found in children's toothpaste (42mg in 100mL toothpaste). Therefore if used as directed it is safe to be used by pregnant or lactating women.

The low concentration of fluoride is unlikely to lead to intoxication or overdoses even when high amounts of Oralube are administered clinically.

Effects on ability to drive and use machines:

Oralube has no influence on the ability to drive or use machines.

Drug Interactions

Oralube has a composition manufactured to mimic saliva. No interactions with any other orally taken medicinal products have been observed.

Adverse Reactions

Side effects are uncommon. However, some stinging of the oral mucosa and tongue may occur initially when Oralube is used. This may pass, especially with continued use of Oralube as the effects of xerostomia are treated.

Overdosage

Overdosage with Oralube is unlikely. If very large quantities of Oralube are ingested, far exceeding those given clinically, serious symptoms are unlikely. Discontinue use of Oralube. Symptomatic and supportive treatment can be given if necessary. No case of overdosage has been reported.
Storage
Store below 25°C. Protect from light.

Presentation
ARTG 146731: Oralube is supplied in semi-clear 125mL plastic bottles with spray applicator.

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