

DATA SHEET SALIVIX SPRAY

PRESENTATION:

Oral spray (peppermint flavoured).

INTENDED USE:

The oral spray relieves the symptoms of a dry mouth by stimulating natural saliva secretion, hydrating the oral cavity, providing anticaries properties and helping to remineralise the tooth enamel.

INSTRUCTIONS FOR USE AND DOSAGE:

Including children > 6 years and the elderly: Apply 2-4 sprays into the oral cavity when needed and up to 16 times a day.

Shake the bottle well before use. Remove the protective cap. Hold the bottle upright and prime the pump into a tissue by depressing it firmly several times. After use replace the protective cap.

CONTRA-INDICATIONS, WARNINGS ETC.

For use in patients who have an intact oral cavity, i.e. no bleeding ulcers.

Contra-indicated in cases where there is no synthesis of saliva or where there are no salivary glands or they are severely damaged.

Contra-indicated in cases of hypersensitivity to any of the ingredients listed below.

Not suitable for children under 6 years of age.

This product can be used in pregnancy and during lactation.

There are no known side-effects.

Warnings to appear on the packaging:

Do not use this product after the expiry date.

Keep out of the reach and sight of children.

Avoid contact with eyes.

Do not use the product if the bottle or the spray part is not intact.

If side effects occur or the symptoms worsen during use, stop using the product or consult your doctor.

You may want to read this leaflet again, so please keep it readily available until you have finished the product.

PHARMACEUTICAL PRECAUTIONS: Store the bottle closed at room temperature.

SHELF-LIFE: 24 months from the date of manufacture.

PACKAGE INFORMATION: 50ml bottle, packed in a carton with a leaflet.

INGREDIENTS: Malic acid (E296), xylitol (E967), sodium fluoride, calcium lactate (E327), disodium hydrogen phosphate (E339), sodium citrate (E331), potassium chloride (E508), magnesium chloride (E511), glycerol (E422), carboxymethyl cellulose (E466), peppermint aroma liquid, sodium methyl p-hydroxybenzoate (E219), water.

FURTHER INFORMATION:

The product can be used for stimulation of saliva production, when secretion is impaired and potentially functioning gland tissue is still present. The main ingredients act locally in the oral and buccal cavity. The mechanisms of action are based on the ingredients and physico-chemical properties of the solution as described below. The product can be classified as a sialogogue and oral moisturiser.

Malic acid stimulates production of saliva via acidity. Acidifying the oral cavity promotes secretion of saliva but may be harmful to teeth. Therefore, several compounds have been included in Salivix Spray to antagonise the possible cariogenic effect. Xylitol inhibits formation of cavities in tooth enamel (caries) and helps in remineralisation of tooth enamel. Calcium lactate is used for adjusting and buffering pH and supporting xylitol in remineralisation of tooth enamel. Sodium fluoride prevents formation of caries, and catalyses the remineralisation process of tooth enamel. It thus counteracts the possible harmful effect of acidity on tooth enamel.

Disodium hydrogen phosphate is an alkaline compound, which is used to modify pH. Also, sodium citrate is alkaline, and it is included in the product to balance and buffer pH.

Potassium chloride and magnesium chloride are acidity regulators. They counteract the acidity of malic acid and maintain the aimed pH, i.e. they act as buffering agents.

Glycerol and carboxymethyl cellulose increase viscosity of the spray and form a coating, which retains moisture on the oral mucous membranes. Peppermint oil is added in Salivix Spray to give flavour, and sodium methyl p-hydroxybenzoate is a preservative.

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Class I Medical Device

The Galen logo features the word 'GALEN' in a bold, black, sans-serif font, centered between two horizontal blue bars of equal length.