Buccaline

Inactivated vaccine for oral, antibacterial prophylaxis against colds and chills

Composition

One tablet contains the following inactivated bacteria: 1.5 x 10° Haemophilus influenzae, 1 x 10° Streptococcus pneumoniae (I, II, III), 1 x 10° Streptococcus haemolyticus, 1 x 10° Staphylococcus aureus. Excipients: 173 mg lactose, 25 mg fel bovis siccum, 4.5 mg polyvinylpyrrolidone, 4.6 mg magnesium stearate.

Properties/Effects

Buccaline is an inactivated whole cell vaccine for oral application. The constituent bacteria are very often found as pathogens in colds and chills.

On contact with the bacterial surface antigens contained in Buccaline, the differentiation and maturation of immunocompetent lymphocytes are specifically stimulated.

Pharmacokinetics

The tablets have a coating that is resistant to gastric juice. After dissolution in the small intestine, the bacterial antigens undergo phagocytosis by macrophages found in the intestinal wall and then pass with them into the local reticuloendothelial tissue, where they stimulate the immune system to build up a systemic, specific immunity.

Indications/Possible application

Oral antibacterial prophylaxis against colds and chills.

Dosage/Administration

The tablets are to be swallowed whole with some fluid, best one hour before breakfast or one hour before the midday meal. Children under 7 years of age are given one tablet on the first and sec-

Children under 7 years of age are given one tablet on the first and second day and two tablets on the third day.

Children over 7 years of age and adults receive one tablet on the first

day, two tablets on the second and four tablets on the third day.

Restriction for use

Contraindications

There are no known contraindications.

Precautions

Vaccinations are generally to be avoided during acute feverish illnesses.

Pregnancy/Lactation

Pregnancy category C:

oral inactivated vaccines are not, in principle, contraindicated in pregnancy. However, as neither controlled studies in animals nor in pregnant women have been undertaken, Buccaline should only be given if the potential benefits outweigh the possible risks.

Lactation:

administration of Buccaline during breast-feeding has no negative effects on the child.

Adverse reactions

Rarely nausea, vomiting, abdominal pain, diarrhoea, fever, thrombocytopoenia, stomatitis, dermatitis, maculopapular rash, facial oedema.

Interactions

No interactions are known.

Overdosage

No experience is available on the consequences of overdosage.

Further information

The product can be stored at room temperature (max. 25 °C), protected from light.

The expiry date is given on every packing; the product should not be used after this date.

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' tablets for adults

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aboratorio Farmaceutico SIT S.R.L. - Italy

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