Name of Medicine
BUCCALINE tablets
Haemophilus influenzae, pneumococci (I, II, III), streptococci, staphylococci.

Presentation
Each biconvex brown coated tablet contains: $1.5 \times 10^9$ Haemophilus influenzae, $10^9$ pneumococci (I, II, III), $10^9$ Streptococcus agalactiae, $10^9$ Staphylococcus aureus.

Uses
Actions
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
Oral antibacterial prophylaxis of complications of colds.

Dosage and 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 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.

Contraindications
There are no known contraindications.

Warnings and Precautions
Vaccinations should not be given during acute febrile illnesses. Buccaline is not intended as an alternative to influenza vaccination and does not offer protection against viral coughs and colds. Buccaline may be used as an adjunct to influenza vaccination.

Use in Pregnancy
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.

Use in Lactation
Administration of Buccaline during breast-feeding has no negative effects on the child.

Adverse Effects
Rarely nausea, vomiting, abdominal pain, diarrhoea.
Interactions
No interactions are known.

Overdosage
No experience is available on the consequences of overdosage.

Pharmaceutical Precautions
The product should be stored at or below 25ºC, protected from light.

Medicine Classification
Pharmacist Only Medicine

Package Quantities
Packs of 7 tablets.

Further Information

Excipients
Lactose, dried ox bile, povidone, magnesium stearate, shellac, iron oxide, talc.

Clinical Trials
A study¹ was conducted that compared the incidence of reported flu cases in 172 workers vaccinated with Buccaline with that of 68 unvaccinated workers over 3 months in a mechanical plant in the town of Graz. 19 (11%) of the vaccinated and 20 (29%) of the unvaccinated workers fell ill. This indicates a protective effect of 62%. The difference in incidence is highly significant (p < 0.001).

C. Melino² conducted a large controlled trial on employees of the Italian National Railways in which 1,550 employees took Buccaline and 1,415 employees received a placebo. The observation period lasted from December 1968 to April 1969 (5 months). In the group vaccinated with Buccaline, 254 (16.4%) contracted a respiratory condition, as did 410 persons (29%) in the group treated with placebo. A protective effect of 43% can be deduced from these figures. The difference is statistically highly significant (p < 0.001). The efficacy of the vaccine can be seen even better if days of absence are taken into account. 1,057 days lost were registered for the vaccinated employees (682 days per 1,000 employees) and 3,317 days (2,288 days per 1,000 employees) for the placebo treated employees. If the two groups are compared, the gain in workdays not lost was 68%. In other words, the work lost in the unvaccinated group was 3.35 times as high as in the vaccinated group. The difference is also statistically highly significant with regard to days of absence (p < 0.001).

C. Melino³ conducted a second study on the prophylaxis of cold illnesses in employees of the Italian National Railways. The observation period lasted from October 1974 to March 1975 (6 months). Some of the employees received (according to place or works) Buccaline (N = 812), influenza vaccine (N = 1,243) or Buccaline + vaccine (N = 1,649). Control groups were registered in each works (for Buccaline: N = 390). Of the persons vaccinated with Buccaline, 44 (5.4%) caught the flu; 106 persons (27%) in the respective controls fell ill. The protective effect imparted by Buccaline was 80% (82% in Voghera, 74% in Rome). In comparison, the protection through influenza vaccine injections was 86% and the protection through influenza vaccination + Buccaline was 86 to 96%.

A follow-up study⁴ concerned immunoprophylaxis in patients from the Italian National Railways who were suffering from chronic bronchitis. For prophylaxis against bronchitic exacerbation, the patients were inoculated twice with influenza vaccine at an interval of 30 - 40 days. Apart from this, they received Buccaline three times, also at 3 - 4 week intervals. The two vaccination courses were initiated simultaneously in October 1974; the last vaccination (Buccaline) was thus given in January 1975. Observations were made from October 1974 to March 1975 (5 months). 338 patients were vaccinated in Rome and 22 of them (6.4%) fell ill; 811 patients were
not vaccinated and 135 of them (16.6%) fell ill. The author himself calculates a protective effect of 83.2%, whereas the writer of this report arrives at a protective effect of 61%. 311 patients were vaccinated in Milan and 33 of them (10.6%) fell ill; of 969 unvaccinated patients, 320 (34.1%) fell ill, which produces a protective effect of 69%. If both collectives (Rome and Milan) are taken together, a protective effect of 66% is produced.

Another study reported a vaccination campaign with Buccaline by the works medical service of a Swiss industrial company, with an observation period lasting from January to April 1970 (4 months). The collective observed included a total of 1,934 employees of whom 624 received Buccaline and 1,310 did not receive any form of prophylaxis. All absences due to flu or colds were registered. Diagnosis and frequency of absence were assessed on the basis of the findings of the works medical service and the records of the company’s own health insurance fund. Of those who were not vaccinated, 231 (17.6%) caught "the flu", as did 77 (12.3%) of those who were vaccinated. The protective effect was 30%. The difference between the two groups is statistically highly significant (p < 0.001).

References


3. C. Melino. Studio comparativo sulla profilassi immunitaria delle malattie da raffreddamento (Comparative study on the immunologic prophylaxis of the cold illnesses). Nuovi annali d'igiene e microbiologia 26, 313-328 (1975)


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