New Zealand Datasheet

1 PRODUCT NAME
BUCCALINE tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION
Haemophilus influenzae, pneumococci (I, II, III), streptococci, staphylococci.

3 PHARMACEUTICAL FORM
Each biconvex brown coated tablet contains: 1.5 x 10^9 Haemophilus influenzae, 10^9 pneumococci (I, II, III), 10^9 Streptococcus agalactiae, 10^9 Staphylococcus aureus.

4 CLINICAL PARTICULARS
4.1 Therapeutic indications
Oral antibacterial prophylaxis of complications of colds.

4.2 Dose and method of 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.

4.3 Contraindications
There are no known contraindications.

4.4 Special warnings and precautions for use
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.

4.5 Interaction with other medicines and other forms of interaction
No interactions are known.

4.6 Fertility, pregnancy and lactation
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.

4.7 Effects on ability to drive and use machines
Buccaline has negligible influence on the ability to drive and use machines.

4.8 Undesirable effects
Rarely nausea, vomiting, abdominal pain, diarrhoea.

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare professionals are asked to report any suspected adverse reactions https://nzphvc.otago.ac.nz/reporting/.

4.9 Overdose

No experience is available on the consequences of overdosage.

For advice on the management of overdose please contact the National Poisons Centre on 0800 POISON (0800 764766).

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic Group – Other bacterial vaccines -J07AX.
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.

Clinical Trials
C. Melino 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. Melino 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%.

5.2 Pharmacokinetic properties

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.

5.3 Preclinical safety data

No data is available. The safety of Buccaline has been in clinical use for many years are observed.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

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

6.2 Incompatibilities
None known.

6.3 Shelf life
Shelf life is 60 months (5 years) from manufacture.

6.4 Special precautions for storage
The product should be stored at or below 25ºC, protected from light.

6.5 Nature and contents of container
Packs of 7 tablets.

6.6 Special precautions for disposal
No special precautions required.

7 MEDICINE SCHEDULE
Pharmacist Only Medicine

8 SPONSOR
Pharmabroker Sales Ltd
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9 DATE OF FIRST APPROVAL
14 January 1965

10 DATE OF REVISION OF THE TEXT
8 September 2017

SUMMARY TABLE OF CHANGES

Section changed	Summary of new information