Data sheet : DF Fluvirin absorbed surface antigen influenza vaccine.

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DATA SHEET To The Medical Profession

DF FLUVIRIN ▼

ADSORBED SURFACE ANTIGEN INFLUENZA VACCINE

Presentation

Fluvirin is a new adsorbed surface antigen influenza vaccine containing highly purified haemagglutinin and neuraminidase antigens of the strains of influenza virus currently recommended by the World Health Organisation.
Each 0.5 ml dose contains the haemagglutinin and neuraminidase antigens derived from :

200 International Units of A/Victoria/3/75 (H_3N_2)
200 International Units of B/Hong Kong/8/73

adsorbed onto aluminium hydroxide (0.425 mg in each 0.5 ml). The content of aluminium does not exceed 1.25 mg per 0.5 ml dose.

Indications

Protection against influenza especially in those cases deemed to be at special risk, viz.
Chronic pulmonary disease, e.g. chronic bronchitis and emphysema, asthma, bronchiectasis, pulmonary tuberculosis and fibrosis ;
Chronic heart disease, e.g. valvular and hypertensive heart disease ;
Chronic renal disease, e.g. chronic nephritis ; patients with renal disease on immuno-suppressive drugs ;
Diabetes and possibly other less common endocrine disorders.

Immunisation against influenza is also recommended in :

School children over nine years of age and in elderly persons living in residential establishments, in which rapid spread is likely to follow the introduction of infection.
Doctors, nurses, ambulance men, and others at special risk of infection by reason of their contacts with persons suffering from influenza.

Dosage and administration

Adults and children over the age of 9: 0.5 ml.

Fluvirin should be administered by deep subcutaneous or intramuscular injection ; it must NOT be given intradermally.
If the vaccine has been stored in a refrigerator it must be allowed to reach room temperature before use ; the container should be well shaken immediately before making the injection.

Contra-indications, warnings, etc.

Contra-indications: Fluvirin is contra-indicated in persons sensitive to egg protein.
Precautions: Because the vaccine contains highly purified haemagglutinin and neuraminidase antigens

continued overleaf

the total viral content of the vaccine has been reduced to about one tenth of that of whole virus vaccines ; (the total protein nitrogen content of a single dose of Fluvirin is less than 5 micrograms). Even so in patients with a personal or family history of allergy the potential risk of adverse reactions to vaccines should be considered.
Spirit should not be allowed to come in contact with the vaccine.
Side-effects: Local effects such as redness and soreness at the site of injection may occur, but these may be minimised by ensuring that the injection is given sufficiently deeply.
Systemic effects, such as headache, pyrexia and a feeling of malaise may occur but these are less frequent with Fluvirin than with Influenza Vaccine BP.
Over-dosage: Not applicable.

Pharmaceutical precautions

Fluvirin should be protected from light and stored at between 2° and 10°C (36° and 50°F) ; it must never be frozen. Though limited exposure to light and higher temperatures has no adverse effect on the vaccine, temperatures above 20°C (68°F) should be avoided.

Legal category

No legal restrictions on sale or supply.

Package quantities

Fluvirin is available in 0.5 ml single dose ampoules and in 5 ml multidose vials.

Further information

Field studies with adsorbed surface antigen influenza vaccine have shown that the purified haemagglutinin and neuraminidase antigens contained in a single dose of Fluvirin will produce a protective antibody response in up to 90% of patients aged between 18 and 60 years of age. A volunteer study has shown that, in this age range, adequate serum antibody levels were maintained, in the majority of cases, for at least ten months.
It has been suggested that the immune response to influenza vaccination in geriatric patients may be poor in comparison to that experienced in younger age groups ; a limited trial in geriatric patients, aged up to 76 years, showed the antibody level after a single dose was comparable to that obtained in the younger age group – the vaccine elicited a fourfold or greater rise in antibody level in more than half of the individuals tested.

Product licence number

0021/0063.

DF

Product licence holder

Fluvirin is a trade mark of
Duncan, Flockhart & Co. Limited, London, E2 6LA
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