PROFESSIONAL INFORMATION

Scheduling Status: S2

PROPRIETARY NAME AND DOSAGE FORM:

MeasBio (freeze-dried powder for reconstitution and injection)

DESCRIPTIVE NAME OF MEDICINE:

Measles Virus Vaccine Live Attenuated

COMPOSITION:

Each single dose when reconstituted with 0,5 ml diluent contains not

less than 1000 $CCID_{50}$ CAM-70 strain of measles live, attenuated

virus, prepared in SPF chicken embryo.

The vaccine may contain traces of Erythromycin and Kanamycin.

The other ingredients are: D-sorbitol, Lactose monohydrate, Gelatin,

L-cysteine,NaOH and PBS + phenol red 0,002 %.

The diluent is sterile water for injection.

PHARMACOLOGICAL CLASSIFICATION:

A.30.1 Biologicals - Antigen

PHARMACOLOGICAL ACTION:

For the active immunisation against measles.

INDICATIONS:

The recommended age for immunisation of children with the measles vaccine,

is at 9 months of age and a booster dose at 18 months.

An additional dose at 6 months of age is recommended for HIV positive patients.

CONTRA - INDICATIONS:

Measles vaccine should not be administered to patients with active or developing acute respiratory infection including active untreated tuberculosis. The vaccine should not be given in acute infectious diseases, leukaemia, severe anaemia and other severe diseases of the blood system, severe impairment of the renal function and decompensated heart diseases. Low grade fever, mild respiratory infections or diarrhoea and other mild illness should not be considered as contra-indications. Measles vaccine may be used in children with known or suspected HIV infection. Although the data are limited and further studies are being encouraged, there is no evidence to date of any increased rate of adverse reactions using measles vaccines in symptomatic or asymptomatic HIV- infected children.

Measles vaccine should be avoided in other cell-mediated immune deficiency states.

MeasBio is contra-indicated in patients with a known allergy to kanamycin sulphate and erythromycin.

WARNINGS:

Antibody response in patients with endogenous (due to illness) or Iatrogenic (due to medicine) immunosuppression may be insufficient. Not to be administered intravenously. Caution should be exercised in

children with a history of convulsions and vaccination should preferably not be carried out until the age of 24 months.

MeasBio is not to be used with other childhood vaccines.

INTERACTIONS:

Individuals receiving corticosteroids, other immuno-suppressive drugs or undergoing radiotherapy may not develop an optimal immune response. Following administration of gammaglobulin or blood transfusions, vaccination should be delayed for at least 3 months, because of the likelihood of vaccine failure due to passively acquired measles antibodies.

PREGNANCY AND LACTATION:

MeasBio should not be given to a pregnant woman, as the effect of the virus on the foetus is not known.

DOSAGE AND DIRECTIONS FOR USE:

The vaccine should be reconstituted only with the diluent supplied (Sterile water for injection) using a sterile syringe and needle [<26 G; 1 inch]. When the multidose vial is used: A separate sterile syringe and needle [26-30 G, ½ - 5/8 inch (SC)] must be used for each patient. Rotate the vial between palms of hands after adding sterile water for injection. Do not shake since this will cause frothing.

Administer 0,5 ml subcutaneously. The preferred site of injection is the upper arm.

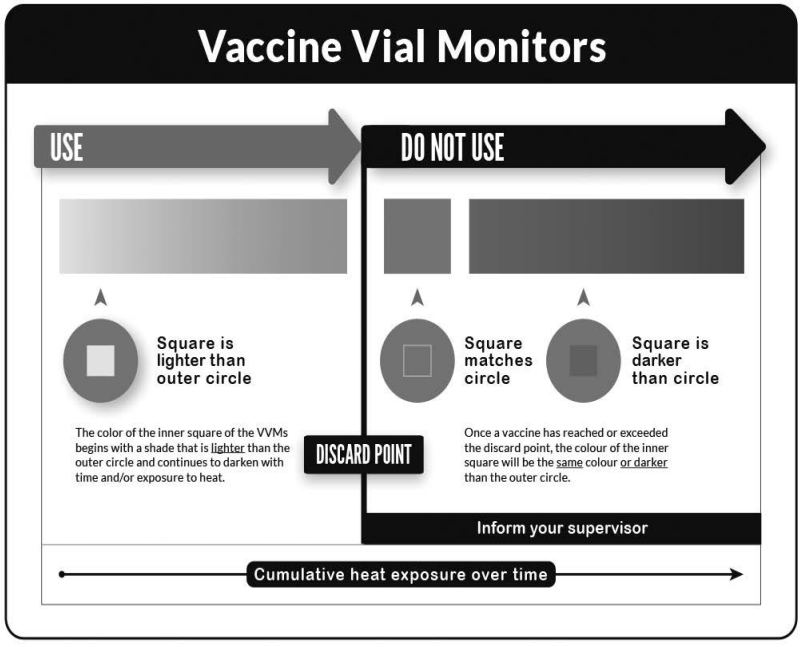
After reconstitution the vaccine should be used immediately. If the

vaccine is not used immediately then it should be stored, protected from light at 2 – 8 ºC for no longer than 6 hours.

If sterile procedures have not been fully observed, or there is a suspicion that an open vial of vaccine has been contaminated, it must be discarded immediately.

Vaccine Vial Monitor (Figure 1): A vaccine vial monitor (VVM) contains a heat- sensitive material that is printed on the vaccine vial product label or cap to register cumulative heat exposure over time. Health workers must compare the colour of the heat sensitive square to a reference circle to determine whether or not a vial of vaccine should be discarded because it has been exposed to too much heat.

Figure 1: The Vaccine Vial Monitor



SIDE EFFECTS AND SPECIAL PRECAUTIONS:

Side-effects:

Very common (>1/10); common (>1/100, <1/10); uncommon (>1/1 000, <1/100); rare (>1/10 000, <1/1 000); very rare (<1/10 000), including isolated reports.

Blood and the lymphatic system disorders

Rare: thrombocytopenic purpura; lymphadenopathy

General disorders and administration site conditions

Common: burning or stinging at the injection site; fever

Uncommon: skin rash; allergic reactions, such as itching, swelling, redness, tenderness or hard lump at the injection site; malaise

Rare: severe and extensive swelling, blistering or pain at the injection site; encephalitis or meningo-encephalitis; convulsions may accompany fever in susceptible individuals

Immune system disorders

Rare: anaphylactic reaction

Nervous system disorders

Uncommon: headache

Respiratory disorders

Uncommon: cough; pharyngitis; coryza

These side-effects are generally transient. When they appear, it is advisable to consult a physician.

Special precautions:

As with all injectable vaccines, appropriate medical treatment and supervision should always be readily available in case of a rare anaphylactic event following the administration of the vaccine.

Measures to treat anaphylaxis including a syringe containing1 ml adrenaline (1:1 000) should be available when administering measles vaccine. Caution should be exercised in children with a history of convulsions and vaccination should preferably not be carried out until the age of 24 months.

Attenuated measles vaccine is rapidly inactivated by ether, alcohol and detergents. Special care must be taken in preparing the syringes and the swabbed skin must be allowed to dry before vaccination.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF TREATMENT:

See **"Side Effects and Special Precautions**". Treatment is symptomatic and supportive.

IDENTIFICATION:

Lyophilised vaccine: A yellowish white freeze-dried mass

Reconstituted vaccine: A yellowish red solution

Diluent: A clear, colourless, odourless, tasteless liquid

PRESENTATION:

Ten or 50, 10 dose clear glass vials, sealed with a grey rubber stopper and aluminium cap with an orange flip-off seal, containing

the lyophilised powder for 10 doses. Ten or 50 x 5 ml diluent (water for injection) in clear glass ampoules. Vials and diluent are packed in a cardboard box.

Ten or 50, 20 dose clear glass vials, sealed with a grey rubber stopper and aluminium cap with a plastic gold flip- off seal, containing the lyophilised powder for 20 doses. Ten or 50 x 10 ml diluent (water for injection) in clear glass ampoules. Vials and diluent are packed in a cardboard box.

STORAGE INSTRUCTIONS:

Store the lyophilized vaccine at 2 ºC to 8 ºC and the diluent at or below 25 ºC OR at 2 ºC to 8 ºC. The diluent must not be frozen, but must be cooled (between 2 ºC to 8 ºC) before being used for reconstitution. Reconstituted vaccine may be kept cold (between 2 ºC to 8 ºC) for up to six hours, both the lyophilised and reconstituted vaccine must be protected from light. Do not freeze the reconstituted

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER:

43/30.1/0541

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:

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