

PATIENT INFORMATION LEAFLET

MEASBIO

SCHEDULING STATUS: S2

PROPRIETARY NAME, AND PHARMACEUTICAL FORM:

MeasBio (freeze-dried powder for reconstitution and injection)

DESCRIPTIVE NAME OF MEDICINE:

Measles Virus Vaccine Live Attenuated

1. WHAT MeasBio VACCINE CONTAINS

- The active substance is measles virus.

Each single dose when reconstituted with 0,5 ml diluent contains not less than 1000 CCID50 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 %

2. WHAT MeasBio VACCINE IS USED FOR

Measles vaccine is an immunizing agent used to prevent infection by the measles virus. It works by causing your body to produce its own protection or anti-bodies against the virus.

3. BEFORE YOU USE MeasBio VACCINE

Do not use MeasBio VACCINE:

- if you are hypersensitive (allergic) to any of the ingredients of

MeasBio VACCINE

- if you have an immune deficiency condition or a family history thereof
- if you have severe illness with fever

MeasBio is not to be used with other childhood

Take special care with MeasBio VACCINE:

- if you have severe kidney, heart or blood disorders

Children

Immunization against measles is usually not recommended for infants up to 9 months

Pregnancy and Breast-feeding:

Safety in pregnancy and during breast feeding has not been established. A live vaccine should not be given to a pregnant woman, as the effect of the virus on the foetus is not known.

If you are pregnant or breast-feeding your baby while using this medicine, please consult your doctor, pharmacist or other healthcare professional for advice

Using other medicines with MeasBio VACCINE:

If you are using other medicines on a regular basis, including

complementary or traditional medicines, the use of MeasBio VACCINE with

these medicines may cause undesirable interactions.

If you are using the following, please consult your doctor, pharmacist or

- other healthcare professional, for advice:
- treatment with x-rays or cancer medicines
- corticosteroids
- other immuno-suppressive drugs
- blood transfusions
- gamma globulin

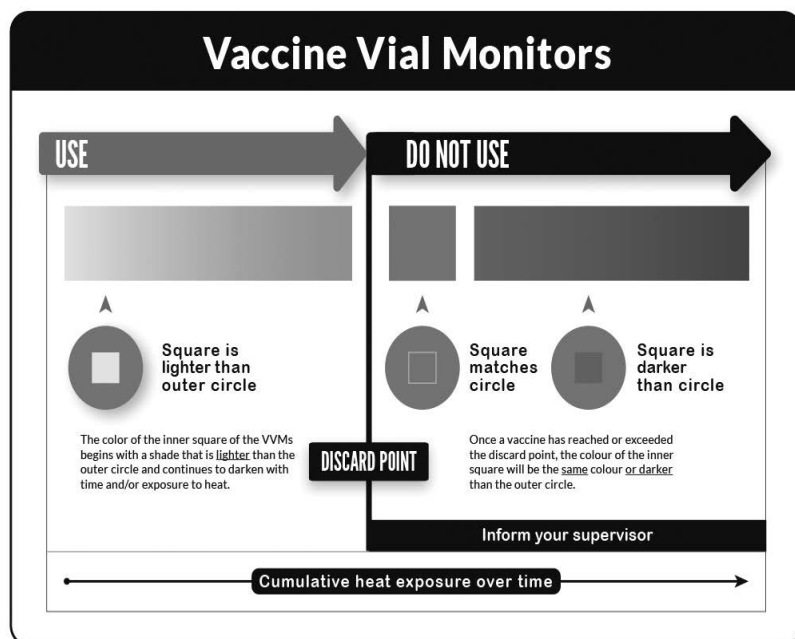
4. HOW TO USE MeasBio Vaccine

This vaccine must be administered only by or under the supervision of your doctor or healthcare professional.

Administer 0, 5 ml under the skin. 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 °C for no longer than 6 hours. 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.

Compare the colour of the heat sensitive square to the 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



If you use more MeasBio VACCINE than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, seek help at the nearest hospital or poison control centre.

5. POSSIBLE SIDE-EFFECTS:

MeasBio VACCINE can have side-effects.

Check with your doctor immediately if any of the following side-effects occur:

Get emergency help immediately if any of the following side effects occur:

Symptoms of allergic reaction i.e. difficulty in breathing or swallowing; hives; itching; especially of feet or hands; reddening of skin, especially around ears; swelling of eyes, face, or inside of nose, unusual tiredness or weakness.

Check with your doctor or healthcare professional if any of the following side-effects occur and continue to be bothersome:

More frequent: Fever over 39,4 °C; burning or stinging at the injection site.

Less frequent: Fever between 37,7 °C and 39,4 °C; itching, swelling, redness, tenderness or hard lump at place of injection; severe skin rash.

Rare: Bruising or purple spots on the skin; confusion; convulsions; double vision; headache; irritability; stiff neck; swelling; blistering or pain at place of injection; swelling of glands in neck; vomiting

Other side-effects may occur that do not need medical attention. These side-effects may go away during treatment as your body adjusts to the medicine.

Not all side-effects reported for this medicine are included in this leaflet.

Should your general health worsen while using this medicine, please consult your doctor, pharmacist or other healthcare professional for advice.

6. STORING AND DISPOSING OF MeasBio VACCINE

Store the lyophilized vaccine at 2 °C - 8 °C and the diluent at or below 25 °C

OR at 2 °C - 8 °C. The diluent must not be frozen, but must be cooled (between 2 °C - 8 °C) before being used for reconstitution.

Do not freeze the reconstituted vaccine.

Reconstituted vaccine may be kept cold (between 2 °C – 8 °C) for up to 6 hours, both the lyophilised and reconstituted vaccine must be protected from light.

KEEP OUT OF REACH OF CHILDREN

Do not store in bathrooms

Do not use after the expiry date stated on the container

Return all unused medicine to your pharmacist

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets)

7. PRESENTATION OF MeasBio VACCINE

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.

8. IDENTIFICATION OF MeasBio VACCINE

Lyophilised vaccine: A yellowish white freeze-dried mass

Reconstituted vaccine: A yellowish red solution

Diluent: A clear, colourless, odourless, tasteless liquid

9. REGISTRATION NUMBER:

43/30.1/0541

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

The Biovac Institute

15 Alexandra Road

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Cape Town

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11. DATE OF PUBLICATION OF THIS PATIENT INFORMATION LEAFLET

Date of registration: 20 April 2015

Date of most recently revised patient information leaflet: 13 July 2021