

Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

MEASAVAX Powder and solvent for suspension for injection.
Measles Vaccine (Live).

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 0.5 millilitre dose contains:

Measles virus¹ (Schwarz strain) (live, attenuated) containing not less than 1000 TCID₅₀

¹Produced on primary chick embryo cells.

For a full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Powder and solvent for suspension for injection.

Powder: A lyophilised pellet, yellow to pinkish beige in colour.
Solvent: A clear colourless liquid.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

For active immunisation against measles.

It may also be given within 3 days of exposure to measles to help suppress the full clinical disease.

4.2 Posology and method of administration

Administer by intramuscular or deep subcutaneous injection.

Adults, Children and the Elderly

Single dose of 0.5 ml of the reconstituted vaccine.

Infants less than 12 months of age

Not recommended.

4.3 Contraindications

Measavax should not be given in the presence of acute infectious disease, or currently evolving acute or chronic disease (particularly tuberculosis or respiratory tract infection).

It is contra-indicated in states of altered immunity including malignancy, leukaemia, lymphoma or in those receiving corticosteroids, cytotoxic drugs or irradiation.

The vaccine contains small traces of egg protein and is therefore contra-indicated in those who have a severe allergy to egg protein (past anaphylactoid reactions to egg protein). It also contains traces of neomycin and must not be given to those known to be hypersensitive to this antibiotic.

Measavax must not be given to those who previously have had severe reactions to measles vaccine.

Use during pregnancy or in females at risk of pregnancy for 3 months post vaccination.

4.4 Special warnings and precautions for use

Children with a personal history of convulsions or whose parents or siblings have a history of idiopathic epilepsy may be immunised with Measavax, provided their parents understand that there may be a febrile response 5-10 days following immunisation. Advice should be given in such cases about measures such as removal of clothing, tepid sponging and the administration of paracetamol which may be indicated.

Because of the potential interference from passive antibodies, measles vaccine should not normally be given to infants below the age of one year, or to subjects who have received blood or human plasma transfusions or human immunoglobulin within the previous three months. If the vaccine is given in these circumstances, serum antibodies should be checked at a later date.

Other live vaccines may be given simultaneously at different sites or after an interval of three weeks between vaccines. A three week interval should be allowed before BCG is given. Tuberculin testing should be delayed after measles vaccination since false-negative results may be obtained for about 8 weeks after vaccination.

Although anaphylaxis is extremely rare, remedial facilities such as a solution of 1:1000 epinephrine (adrenaline) should always be available during immunisation.

4.5 Interaction with other medicinal products and other forms of interaction

The vaccine is rapidly inactivated by ether, alcohol and detergents and therefore care must be taken with any skin cleaning technique to avoid contact with these substances.

This vaccine should not be given within one month of immunisation with any other live vaccine except oral polio virus vaccine.

The vaccine should not be given within 3 months of blood or plasma transfusion or administration of human immune serum globulin in excess of 0.01 mg/kg/ b.w.

4.6 Pregnancy and lactation

There is inadequate data on the theoretical risk of measles vaccine in pregnancy. The vaccine is therefore contra-indicated in pregnant women.

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

These are usually mild and are more likely around the eighth day after vaccination. They may include rash, fever, malaise, cough, pharyngitis, coryza and headache. In a very few subjects convulsions may accompany the fever. Immediate allergic-type reactions have been reported rarely. Very rarely encephalitis has been reported in the period following measles vaccination.

Cases of acute thrombocytopenic purpura have been reported following administration of vaccines containing the measles antigen.

4.9 Overdose

Not applicable.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Not applicable.

5.2 Pharmacokinetic properties

Not applicable.

5.3 Preclinical safety data

Not applicable.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Powder:

Neomycin sulphate (trace)

Human albumin

Phenylalanine

Phosphate buffer

Amino acids

Urea

Solvent:

Water for injections

6.2 Incompatibilities

In the absence of compatibility studies this medicinal product must not be mixed with other medicinal products.

6.3 Shelf Life

2 years.

Use immediately after reconstitution.

6.4 Special precautions for storage

Store in a refrigerator (2C to 8C).

Do not freeze.

Keep the containers in the outer carton in order to protect from light.

6.5 Nature and contents of container

Lyophilised Vaccine: - single type I glass vial with elastomer stopper and flip-off overcap (aluminium polypropylene)

Solvent: - 1 ml disposable syringe type I glass with elastomer needle shield.
- Type I glass ampoule.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

The vaccine should be reconstituted with the supplied solvent prior to administration.

Once reconstituted Measavax is a clear, yellow to pinkish yellow suspension.

Parenteral drug products should be inspected visually for particulate matter and discolouration prior to administration. Discard the product if particulates are present or if it appears discoloured.

Any unused product or waste material should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

Sanofi Pasteur MSD
Block A, Second Floor
Cookstown Court
Old Belgard Road,
Tallaght,
Dublin 24.

8 MARKETING AUTHORISATION NUMBER

PA 0544/003/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 13 July 1989

Date of last renewal: 24 October 2006

10 DATE OF REVISION OF THE TEXT

February 2008