SUMMARY OF PRODUCT CHARACTERISTIC

1. NAME OF THE MEDICAL PRODUCT
MEASLES, MUMPS AND RUBELLA VACCINE LIVE, ATTENUATED (FREEZE-DRIED)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 0.5 ml contains:

- Live, attenuated Measles Virus (Edmonstan-Zagreb strain) not less than 1000 CCID$_{50}$
- Live, attenuated Mumps Virus (Leningrad-Zagreb strain) not less than 5000 CCID$_{50}$
- Live, attenuated Rubella Virus (Wista RA 27/3 strain) not less than 1000 CCID$_{50}$

3. PHARMACEUTICAL FORM
White powders and diluents

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

For active immunization against measles, mumps and rubella in infants older than 12 months of age, children and adolescents. Immunization of susceptible non-pregnant adolescent and adult females is indicated if certain precautions are observed (see CONTRAINDICATIONS). The vaccine can be safely and effectively given simultaneously with DPT, DT, TT, BCG and Polio vaccine (OPV and IPV), Hepatitis B and Yellow Fever Vaccine.

4.2 Posology and method of administration

The vaccine should be reconstituted with the diluent supplied (Sterile water for injection) using a sterile syringe and needle. With gentle shaking the dried cake is easily dissolved. After reconstitution the vaccine should be used immediately. A single dose of 0.5 ml should be administered by deep subcutaneous injection into the upper arm. If the vaccine is not used immediately then it should be stored in the dark 2 - 8°C for no longer than 8 hours.

4.3 Contraindication

Individuals receiving corticosteroids, other immuno-suppressive drugs or undergoing radio-therapy may not develop an optimal immune response. The vaccine should not be given in febrile states, pregnancy, acute infectious diseases, leukemia, sever anemia and other severe diseases of the blood system, severe impairment of the renal function, decompensated heart diseases, following administration of gammaglobulin or blood transfusions or to subjects with potential allergies to vaccine components. Low grade fever, mild respiratory infections or diarrhoea, and other minor illness should not be considered as contraindications. It is particularly important to immunize children with malnutrition.
4.4 Special warnings and precautions for use

- HIV INFECTION

Measles, Mumps and Rubella 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 this or other measles, mumps and rubella vaccines in symptomatic or asymptomatic HIV-infected children. The vaccine should be avoided in other cell-mediated immune deficiency states.

MMR vaccine can also be given to adults at any age in case they have missed the vaccination in childhood and or there is no vaccination record available. However, it is important to note that vaccination in adults can cause higher percentage of adverse reactions as compared to childhood vaccination. Amongst these the commonly encountered side reactions are unilateral or bilateral parotitis and fever.

Please ensure that the vaccine is administered by subcutaneous route only. In rare cases anaphylactic shock may occur in susceptible patient and for such emergency please keep handy 1:1000 adrenaline injection ready to be injected intramuscularly. This will help in tackling the anaphylactic shock/reaction effectively

4.5 Interaction with other medical products and forms of interaction

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4.6 Pregnancy and lactation

Do not administer the vaccine during pregnancy, caution vaccines not to conceive for 28 days period following vaccination.

4.7 Effects on the ability to drive and use machines

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4.8 Undesirable effects

Reactions are generally mild. An increase in temperature (average 37.9°C) may occur in less than 8% of vaccines and a slight rash may develop between 6-14 days after vaccination in 1-2%. The average duration is 1.8 days. The rash is also much milder than would occur with the natural disease. Similarly there may also be a slight enlargement of the cervical and occipital lymph nodes. Very rarely, and enlargement of the parotid and other salivary glands has been observed. When present, it has, in the majority of cases been due to previous exposure to natural disease. Clinical experience has been recorded isolated reactions involving the CNS causing aseptic meningitis in Croatia and Slovenia.

4.9 Overdose

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5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties
**5.2 Pharmacokinetic properties**

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**5.3 Preclinical safety data**

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### 6. PHARMACEUTICAL PARTICULARS

#### 6.1 List of excipients

Each 0.5 ml contains:

- Partially hydrolysed gelatin 2.5% (final concentration)
- Sorbitol 5.0% (final concentration)

#### 6.2 Incompatibilities

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#### 6.3 Shelf life

24 months from the date of last satisfactory potency test.

#### 6.4 Special precautions for storage

It is important to protect both the lyophilized and reconstituted vaccine from the light. The vaccine should be stored in the dark at a temperature between 2-8°C. For long term storage a temperature of -20°C is recommended for the vaccine. The diluent should not be frozen, but should be kept cool.

#### 6.5 Nature and contents of container

Glass vial and diluent in ampoule

#### 6.6 Special precautions for disposal and other handling

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### 7. MARKETING AUTHORISATION HOLDER

MASU CO., LTD.

### 8. MARKETING AUTHORISATION NUMBER (S)

3/2536

### 9. DATE OF FIRST AUTHORISATION / RENEWAL OF THE AUTHORISATION

21 June 2005

### 10. DATE OF REVISION OF THE TEXT

22 June 2012