NEW ZEALAND DATA SHEET

1 PRODUCT NAME

M-M-R® II 0.5 mL Suspension for injection

Measles mumps and rubella virus vaccine live

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

M-M-R II is a sterile lyophilised preparation of (1) ATTENUVAX® (Measles Virus Vaccine Live, MSD), a more attenuated line of measles virus, derived from Enders' attenuated Edmonston strain and propagated in chick embryo cell culture; (2) MUMPSVAX® (Mumps Virus Vaccine Live, MSD), the Jeryl Lynn (B level) strain of mumps virus propagated in chick embryo cell culture; and (3) MERUVAX® II (Rubella Virus Vaccine Live, MSD), the Wistar RA 27/3 strain of live attenuated rubella virus propagated in WI-38 human diploid lung fibroblasts.

The reconstituted vaccine is for subcutaneous administration. When reconstituted as directed, the dose for injection is 0.5 mL and contains not less than 1,000 $CCID_{50}$ (50% cell culture infectious dose) of measles virus; 12,500 $CCID_{50}$ of mumps virus; and 1,000 $CCID_{50}$ of rubella virus.

Excipients with known effect: Sorbitol

For the full list of excipients, see Section 6.1.

The growth medium for measles and mumps is Medium 199 (a buffered salt solution containing vitamins and amino acids and supplemented with foetal bovine serum) containing SPGA (sucrose, phosphate, glutamate, and recombinant human albumin) as stabiliser and neomycin.

The growth medium for rubella is Minimum Essential Medium (MEM) [a buffered salt solution containing vitamins and amino acids and supplemented with foetal bovine serum] containing recombinant human albumin and neomycin. Sorbitol and hydrolysed gelatin stabiliser are added to the individual virus harvests.

The cells, virus pools, and foetal bovine serum are all screened for the absence of adventitious agents. The product contains no preservative.

3 PHARMACEUTICAL FORM

Suspension for injection

The vaccine is supplied in vials as a sterile lyophilised preparation together with vials of diluent containing sterile water for injection BP. Before reconstitution, the lyophilised vaccine is a light yellow compact crystalline plug.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

M-M-R II is indicated for simultaneous vaccination against measles, mumps, and rubella in individuals 12 months of age or older.

There is some evidence to suggest that infants who are born to mothers who had wild-type measles and who are vaccinated at less than one year of age may not develop sustained antibody levels when later revaccinated. The advantage of early protection must be weighed against the chance for failure to respond adequately on re-immunisation.

Infants who are less than 12 months of age may fail to respond to the measles component of the vaccine due to presence in the circulation of residual measles antibody of maternal origin: the younger the infant, the lower the likelihood of seroconversion. In geographically isolated or other relatively inaccessible populations for whom immunisation programs are logistically

difficult, and in population groups in which wild-type measles infection may occur in a significant proportion of infants before 15 months of age, it may be desirable to give the vaccine to infants at an earlier age. Infants vaccinated under these conditions at less than 12 months of age should be revaccinated after reaching 12 to 15 months of age.

4.2 Dose and method of administration

Dose

The dose for any age is 0.5 mL administered subcutaneously, preferably into the outer aspect of the upper arm.

Recommended Vaccination Schedule

Individuals first vaccinated at 12 months of age or older, should be revaccinated at 4 to 6 years of age since increased risk of exposure typically occurs around primary school entry. Revaccination is intended to seroconvert those who do not respond to the first dose.

Measles Outbreak Schedule

Infants Between 6 to 12 Months of Age

Local health authorities may recommend measles vaccination of infants between 6 to 12 months of age in outbreak situations. This population may fail to respond to the components of the vaccine. Safety and effectiveness of mumps and rubella vaccine in infants less than 12 months of age have not been established. The younger the infant, the lower the likelihood of seroconversion. Such infants should receive a second dose of M-M-R II at 12 to 15 months of age followed by revaccination at 4 to 6 years of age.

Mumps Outbreak Schedule

Local health authorities may recommend mumps vaccination in a mumps outbreak situation.

Other Vaccination Considerations

Non-Pregnant Adolescent and Adult Females

Immunisation of susceptible non-pregnant adolescent and adult females of childbearing age with live attenuated rubella virus vaccine is indicated if certain precautions are observed (see Section 4.4 Special warnings and precautions for use). Vaccinating susceptible postpubertal females confers individual protection against subsequently acquiring rubella infection during pregnancy, which in turn prevents infection of the foetus and consequent congenital rubella injury.

Women of childbearing age should be advised not to become pregnant for one month after vaccination and should be informed of the reasons for this precaution (see Section 4.6 Fertility, pregnancy and lactation, *Pregnancy*).

If it is practical and if reliable laboratory services are available, women of childbearing age who are potential candidates for vaccination can have serologic tests to determine susceptibility to rubella. However, with the exception of premarital and prenatal screening, routinely performing serologic tests for all women of childbearing age to determine susceptibility (so that vaccine is given only to proven susceptible women) can be effective but is expensive. Also, 2 visits to the health-care provider would be necessary - one for screening and one for vaccination. Accordingly, rubella vaccination of a woman who is not known to be pregnant and has no history of vaccination is justifiable without serologic testing - and may be preferable, particularly when costs of serology are high and follow-up of identified susceptible women for vaccination is not assured.

Postpubertal females should be informed of the frequent occurrence of generally self-limited arthralgia and/or arthritis beginning 2 to 4 weeks after vaccination (see Section 4.8 Undesirable effects).

Postpartum Women

It has been found convenient in many instances to vaccinate rubella-susceptible women in the immediate postpartum period (see Section 4.6 Fertility, pregnancy and lactation, *Breast-feeding*).

Other Populations

Previously unvaccinated children older than 12 months who are in contact with susceptible pregnant women should receive live attenuated rubella vaccine (such as that contained in monovalent rubella vaccine or in M-M-R II) to reduce the risk of exposure of the pregnant woman.

Individuals planning travel abroad, if not immune, can acquire measles, mumps or rubella and import these diseases to their country. Therefore, prior to international travel, individuals known to be susceptible to one or more of these diseases can receive either a monovalent vaccine (measles, mumps, or rubella), or a combination vaccine as appropriate. However, M-M-R II is preferred for persons likely to be susceptible to mumps and rubella; and if monovalent measles vaccine is not readily available, travellers should receive M-M-R II regardless of their immune status to mumps or rubella.

Vaccination has been recommended for susceptible individuals in high-risk groups such as college students, health-care workers, and military personnel.

Post Exposure Vaccination

Vaccination of individuals exposed to wild-type measles may provide some protection if the vaccine can be administered within 72 hours of exposure. If, however, vaccine is given a few days before exposure, substantial protection may be afforded. There is no conclusive evidence that vaccination of individuals recently exposed to wild-type mumps or wild-type rubella will provide protection.

Method of administration

FOR SUBCUTANEOUS ADMINISTRATION

Do not inject intravascularly.

Do not give immune globulin (IG) concurrently with M-M-R II. (See Section 4.5 Interactions with other medicines and other forms of interactions.)

CAUTION: A sterile syringe free of preservatives, antiseptics, and detergents should be used for each injection and/or reconstitution of the vaccine because these substances may inactivate the live virus vaccine. A 25 gauge, 5/8" needle is recommended.

To reconstitute, use only the diluent supplied, since it is free of preservatives or other antiviral substances which might inactivate the vaccine.

Parenteral drug products should be inspected visually for particulate matter and discolouration prior to administration whenever solution and container permit. Before reconstitution, the lyophilised vaccine is a light yellow compact crystalline plug. M-M-R II, when reconstituted, is clear yellow.

Single Dose Vial

First withdraw the entire volume of diluent into the syringe to be used for reconstitution. Inject all the diluent in the syringe into the vial of lyophilised vaccine, and agitate to mix thoroughly. If the lyophilised vaccine cannot be dissolved, discard. Withdraw the entire contents into a syringe and inject the total volume of reconstituted vaccine subcutaneously.

It is important to use a separate sterile syringe and needle for each individual patient to prevent transmission of Hepatitis B and other infectious agents from one person to another.

4.3 Contraindications

- Hypersensitivity to any component of the vaccine, including gelatin.
- Do not give M-M-R II to pregnant females; the possible effects of the vaccine on foetal development are unknown at this time. If vaccination of postpubertal females is undertaken, pregnancy should be avoided for one month following vaccination. (See Section 4.6 Fertility, pregnancy and lactation*, Pregnancy*.)
- Anaphylactic or anaphylactoid reaction to neomycin (each dose of reconstituted vaccine contains approximately 25 mcg of neomycin).
- Any febrile respiratory illness or other active febrile infection.
- Active untreated tuberculosis.
- Patients receiving immunosuppressive therapy. This contraindication does not apply to patients who are receiving corticosteroids as replacement therapy, e.g. for Addison's disease.
- Individuals with blood dyscrasias, leukaemia, lymphomas of any type, or other malignant neoplasms affecting the bone marrow or lymphatic systems.
- Primary and acquired immunodeficiency states, including patients who are immunosuppressed in association with AIDS or other clinical manifestations of infection with human immunodeficiency viruses; cellular immune deficiencies, hypogammaglobulinaemic and dysgammaglobulinaemic states. Measles inclusion body encephalitis (MIBE), pneumonitis and death as a direct consequence of disseminated measles vaccine virus infection have been reported in severely immunocompromised individuals inadvertently vaccinated with measles-containing vaccine.
- Individuals with a family history of congenital or hereditary immunodeficiency, until the immune competence of the potential vaccine recipient is demonstrated.

4.4 Special warnings and precautions for use

General

Adequate treatment provisions including epinephrine injection (1:1000) should be available for immediate use should an anaphylactic or anaphylactoid reaction occur.

Due caution should be employed in administration of M-M-R II to persons with individual or family histories of convulsions, a history of cerebral injury or any other condition in which stress due to fever should be avoided. The physician should be alert to the temperature elevation which may occur following vaccination. (See Section 4.8 Undesirable effects.)

Hypersensitivity to eggs

Live measles vaccine and live mumps vaccine are produced in chick embryo cell culture. Persons with a history of anaphylactic, anaphylactoid, or other immediate reactions (e.g., hives, swelling of the mouth and throat, difficulty breathing, hypotension, or shock) subsequent to egg ingestion may be at an enhanced risk of immediate-type hypersensitivity reactions after receiving vaccines containing traces of chick embryo antigen. The potential risk to benefit ratio should be carefully evaluated before considering vaccination in such cases. Such individuals may be vaccinated with extreme caution, having adequate treatment on hand should a reaction occur.

Thrombocytopaenia

Individuals with current thrombocytopaenia may develop more severe thrombocytopaenia following vaccination. In addition, individuals who experienced thrombocytopaenia with the first dose of M-M-R II (or its component vaccines) may develop thrombocytopaenia with repeat doses. Serologic status may be evaluated to determine whether or not additional doses of vaccine are needed. The potential risk to benefit ratio should be carefully evaluated before considering vaccination in such cases (see Section 4.8 Undesirable effects).

Other

Children and young adults who are known to be infected with human immunodeficiency viruses and are not immunosuppressed may be vaccinated. However, the vaccinees who are infected with HIV should be monitored closely for vaccine-preventable diseases because immunisation may be less effective than for uninfected persons (see Section 4.3 Contraindications).

Excretion of small amounts of the live attenuated rubella virus from the nose or throat has occurred in the majority of susceptible individuals 7 to 28 days after vaccination. There is no confirmed evidence to indicate that such virus is transmitted to susceptible persons who are in contact with the vaccinated individuals. Consequently, transmission through close personal contact, while accepted as a theoretical possibility, is not regarded as a significant risk. However, transmission of the rubella vaccine virus to infants via breast milk has been documented (see Section 4.6 Fertility, pregnancy and lactation, *Breast-feeding*).

There are no reports of transmission of live attenuated measles or mumps viruses from vaccinees to susceptible contacts.

It has been reported that live attenuated measles, mumps, and rubella virus vaccines given individually may result in a temporary depression of tuberculin skin sensitivity. Therefore, if a tuberculin test is to be done, it should be administered either any time before, simultaneously with, or at least 4 to 6 weeks after M-M-R II.

Children under treatment for tuberculosis have not experienced exacerbation of the disease when immunised with live measles virus vaccine; no studies have been reported to date of the effect of measles virus vaccines on untreated tuberculous children.

As for any vaccine, vaccination with M-M-R II may not result in protection in 100% of vaccinees.

Paediatric population

Safety and effectiveness of measles vaccine in infants below the age of 6 months have not been established. Safety and effectiveness of mumps and rubella vaccine in infants less than 12 months of age have not been established.

4.5 Interactions with other medicines and other forms of interactions

Administration of immune globulins concurrently with M-M-R II may interfere with the expected immune response. Vaccination should be deferred for 3 months or longer following administration of immune globulin (human) and blood or plasma transfusions.

Use with Other Vaccines

M-M-R II should be given one month before or after administration of other live viral vaccines.

M-M-R II has been administered concurrently with live attenuated varicella and inactivated *Haemophilus influenzae* type b (Hib) conjugate vaccines using separate injection sites and syringes. No impairment of immune response to individually tested vaccine antigens was demonstrated. The type, frequency, and severity of adverse experiences observed with M-M-R II were similar to those seen when each vaccine was given alone.

Routine administration of DTP (diphtheria, tetanus, pertussis) and/or OPV (oral poliovirus vaccine) concurrently with measles, mumps, and rubella vaccines is not recommended because there are limited data relating to the simultaneous administration of these antigens.

However, other schedules have been used. Data from published studies concerning the simultaneous administration of the entire recommended vaccine series (i.e., DTaP [or DTwP], IPV [or OPV], Hib with or without Hepatitis B vaccine, and varicella vaccine), indicate no interference between routinely recommended childhood vaccines (either live, attenuated, or killed).

4.6 Fertility, pregnancy and lactation

Pregnancy

It is not known whether M-M-R II can cause foetal harm when administered to a pregnant woman or can affect reproduction capacity. Therefore, the vaccine should not be administered to pregnant females; furthermore, pregnancy should be avoided for one month following vaccination (see Section 4.3 Contraindications).

In an 18-year survey involving over 1200 pregnant women who received rubella vaccine within 3 months before or after conception (of whom 683 received the Wistar RA 27/3 strain), none of the newborns had abnormalities compatible with congenital rubella syndrome. Additional data from post-marketing reports and published observational studies have not identified abnormalities compatible with congenital rubella syndrome in patients who received M-M-R II. Mumps infection during the first trimester of pregnancy may increase the rate of spontaneous abortion. Although mumps vaccine virus has been shown to infect the placenta and foetus, there is no evidence that it causes congenital malformations in humans. Reports have indicated that contracting of wild-type measles during pregnancy enhances foetal risk.

Increased rates of spontaneous abortion, stillbirth, congenital defects and prematurity have been observed subsequent to infection with wild-type measles during pregnancy. There are no adequate studies of the attenuated (vaccine) strain of measles virus in pregnancy. However, it would be prudent to assume that the vaccine strain of virus is also capable of inducing adverse foetal effects.

Breast-feeding

It is not known whether measles or mumps vaccine virus is secreted in human milk. Recent studies have shown that lactating postpartum women immunised with live attenuated rubella vaccine may secrete the virus in breast milk and transmit it to breast-fed infants. In the infants with serological evidence of rubella infection, none exhibited severe disease; however, one exhibited arthritis and one had a typical course of acquired rubella. Caution should be exercised when M-M-R II is administered to nursing women.

Fertility

M-M-R II has not been evaluated for its potential to impair fertility.

4.7 Effects on ability to drive and use machines

No studies on the effects on the ability to drive and use machines have been performed. M-M-R II is expected to have no or negligible influence on ability to driver and use machines.

4.8 Undesirable effects

The adverse reactions associated with the use of M-M-R II are those which have been reported following administration of the monovalent or combination vaccines.

Common

Burning and/or stinging of short duration at the injection site.

Occasional

Body as a whole: Fever (101°F [38.3°C] or higher).

Skin: Rash, or measles-like rash, usually minimal but may be generalised. Generally, fever, rash, or both appear between the 5th and the 12th day.

Rare

Body as a whole: Mild local reactions such as erythema, induration and tenderness; sore throat, malaise, atypical measles, syncope, irritability

Cardiovascular: Vasculitis

Digestive: Parotitis, nausea, vomiting, diarrhoea

Haematologic/Lymphatic: Regional lymphadenopathy, thrombocytopaenia, purpura

Hypersensitivity: Allergic reactions such as wheal and flare at injection site, anaphylaxis and anaphylactoid reactions, as well as related phenomena such as angioneurotic oedema (including peripheral or facial oedema) and bronchial spasm, urticaria in individuals with or without an allergic history

Musculoskeletal: Arthralgia and/or arthritis (usually transient and rarely chronic [see below]), myalgia

Nervous/Psychiatric: Febrile convulsions in children, afebrile convulsions or seizures, headache, dizziness, paresthesia, polyneuritis, polyneuropathy, Guillain-Barré syndrome, ataxia, acute disseminated encephalomyelitis (ADEM), transverse myelitis, aseptic meningitis (see below), measles inclusion body encephalitis (MIBE) (see Section 4.3 Contraindications), encephalitis/encephalopathy (see below)

Respiratory System: Pneumonia, pneumonitis (see Section 4.3 Contraindications), cough, rhinitis

Skin: Erythema multiforme, Stevens-Johnson syndrome, Henoch-Schőnlein purpura, Acute Haemorragic Oedema of Infancy, vesiculation at injection site, swelling, pruritus

Special senses: Forms of optic neuritis, including retrobulbar neuritis, papillitis, and retinitis; ocular palsies, otitis media, nerve deafness, conjunctivitis

Urogenital: Epididymitis, orchitis

Other: Death from various, and in some cases unknown, causes has been reported rarely following vaccination with measles, mumps, and rubella vaccines; however, a causal relationship has not been established in healthy individuals (see Section 4.3 Contraindications). No deaths or permanent sequelae were reported in a published post-marketing surveillance study in Finland involving 1.5 million children and adults who were vaccinated with M-M-R II during 1982 to 1993.

Arthralgia and/or arthritis: Arthralgia and/or arthritis (usually transient and rarely chronic), and polyneuritis are features of infection with wild-type rubella and vary in frequency and severity with age and sex, being greatest in adult females and least in prepubertal children.

Chronic arthritis has been associated with wild-type rubella infection and has been related to persistent virus and/or viral antigen isolated from body tissues. Only rarely have vaccine recipients developed chronic joint symptoms.

Following vaccination in children, reactions in joints are uncommon and generally of brief duration. In women, incidence rates for arthritis and arthralgia are generally higher than those seen in children (children: 0-3%; women: 12-20%), and the reactions tend to be more marked and of longer duration. Symptoms may persist for a matter of months or on rare occasions for years. In adolescent girls, the reactions appear to be intermediate in incidence between those seen in children and in adult women. Even in older women (35 to 45 years), these reactions are generally well tolerated and rarely interfere with normal activities.

Subacute Sclerosing Panencephalitis (SSPE): There have been reports of subacute sclerosing panencephalitis (SSPE) in children who did not have a history of infection with wild-type measles but did receive measles vaccine. Some of these cases may have resulted from unrecognised measles in the first year of life or possibly from the measles vaccination. Based on estimated nationwide measles vaccine distribution, the association of SSPE cases to measles vaccination is about one case per million vaccine doses distributed. This is far less than the association with infection with wild-type measles, 6-22 cases of SSPE per million cases of measles. The results of a retrospective case-controlled study conducted by the

Centres for Disease Control and Prevention suggest that the overall effect of measles vaccine has been to protect against SSPE by preventing measles with its inherent higher risk of SSPE.

Aseptic meningitis: Cases of aseptic meningitis have been reported following measles, mumps, and rubella vaccination. Although a causal relationship between the Urabe strain of mumps vaccine and aseptic meningitis has been shown, there is no evidence to link Jeryl Lynn™ mumps vaccine to aseptic meningitis.

Encephalitis/encephalopathy: Encephalitis/encephalopathy have been reported approximately once for every 3 million doses of the measles, mumps, and rubella vaccine manufactured by Merck & Co., Inc. Since 1978, post-marketing surveillance indicates that serious adverse events such as encephalitis and encephalopathy continue to be rarely reported. The risk of such serious neurological disorders following live measles virus vaccine administration remains far less than that for encephalitis and encephalopathy with wild type measles (one per one thousand reported cases).

In severely immunocompromised individuals inadvertently vaccinated with measles-containing vaccine, measles inclusion body encephalitis, pneumonitis, and fatal outcome as a direct consequence of disseminated measles vaccine virus infection have been reported (see Section 4.3 Contraindications); disseminated mumps and rubella vaccine virus infection have also been reported.

Panniculitis: Panniculitis has been reported rarely following administration of measles vaccine.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare professionals are asked to report any suspected adverse reactions https://nzphvc.otago.ac.nz/reporting/.

4.9 Overdose

Overdose has been reported rarely and was not associated with any serious adverse events.

For advice on the management of overdose please contact the National Poisons Centre on 0800 POISON (0800 764766).

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Viral vaccine, ATC code J07BD52.

Mechanism of action

M-M-R II is a live virus vaccine for vaccination against measles (rubeola), mumps and rubella (German Measles).

See Section 5.1 Pharmacodynamic properties, *Clinical efficacy and safety*

Clinical efficacy and safety

Measles, mumps, and rubella are three common childhood diseases, caused by measles virus, mumps virus (paramyxoviruses), and rubella virus (togavirus), respectively, that may be associated with serious complications and/or death. For example, pneumonia and encephalitis are caused by measles. Mumps is associated with aseptic meningitis, deafness and orchitis; and rubella during pregnancy may cause congenital rubella syndrome in the infants of infected mothers.

Clinical studies of 284 triple seronegative children, 11 months to 7 years of age, demonstrated that M-M-R II is highly immunogenic and generally well tolerated. In these studies, a single

injection of the vaccine induced measles haemagglutination-inhibition (HI) antibodies in 95 percent, mumps neutralising antibodies in 96 percent, and rubella HI antibodies in 99 percent of susceptible persons. However, a small percentage (1-5%) of vaccinees may fail to seroconvert after the primary dose.

A study of 6-month-old and 15-month-old infants born to vaccine-immunized mothers demonstrated that, following vaccination with ATTENUVAX, 74% of the 6-month-old infants developed detectable neutralizing antibody (NT) titers while 100% of the 15-month-old infants developed NT. This rate of seroconversion is higher than that previously reported for 6-month-old infants born to naturally immune mothers tested by HI assay. When the 6-month-old infants of immunized mothers were revaccinated at 15 months, they developed antibody titers equivalent to the 15-month-old vaccinees. The lower seroconversion rate in 6-month-olds has two possible explanations: 1) Due to the limit of the detection level of the assays (NT and enzyme immunoassay [EIA]), the presence of trace amounts of undetectable maternal antibody might interfere with the seroconversion of infants; or 2) the immune system of 6-month-olds is not always capable of mounting a response to measles vaccine as measured by the two antibody assays.

Efficacy of measles, mumps, and rubella vaccines was established in a series of double-blind controlled field trials which demonstrated a high degree of protective efficacy afforded by the individual vaccine components. These studies also established that seroconversion in response to vaccination against measles, mumps, and rubella paralleled protection from these diseases.

Following vaccination, antibodies associated with protection can be measured by neutralization assays, HI, or ELISA (enzyme linked immunosorbent assay) tests. Neutralizing and ELISA antibodies to measles, mumps, and rubella viruses are still detectable in most individuals 11 to 13 years after primary vaccination.

5.2 Pharmacokinetic properties

Not applicable.

5.3 Preclinical safety data

Animal Toxicity

Animal reproduction studies have not been conducted with M-M-R II. M-M-R II has not been evaluated for carcinogenic or mutagenic potential.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Dibasic potassium phosphate
Dibasic sodium phosphate
Monobasic potassium phosphate
Monobasic sodium phosphate
Monosodium glutamate monohydrate
Phenolsulfonphthalein
Sodium bicarbonate
Sorbitol
Sucrose
Hydrolysed gelatin
Neomycin
Other buffer and media ingredients

6.2 Incompatibilities

In the absence of compatibility studies, this medicine must not be mixed with other medicines. Please refer to Section 4.5 Interactions with other medicines and other forms of interactions for further information.

6.3 Shelf life

Prior to reconstitution the vaccine has a shelf life of 24 months when stored at 2°C to 8°C and protected from light.

It is recommended that the vaccine be used as soon as possible after reconstitution. Store reconstituted vaccine in the vaccine vial in a dark place at 2°C to 8°C (36°F to 46°F) and discard if not used within 8 hours.

6.4 Special precautions for storage

To maintain potency, M-M-R II must be stored between -50°C and +8°C (-58°F to +46°F). Use of dry ice may subject M-M-R II to temperatures colder than -50°C (-58°F). Protect the vaccine from light at all times, since such exposure may inactivate the viruses.

Before reconstitution, store the lyophilised vaccine at 2°C to 8°C (36°F to 46°F). The diluent may be stored in the refrigerator with the lyophilised vaccine or separately at room temperature. **Do not freeze the diluent.**

Combination pack containing lyophilised vaccine and diluent together should be stored at 2°C to 8°C (36°F to 46°F).

For storage conditions after reconstitution of the medicine, see Section 6.3.

6.5 Nature and contents of container

M-M-R II is supplied as a single dose vial of lyophilised vaccine and a vial of diluent or a box of ten single-dose vials of lyophilised vaccine, together with a box of ten diluent-containing vials.

6.6 Special precautions for disposal

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

7 MEDICINE SCHEDULE

Prescription Medicine

8 SPONSOR

Merck Sharp & Dohme (New Zealand) Limited
P O Box 99 851
Newmarket
Auckland 1149
New Zealand
Tel: 0800 500 673

9 DATE OF FIRST APPROVAL

17 May 1990

10 DATE OF REVISION OF THE TEXT

06 November 2020

SUMMARY TABLE OF CHANGES

Section Changed	Summary of new information
4.2, 4.3, 4.6	Revision to text to reduce the waiting period for pregnancy from 3 months to 1 month
4.4	Addition of time frame for the tuberculin skin testing
4.6	Updated post-approval pregnancy data

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