M-M-RvaxPro®
Measles, mumps, and rubella vaccine (live)

PRESCRIBING INFORMATION
Refer to Summary of Product Characteristics before prescribing

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. Adverse events should also be reported to MSD, UK (Tel: 0208 1548000).
By clicking the above link you will leave the MSD website and be taken to the MHRA website.

PRESENTATION
Vial of powder and pre-filled syringe of solvent for suspension for injection. Each 0.5 mL dose contains live, attenuated Measles virus (Enders' Edmonston strain) not less than $1x10^3$ $TCID_{50}$, Mumps virus (Jeryl Lynn™ Level B strain) not less than $12.5x10^3$ $TCID_{50}$ and Rubella virus (Wistar RA 27/3 strain) not less than $1x10^3$ $TCID_{50}$.

USES
Simultaneous vaccination against measles, mumps and rubella in individuals from 12 months of age. Can be administered to infants from 9 months of age under special circumstances. For use in measles outbreaks, or for post-exposure vaccination, or, for use in previously unvaccinated individuals older than 9 months who are in contact with susceptible pregnant women, and persons likely to be susceptible to mumps and rubella. Use on the basis of official recommendations.

DOSAGE AND ADMINISTRATION
Individuals 12 months of age or older: one dose at an elected date. If non-response to first dose, a second dose may be administered at least 4 weeks after the first dose.
Infants between 9 and 12 months of age: administer in accordance with official recommendations or when an early protection is considered necessary. Revaccinate at 12 to 15 months of age. Consider a further dose of a measles–containing vaccine according to official recommendations. Inject intramuscularly or subcutaneously. Do not inject intravascularly. Administer subcutaneously in patients with thrombocytopenia or any coagulation disorder.

CONTRA-INDICATIONS
Temperature may be elevated temporarily post vaccination. Therefore postpone vaccination if temperature above 38.5°C. Pregnancy. Avoid pregnancy for 1-month post-vaccination. Hypersensitivity to any measles, mumps, or rubella vaccine, or to any of the excipients, including neomycin. Active, untreated tuberculosis. Blood dyscrasias, leukaemia, lymphomas of any type, or other malignant neoplasms affecting the haematopoietic and lymphatic systems. Current immunosuppressive therapy (including high doses of corticosteroids). Not contraindicated in individuals who are receiving topical or low dose parenteral corticosteroids (e.g. for asthma prophylaxis or replacement therapy). Severe humoral or cellular (primary or acquired) immunodeficiency, e.g. severe combined immunodeficiency, agammaglobulinemia and AIDS or symptomatic HIV infection or an age-specific CD4+ T-lymphocyte percentage in children below 12 months: CD4+ <25%; children between 12-35 months: CD4+ < 20%; children between 36-59 months: CD4+ < 15%. Family history of congenital or hereditary immunodeficiency unless immune competence of potential vaccine recipient is demonstrated.

PRECAUTIONS
Always ensure appropriate medical treatment is available in case of anaphylaxis. Adults and adolescents with a history of allergies may potentially be at increased risk of anaphylaxis or anaphylactoid reactions and should always be closely monitored post vaccination. Chick embryo culture and recombinant human albumin are used during vaccine manufacture. Caution in those with a history of anaphylactic or anaphylactoid reaction to eggs or hypersensitivity to recombinant human albumin. Caution should be exercised in those with an individual or family history of convulsions or a history of cerebral injury. Vaccination may be considered in patients with selected immune deficiencies where the benefits outweigh the risks (asymptomatic HIV patients, IgG subclass deficiencies, congenital neutropenia, chronic granulomatous disease, and complement deficiency diseases). Immunocompromised patients who have no contraindication for this

vaccination may not respond as well as immunocompetent patients. Monitor carefully for signs of measles, parotitis, and rubella. Infants aged 9-12 months may fail to respond due to the presence of circulating maternal antibodies and/or immaturity of the immune system. Individuals who experienced thrombocytopenia with the first dose of M-M-RvaxPro (or its component vaccines) may develop severe thrombocytopenia with repeat doses. Serologic status may be evaluated to determine whether or not additional doses of vaccine are needed. Caution should be exercised when administered to lactating women. This vaccine contains sorbitol and may have an additive effect with other concomitantly administered products containing sorbitol (or fructose). Do not give concomitantly with Immuno Globulin. Vaccination should be deferred for at least 3 months following blood or plasma transfusions, or administration of human immune serum globulin. M-M-RvaxPro should be given concomitantly at separate injection sites, or one month before or after administration of other live virus vaccines.

SIDE EFFECTS

Refer to Summary of Product Characteristics for complete information on side-effects.

Very common: fever (38.5°C or higher), injection site erythema, injection site pain, injection site swelling. *Common:* injection site bruising, rash morbilliform or other rash. Other reported side effects that may potentially be serious include: aseptic meningitis, thrombocytopenia, anaphylaxis and anaphylactoid reactions, angioneurotic oedema, bronchial spasm, pneumonia, afebrile convulsions or seizures, ataxia, encephalitis, encephalopathy, febrile convulsion (in children), polyneuritis, polyneuropathy, Guillain-Barré syndrome, measles inclusion body encephalitis, optic neuritis, retrobulbar neuritis, ocular palsies, retinitis, subacute sclerosing panencephalitis, epididymitis, orchitis, parotitis, vasculitis, Stevens-Johnson syndrome, urticaria, nerve deafness, arthritis, arthralgia and myalgia.

PACKAGE QUANTITIES AND BASIC NHS COST

Pack containing one single dose vial (powder) and one single dose 0.5 millilitre pre-filled syringe (solvent) with two unattached needles: £11.00

Marketing Authorisation number:
Great Britain: PLGB 53095/0041
UK (Northern Ireland): EU/1/06/337/011

Marketing Authorisation Holder:
GB: Merck Sharp & Dohme (UK) Ltd, 120 Moorgate, London EC2M 6UR, United Kingdom
UK(NI):
Merck Sharp & Dohme B.V., Waarderweg 39, 2031 BN Haarlem, The Netherlands

Legal Category: POM

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