Applicant: MSD (Pty) Ltd
APPROVED PATIENT INFORMATION LEAFLET
OMZYTA Powder and Solvent for Suspension for Injection

SCHEDULING STATUS

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1 NAME OF THE MEDICINE

OMZYTA® Powder and Solvent for Suspension for Injection

(Measles, Mumps and Rubella Virus Vaccine Live)

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

When reconstituted as directed, the dose for injection is approximately 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.

3 PHARMACEUTICAL FORM

Powder

Before reconstitution, the lyophilised vaccine is a light yellow compact crystalline plug.

Reconstituted solution

OMZYTA, when reconstituted, is a clear yellow solution.

Diluent

Clear, colourless liquid

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

OMZYTA is indicated for simultaneous vaccination against measles, mumps and rubella in individuals 12 months of age or older (see section 4.2).

There is some evidence to suggest that infants who are born to mothers who had wild type measles and who are vaccinated at < 1 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 < 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 < 12 months of age should be revaccinated after reaching 12 to 15 months of age.

4.2 Posology and method of administration

Posology

The dose for any age is approximately 0,5 mL administered intramuscularly or 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 < 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 OMZYTA 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). Vaccinating susceptible post-pubertal 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 1 month after vaccination and should be informed of the reasons for this precaution (see section 4.6).

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 healthcare 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.

Post-pubertal 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).

Post-partum Women

It has been found convenient in many instances to vaccinate rubella susceptible women in the immediate postpartum period (see section 4.6).

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 OMZYTA) 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, OMZYTA is preferred for persons likely to be susceptible to mumps and rubella; and if monovalent measles vaccine is not readily available, travellers should receive OMZYTA regardless of their immune status to mumps or rubella.

Vaccination has been recommended for susceptible individuals in high risk groups such as college students, healthcare 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.

Single Dose Vial

If the prevention of sporadic measles outbreaks is the sole objective, revaccination with a measles containing vaccine should be considered (see appropriate product professional information). If concern also exists about immune status regarding mumps or rubella, revaccination with appropriate mumps or rubella containing vaccine should be considered after consulting the appropriate product professional information.

First withdraw the entire volume of diluent into the syringe to be used for reconstitution (if a pre-filled syringe is available, this step is not necessary). 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 intramuscularly or 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.

Method of Administration

FOR INTRAMUSCULAR OR SUBCUTANEOUS ADMINISTRATION. Do not inject intravascularly.

Do not give immune globulin (IG) concurrently with OMZYTA (see section 4.5).

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

vaccine viruses.

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

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. OMZYTA, when reconstituted, is a clear yellow liquid.

4.3 Contraindications

Hypersensitivity to any component of the vaccine, including gelatin.

Do not give OMZYTA to pregnant females. If vaccination of post-pubertal females is undertaken, pregnancy should be avoided for one month following vaccination (see section 4.6).

Anaphylactic or anaphylactoid reactions to neomycin (each dose of reconstituted vaccine contains approximately 25 µg 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 and hypogammaglobulinemic and dysgammaglobulinemic 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

Precautions

General

Adequate treatment provisions, including epinephrine injection (1:1 000), should be available for immediate use should an anaphylactic or anaphylactoid reaction occur.

Due caution should be employed in administration of OMZYTA to persons with individual or family history 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).

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.

Thrombocytopenia

Individuals with current thrombocytopenia may develop more severe thrombocytopenia following vaccination. In addition, individuals who experienced thrombocytopenia following the first dose of OMZYTA (or its component vaccines) may develop thrombocytopenia 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).

Paediatric Use

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 < 12 months of age have not been established.

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).

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).

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 OMZYTA. 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 OMZYTA may not result in protection in 100 % of vaccinees.

4.5 Interaction with other medicinal products and other forms of interaction

Administration of immune globulins (IG) concurrently with OMZYTA 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

OMZYTA should be given one month before or after administration of other live viral vaccines.

OMZYTA 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 OMZYTA 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

The vaccine should not be administered to pregnant females; furthermore, pregnancy should be avoided for one month following vaccination (see section 4.3).

Wild-type rubella infection during pregnancy, especially in the first trimester, can lead to miscarriage, stillbirth or Congenital Rubella Syndrome (CRS). In an 18-year survey involving over 1 200 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 CRS. Subsequent post-marketing surveillance identified CRS associated with a rubella vaccine strain following inadvertent vaccination of a pregnant female with a measles, mumps and rubella vaccine.

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.

Breastfeeding

It is not known whether measles or mumps vaccine virus is secreted in human milk. Recent studies have shown that lactating post-partum women immunised with live attenuated rubella vaccine may secrete the virus in breast milk and transmit it to breastfed infants. In the infants with serological evidence of rubella infection, none exhibited severe disease; however, one exhibited mild clinical illness typical of acquired rubella. Caution should be exercised when OMZYTA is administered to a nursing woman.

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. OMZYTA is expected to have no or negligible influence on ability to drive and use machines.

4.8 Undesirable effects

Adverse reactions are ranked under headings of frequency using the following convention:

Very common (≥1/10), Common (≥1/100 to <1/10), Uncommon (≥1/1 000 to <1/100), Frequency not known (frequency cannot be estimated for post-marketing data)

Infections and infestations

Uncommon: nasopharyngitis, upper respiratory tract infection or viral infection

Frequency not known: aseptic meningitis, atypical measles, epididymitis, orchitis, otitis media, parotitis, rhinitis, subacute sclerosing panencephalitis

Blood and lymphatic disorders

Frequency not known: regional lymphadenopathy, thrombocytopenia

Immune system disorders

Frequency not known: anaphylactoid reaction, anaphylaxis and related phenomenon such as angioneurotic oedema, facial oedema and peripheral oedema

Psychiatric disorders

Frequency not known: irritability

Nervous system disorders

Frequency not known: acute disseminated encephalomyelitis (ADEM), afebrile convulsions or seizures, aseptic meningitis, ataxia, dizziness, encephalitis, encephalopathy, febrile convulsion (in children), Guillain- Barre syndrome, headache, Measles inclusion body encephalitis (MIBE), ocular palsies, optic neuritis, paraesthesia, polyneuritis, polyneuropathy, retrobulbar neuritis, transverse myelitis, syncope

Eye disorders

Frequency not known: conjunctivitis, retinitis

Ear and labyrinth disorders

Frequency not known: nerve deafness

Respiratory, thoracic and mediastinal disorders

Uncommon: rhinorrhoea

Frequency not known: bronchial spasm, cough, pneumonia, pneumonitis, sore throat

Gastrointestinal disorders

Uncommon: diarrhoea, vomiting

Frequency not known: nausea

Skin and subcutaneous tissue disorders

Common: rash morbiliform or other rash

Uncommon: urticaria

Frequency not known: panniculitis, purpura, skin induration, Stevens-Johnson syndrome, Henoch-Schönlein purpura, acute haemorrhagic oedema of infancy, pruritus, skin granuloma associated with vaccine derived rubella virus

Musculoskeletal, connective tissue and bone disorders

Frequency not known: arthritis and/or arthralgia (usually transient and rarely chronic), myalgia

General disorders and administration site conditions

Very common: fever ≥ 38,5 °C, injection site erythema, injection site pain and injection site swelling

Common: injection site bruising

Uncommon: injection site rash

Frequency not known: burning and/or stinging of short duration at the injection site, malaise,

papillitis, peripheral oedema, swelling, tenderness, vesicles at the injection site, wheal and flare at the injection site

Vascular disorders

Frequency not known: vasculitis.

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 pre-pubertal 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 to 3 %; women: 12 to 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 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 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 to 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 Sharp & Dohme LLC, Rahway, NJ 07065, USA. 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); disseminated mumps and rubella vaccine virus infection have also been reported.

Panniculitis

Panniculitis has been reported rarely following administration of measles vaccine.

In a clinical trial, 752 children received OMZYTA, either intramuscularly (n=374) or subcutaneously (n=378). The general safety profiles of the intramuscular and subcutaneous administration routes were comparable; however, fewer subjects experienced injection site adverse reactions in the intramuscular group.

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 providers are requested to report any suspected adverse drug reactions to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.

4.9 Overdose

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

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

A.30.1 Antibodies

Pharmacological action

OMZYTA is a sterile lyophilised preparation of (1) a more attenuated line of measles virus, derived from Enders' attenuated Edmonston strain and propagated in chick embryo cell culture; (2) the Jeryl Lynn™ (B level) strain of mumps virus propagated in chick embryo cell culture; and (3) the Wistar RA 27/3 strain of live attenuated rubella virus propagated in WI 38 human diploid lung fibroblasts.

Pharmacodynamic properties

Evaluation of immunogenicity and clinical efficacy

Clinical studies of 284 triple seronegative children, 11 months to 7 years of age, demonstrated that subcutaneously administered OMZYTA is highly immunogenic and generally well tolerated. In these studies, a single subcutaneous injection of the vaccine induced measles hemagglutination inhibition (HI) antibodies in 95 %, mumps neutralising antibodies in 96 % and rubella HI antibodies in 99 % of susceptible persons. However, a small percentage (1 to 5 %) of vaccinees may fail to seroconvert after the primary dose.

Clinical Studies

A study of 6-month-old and 15-month-old infants born to vaccine-immunised mothers demonstrated that, following vaccination subcutaneously with ATTENUVAX (Measles Virus Vaccine Live), 74 % of the 6-month-old infants developed detectable neutralising antibody (NT) titres 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 immunised mothers were revaccinated at 15 months, they developed antibody titres 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 neutralisation assays, HI or ELISA (enzyme linked immunosorbent assay) tests. Neutralising and ELISA antibodies to measles, mumps and rubella viruses are still detectable in most individuals 11 to 13 years after primary vaccination.

In an open label clinical trial 752 children 12 through 18 months of age received OMZYTA either intramuscularly (n=374) or subcutaneously (n=378), concomitantly with ONVARA. Antibody responses to measles, mumps and rubella viruses were measured by ELISAs using sera obtained 6 weeks post-vaccination. For anti-measles virus, anti-mumps virus and anti-rubella virus, seroresponse rates were defined as the percentage of children seronegative at baseline who achieved antibody titres above the respective seroresponse threshold for each assay 6 weeks post-vaccination. Seroresponse thresholds were defined as 255 mIU/mL, 10 EU/mL, and 10 IU/mL for anti-measles virus, anti-mumps virus and anti-rubella virus antibodies, respectively. For each vaccine antigen at least 89 % of enrolled children were seronegative at baseline. Seroresponse rates to measles, mumps and rubella viruses were noninferior for the intramuscular group compared to the subcutaneous group (the lower bound of the 95 % confidence interval for the difference in seroresponse rates [intramuscular group minus subcutaneous group] was < 10 %). The point estimates of the proportions of children achieving antibody titres above the seroresponse thresholds for measles, mumps and rubella viruses were as follows: 94,3 %, 97,7 % and 98,1 %, respectively, in the intramuscular group and 96,1 %, 98,1 % and 98,1 %, respectively, in the subcutaneous group.

5.2 Pharmacokinetic properties

Not applicable.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sorbitol, sodium phosphate, sucrose, hydrolysed gelatin, recombinant human albumin, foetal

bovine serum, other buffer and media ingredients and approximately 25 µg of neomycin.

The product contains no preservative.

Diluent: Water for injection.

6.2 Incompatibilities

In the absence of compatibility studies, the vaccine must not be mixed with other medicinal products.

6.3 Shelf-life

2 years.

After reconstitution, the vaccine should be used immediately; however, in-use stability has been demonstrated for 8 hours when refrigerated at 2 to 8 °C.

6.4 Special precautions for storage

To maintain potency, OMZYTA must be stored between -50 °C and +8 °C. Use of dry ice may always subject OMZYTA to temperatures colder than -50 °C. Protect the vaccine from light, since such exposure may inactivate the viruses.

Before reconstitution, store the lyophilised vaccine in a refrigerator at 2 to 8 °C. The diluent (pre-filled syringe or vial) should 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 to 8

°C.

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 to 8 °C and discard if not used within 8 hours.

6.5 Nature and contents of container

Vial Powder

3 mL clear Type 1 borosilicate glass vial with a grey stopper (butyl rubber) and a blue plastic cap.

Sterile Diluent Vial

0,7 mL water for injection in a 3 mL glass vial with grey rubber stopper and dark grey plastic flip-off cap.

Carton

3 mL vial of OMZYTA and 3 mL vial of DILUENT are packed together in a cardboard carton with the professional information and patient information leaflet.

Pack sizes of 1 or 10 vials.

Not all pack sizes may be marketed.

7 HOLDER OF CERTIFICATE OF REGISTRATION

MSD (Pty) Ltd

117 16th Road

Halfway House

1685

South Africa

8 REGISTRATION NUMBER

50/30.2/0576

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

29 September 2017

10 DATE OF REVISION OF THE TEXT

26 January 2026