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

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

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OMZYTA® Powder and Solvent for Suspension for Injection

(Measles, Mumps and Rubella Virus Vaccine Live)

Read all of this leaflet carefully, before you are given OMZYTA.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or healthcare provider.
- OMZYTA been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.
- OMZYTA is not for self-medication and must be administered by a healthcare professional.

What is in this leaflet

1. What OMZYTA is and what it is used for
2. What you need to know before you use OMZYTA
3. How to use OMZYTA
4. Possible side effects
5. How to store OMZYTA
6. Contents of the pack and other information

1. What OMZYTA is and what it is used for

Your doctor has recommended or administered OMZYTA to help protect you or your child against measles, mumps and rubella.

The vaccine can be administered to persons 12 months of age or older. A second dose of the vaccine is recommended at a later date which will be decided by your doctor.

2. What you need to know before you are given OMZYTA

You should not be given OMZYTA if you:

- are allergic to any of its components (including neomycin).
- are pregnant (in addition, pregnancy should be avoided for 1 to 3 months after vaccination).
- have a fever.
- have active untreated tuberculosis.
- are taking medications to suppress their immune system (other than corticosteroid replacement).
- have a blood disorder or any type of cancer that affects their immune system.
- have an immune deficiency as a result of a disease or a treatment.

Warnings and precautions

Tell the doctor about any medical problems your child has or has had, and about any allergies (especially to neomycin).

Tell the doctor if your child has a history of convulsions or a brain injury, a low blood platelet count, or have received blood or plasma transfusions or administration of human serum globulin within the last 3 months.

Children

OMZYTA should be used in children 12 months of age or older. However, your doctor may recommend that OMZYTA be given to infants between 6 to 12 months of age in special situations.

Other medicines and OMZYTA

Always tell your healthcare provider if you are taking other medicines. (This includes complementary or traditional medicines.)

Can my child be vaccinated with OMZYTA and other vaccines at the same time?

OMZYTA should be given one month before or after administration of other vaccines. However, other schedules have been used. Your doctor will decide the vaccination schedule.

Pregnancy and breastfeeding

Use in pregnancy

OMZYTA should not be administered to pregnant women. Women of child-bearing age should take the necessary precautions to avoid pregnancy for 1 month following vaccination.

Use in breastfeeding

Tell the doctor if the vaccine recipient is breastfeeding or intends to breastfeed. Your doctor will decide if OMZYTA should be given.

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking this medicine.

Driving and using machinery

The use of OMZYTA generally does not interfere with the ability to drive or operate machinery.

OMZYTA contains neomycin as an inactive ingredient. Tell the doctor if you or your child has ever had an allergic reaction to this ingredient.

3. How to use OMZYTA

Do not share medicines prescribed for you with any other person.

OMZYTA is given by injection as follows:

- OMZYTA is given to persons 12 months of age or older. The dose of the vaccine is the same for everyone.
- For children vaccinated at 12 to 15 months of age or older, a second dose is recommended at the time of primary school entry (4 to 6 years of age).
- Children first vaccinated at less than 12 months of age should receive a second dose at 15 months of age followed by revaccination at the time of primary school entry (4 to 6 years of age).

- Non-pregnant adolescent and adult females of childbearing age who are susceptible to rubella can be vaccinated with OMZYTA (or live attenuated rubella virus vaccine) if certain precautions are observed (see **Pregnancy and breastfeeding**). It has been found convenient in many instances to vaccinate women who are susceptible to rubella in the immediate post-partum period (see **Pregnancy and breastfeeding**).

If you use more OMZYTA than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, seek help at the nearest hospital or poison control centre.

Since a healthcare professional will administer this medicine, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

If you missed a dose of OMZYTA

Your doctor will decide when to give the missed dose.

4. Possible side effects

OMZYTA can have side effects.

Not all side effects reported for OMZYTA are included in this leaflet. Should your child's general health worsen or if you experience any untoward effects after been given this medicine, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing
- rash or itching
- fainting
- yellowing of the skin and eyes, also called jaundice.

These are all very serious side effects. If you have them, you have had a serious allergic reaction to OMZYTA. You may need urgent medical attention or hospitalisation.

The most common is burning and/or stinging at the injection site for a short time. Transient joint pain and/or swelling have occurred more frequently in adult females; sometimes these symptoms may be chronic. Occasionally, fever and rash may occur. Rarely, unusual bleeding or bruising under the skin and swelling of the testicles, and skin granuloma (clumps of inflammatory cells) may occur.

Other side effects may also occur rarely and some of these may be serious. These include allergic reactions, seizures and inflammation of the nervous system (brain and/or spinal cord).

Like all vaccines and medicines, this vaccine can cause side effects, although not everybody gets them.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you

notice any of the following:

The following side effects were reported with the use of OMZYTA:

Very common (may affect more than 1 in 10 vaccinees)

- fever (38,5 °C or higher)
- injection site redness; injection site pain; injection site swelling.

Common (may affect 1 to 10 in 100 vaccinees)

- rash (including measles-like rash)
- injection site bruising.

Uncommon (may affect 1 to 10 in 1 000 vaccinees)

- nasal congestion and sore throat; upper respiratory tract infection or viral infection; runny nose
- diarrhoea, vomiting
- hives
- injection site rash.

Frequency not known (Frequency cannot be estimated from the available data)*

- aseptic meningitis (fever, feeling sick, vomiting, headache, stiff neck and sensitivity to light); swollen testicles; infection of the middle ear; inflamed salivary glands; atypical measles (described in patients who received a killed measles virus vaccine, usually given before 1975)
- swollen lymph nodes
- bruising or bleeding more easily than normal
- severe allergic reaction that may include difficulty in breathing, facial swelling, localised swelling and swelling of the limbs

- irritability
- seizures (fits) without fever; seizures (fits) with fever in children; walking unsteadily; dizziness; illnesses involving inflammation of the nervous system (brain and/or spinal cord)
- an illness consisting of muscle weakness, abnormal sensations, tingling in the arms, legs and upper body (Guillain-Barré syndrome)
- headache; fainting; nerve disorders which can cause weakness, tingling or numbness; eye nerve disturbances
- discharge and itching of the eyes with crusting of eyelids (conjunctivitis)
- inflammation of the retina (in the eye) with changes in sight
- deafness
- cough; lung infection with or without fever
- feeling sick (nausea)
- itching; inflammation of the fatty tissue under the skin; red or purple, flat, pinhead spots under the skin; hardened, raised area of the skin; serious illness with ulcers or blistering of the skin, mouth, eyes and/or genitals (Stevens-Johnson syndrome)
- joint pain and/or swelling (usually transient and rarely chronic); muscle pain
- burning and/or stinging of short duration at the injection site; blisters and/or hives at the injection site
- generally feeling unwell (malaise); swelling; soreness
- inflammation of blood vessels.

*These side effects were reported with the use of OMZYTA or with the measles, mumps and rubella vaccine manufactured by Merck Sharp & Dohme LLC, Rahway, NJ 07065, USA, or with its monovalent (single) components, during post-marketing use and/or during clinical studies.

Tell the doctor promptly about any of these or any other unusual symptoms. If the condition persists or worsens, seek medical attention.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of OMZYTA.

5. How to store OMZYTA

Store all medicines out of the reach of children.

Store at 2 to 8 °C (in a refrigerator). The diluent may be stored in the refrigerator with the lyophilised vaccine or separately at room temperature**. Do not freeze the diluent.**

Keep vial in the outer carton to protect from light.

After reconstitution, the vaccine should be used immediately. **Discard the vaccine if it is not used within 30 minutes after its preparation.**

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. Contents of the pack and other information

What OMZYTA contains

OMZYTA (measles, mumps and rubella virus vaccine live) is an injectable live virus vaccine to help prevent measles, mumps and rubella.

Inactive ingredients: Powder: 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.

What OMZYTA looks like and contents of the pack

Before reconstitution: the lyophilised powder is a light yellow compact crystalline plug.

After reconstitution: a clear yellow solution.

Diluent: clear, colourless liquid.

OMZYTA is packed in a 3 mL glass vial (with a grey rubber stopper and a blue plastic cap) containing powder together with a sterile vial with water for injection packed in a cardboard carton together with a professional information and patient information leaflet.

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

Pack sizes: 1 or 10 vials.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

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