APPROVED PATIENT INFORMATION LEAFLET

Measles Rubella Cipla

Measles and Rubella Vaccine Live, Attenuated (Freeze-Dried)

This vaccine is Not for self-administration and should be administered by a Health Care Professional

SCHEDULING STATUS

S2

Measles Rubella Cipla Powder and diluent for solution for injection

Measles and rubella vaccine (live)

Each dose contains 25 mg of sorbitol.

Read all of this leaflet carefully because it contains important information for you.

Measles Rubella Cipla is available without a doctor's prescription, to prevent infection by measles and rubella viruses.

Read all of this leaflet carefully before you start using Measles Rubella Cipla

- Keep this leaflet. You may need to read it again
- If you have any further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.

What is in this leaflet

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

1. What Measles Rubella Cipla is and what it is used for

Measles Rubella Cipla is a vaccine used to prevent measles and rubella infection.

Measles Rubella Cipla is a vaccine containing live weakened measles and rubella viruses.

When you are given the vaccine, it triggers the body's immune system (the body's natural defences) to make antibodies that help to protect against infections caused by the measles and rubella viruses in the future.

Measles Rubella Cipla can be administered to infants and children 9 months of age or older, adolescents and young adults at risk.

Measles Rubella Cipla is also used in susceptible non-pregnant adolescents and adult females of childbearing age to protect against rubella, if certain precautions are observed.

2. What you need to know before you are vaccinated with Measles Rubella Cipla.

Do not take Measles Rubella Cipla:

- If you or your child are hypersensitive (allergic) to measles and /or rubella or any of the ingredients of this vaccine, including gelatin
- If you or your child are allergic to neomycin, which is an antibiotic see **section 6**
- If you or your child experienced a severe reaction to a previous dose of this vaccine or other measles or rubella containing vaccines
- If you or your child are allergic to cow's milk
- If you are pregnant or plan to get pregnant within the next three months (in addition, pregnancy should be avoided for one month after vaccination, see Pregnancy)
- If you or your child have a poor or weakened immune system for any reason, such as illness or medical treatments
- If you or your child have untreated, active TB.

Warnings and precautions

Talk to your doctor or health care provider before being given the vaccine.

Special care should be taken before being vaccinated with Measles Rubella Cipla. Please inform your healthcare provider:

- If you or your child have a history or family history of allergies or
- If you or your child had a side effect after previous vaccination with measles or rubella containing vaccine that involved easy bruising or bleeding for longer than usual
- If you or your child have infection with Human Immunodeficiency Virus (HIV)
- If you or your child have or have had any medical problem
- If you or your child have received blood or plasma transfusions or human serum globulin in the past 3 months.

Other medicines with Measles Rubella Cipla:

Always tell your health care provider if you or your child are taking any other medicine, including complementary, herbal or traditional medicines as these medicines may affect the immune response to **Measles Rubella Cipla**.

The doctor may delay vaccination for at least 3 months following plasma or blood transfusions, or immunoglobulin (known as IG). After vaccination with Measles Rubella Cipla, IG should not be given for one month, unless your doctor tells you otherwise.

Measles Rubella Cipla may be given with some routine childhood vaccines such as DTP, DT, TT, Td, BCG, Polio vaccine (OPV and IPV), *Haemophilus influenzae* type b, Hepatitis B, Yellow fever vaccine and vitamin A supplementation.

Pregnancy, breast-feeding and fertility

Measles Rubella Cipla should not be given to pregnant females. Females of child-bearing age should take the necessary precautions to avoid pregnancy for one month, or according to doctor's recommendation, after they have been given the vaccine.

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please

consult your doctor, pharmacist or other healthcare provider for advice before being given this vaccine.

Driving and using machinery

The ability of Measles Rubella Cipla to affect driving and use of machines is not known.

Measles Rubella Cipla contains sorbitol.

If you have been told by your doctor that you or your child have an intolerance to some sugars, talk to your doctor before you or your child receive this vaccine.

3. How to take Measles Rubella Cipla

You will not be expected to give yourself Measles Rubella Cipla injection.

It will be given to you by a person who is qualified to do so. Measles Rubella Cipla should be injected into the fatty tissues just beneath the skin either in the area of the outer thigh in infants or upper arm in older children and adults.

Measles Rubella Cipla is given as follows

The dose of the vaccine is the same for everyone, being 0,5 mL of the reconstituted vaccine.

If your child gets the vaccination when he or she is less than one year old, a second dose should be given when they are 15 to 18 months old. If your child gets the vaccination when he or she is one year or older, a second dose is recommended. Often the second dose is given right before the child starts school (4 to 6 years of age).

Non-pregnant adolescent and adult females of childbearing age who are susceptible to rubella can be vaccinated with Measles Rubella Cipla (or a live weakened rubella virus vaccine) if certain precautions are taken.

If you are administered more Measles Rubella Cipla vaccine than you should:

Since a health care provider will administer this vaccine, he/she will control the dosage. However, in the event of over-dosage your doctor will manage the situation. Your symptoms will be monitored, and you will be given medical support accordingly.

If a dose of Measles Rubella Cipla is missed

If a scheduled dose is missed, talk to your healthcare provider and arrange another visit as soon as possible.

4. Possible side effects

Measles Rubella Cipla can have side effects.

Not all side effects reported for Measles Rubella Cipla are included in this leaflet. Should your general health worsen or if you experience any untoward effects after having been vaccinated with Measles Rubella Cipla, please consult your health care provider.

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

- severe allergic reaction that may include difficulty in breathing, facial swelling, localised swelling, and swelling of the limbs
- hives, itching and rash
- ainting.

Other side effects include: Tell your doctor if you notice any of the following:

Frequent side effects

- fever
- injection-site reactions such as redness, pain, swelling, tenderness, hardness, nodule formation
- rash;
- enlarged lymph nodes
- muscle pain, weakness, numbness
- red eyes
- coryza and cold, sore throat
- headache
- a general feeling of discomfort.

Less frequent side effects

- diarrhoea, vomiting
- cough
- seizures (fits) with or without fever, isolated reactions or illnesses involving inflammation of the nervous system (brain and/or spinal cord), fainting
- inflammation of the joints
- reduced platelet count which may cause bruising or bleeding more easily than normal
- deafness
- allergic reactions like hives, itching and allergic rash
- joint pain.

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, pharmacist or nurse. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reaction Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8 or by e-mail: drugsafetysa@cipla.com or telephone: 0860 22 6662 (toll free).

By reporting side effects, you can help provide more information on the safety of Measles Rubella Cipla**.**

5. How to store Measles Rubella Cipla

Vaccine: Store all medicines out of the reach of children.

Store at or between +2 °C to +8 °C (in a refrigerator). Protect from light.

Store in the original package.

Do not use after the expiry date stated on the label.

Diluent: Store at or below 30 °C. **Do Not Freeze**.

Once the vaccine has been mixed with the diluent supplied, it should be either used immediately or stored in the refrigerator, between +2 °C and +8 °C, protected from light and used within 6 hours.

Return all unused medicine to your pharmacist.

Do not throw away any vaccines via the drains or sewage systems (e.g. toilets).

Vaccine Vial Monitor

A vaccine vial monitor (VVM) contains a heat-sensitive material that is printed on the label to register cumulative heat exposure over time.

The healthcare provider will be able to read and know whether or not the vaccine has been exposed to too much heat and should be discarded.

6. Contents of the pack and other information

What Measles Rubella Cipla contains

The active substances are:

After reconstitution, 1 dose (0,5 mL) contains:

Measles virus[1] (Edmonston Zagreb strain) (live attenuated): not less than 1000 $CCID_{50}$[2]

Rubella virus[1] (Wistar RA 27/3 strain) (live attenuated): not less than 1000 $CCID_{50}$[2]

[1] produced in human diploid (MRC-5) cells.

[2] 50 % of a cell culture infectious dose.

The other ingredients are:

Powder: partially hydrolysed gelatin, sorbitol, L-histidine, L-alanine, tricine, L-arginine hydrochloride, lactalbumin hydolysate, minimum essential medium.

Diluent: Sterile Water For injection

What Measles Rubella Cipla looks like and contents of the pack

This product comprises both a powder and diluent for solution for injection.

This product comprises both a powder and diluent for solution for injection. The powder is a yellowish-white friable mass. The diluent is a clear, colourless liquid, and free from visible particulate matter.

The vaccine is available in single and 10 doses vials and pack size of 50's

The diluents are available in 0,5 mL (single dose) and 5 mL (10 doses) vials and pack sizes of 50's.

The diluents are pack in separate boxes from the vaccine.

Holder of Certificate of Registration

CIPLA MEDPRO (PTY) LTD.

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