1. **SCHEDULING STATUS**
2. S4
3.
4.
5. **ONVARA lyophilised powder and solvent for suspension for injection**
6. Active ingredient: Varicella Virus Vaccine Live
7.
8. **Read all of this leaflet carefully before you are given ONVARA.**
   - Keep this leaflet. You may need to read it again.
   - If you have further questions please ask your doctor, pharmacist, nurse or other health care provider.
   - ONVARA has 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.
9.
10. **What is in this leaflet**

11. 1. What ONVARA is and what it is used for
12. 2. What you need to know before you are given ONVARA
13. 3. How to take ONVARA
14. 4. Possible side effects
15. 5. How to store ONVARA
16. 6. Contents of the pack and other information

17.
18. **1. What ONVARA is and what it is used for**
19. Your doctor has recommended or administered ONVARA to help protect you or your child against chickenpox.
20.
21. The vaccine can be administered to persons 12 months of age or older.
22.
23. **2. What you need to know before you are given ONVARA**
24. You should not be administered ONVARA:
25. - If you are hypersensitive (allergic) to varicella or any other ingredients of ONVARA, including gelatine and neomycin.
26. - If you have a blood disorder or or any type of cancer that affects your immune system

- If you are taking medications to suppress your immune system
- If you have an immune deficiency including one as a result of a disease (such as AIDS)
- If you have active untreated tuberculosis
- If you have a fever >38.5 °C
- If you inadvertently receive this vaccine while pregnant or breastfeeding (in addition, pregnancy should be avoided for 3 months after vaccination)

**Warnings and precautions**

**Tell your doctor or healthcare professional before being given the injection:**

- If you or your child have or have had any medical problems, and about any allergies (especially to gelatine or neomycin)

In rare circumstances, it is possible to catch chickenpox, including severe chickenpox, from a person who has been vaccinated with ONVARA. This may occur in persons who have not previously been vaccinated or had chickenpox, as well as persons who fall into one of the following categories:

- individuals with a weakened immune system
- pregnant women who never had chickenpox
- newborn babies whose mothers never had chickenpox.

Whenever possible, individuals who have been vaccinated with ONVARA should attempt to avoid close contact, for up to 6 weeks following the vaccination, with anyone who falls into one of the categories above.

Tell your doctor if there is anyone who falls into one of the categories above and is expected to be

- in close contact with the person being vaccinated

**Children**

ONVARA can be used in children 12 months of age or older.

**Other medicines and ONVARA:**

If you are using other medicines on a regular basis, including complementary or traditional medicines, the use of ONVARA with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other healthcare professional for advice.

**Pregnancy and Breastfeeding**

**Use in pregnancy**

ONVARA should not be administered to pregnant women. Women of child-bearing age should take the necessary precautions to avoid pregnancy for 3 months following vaccination.

47.

48. **Use in breastfeeding**

49. Tell your doctor if you are breastfeeding or intend to breastfeed. Your doctor will decide if you should receive ONVARA.

50.

51. If you are pregnant or breastfeeding while been given this medicine, please consult your doctor, pharmacist or other healthcare professional for advice.

52.

53. **Important information about some of the ingredients of ONVARA:**

54. ONVARA contains gelatine and a trace amount of neomycin as inactive ingredients. Tell your doctor if you or your child has ever had an allergic reaction to these ingredients.

55.

56. **3. How to receive ONVARA**

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

58. The usual dose is one vial of 0,5 ml given to children 12 months of age and older.

59. If your child is 12 months to 12 years old and your doctor gives a second dose,
the second dose must be given at least 3 months after the first dose.

60. For persons who are vaccinated at 13 years of age and older, a second dose should be given 4 to 8 weeks after the first dose.

61.

62. **If you use more ONVARA than you should:**

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

64. 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.

65.

66. **If you missed a dose of ONVARA:**

67. Your doctor will decide when to give the missed dose.

68.

69. **4. Possible side effects**

70. ONVARA can have side effects.

71. Not all side effects reported for ONVARA are included in this leaflet. Should you or your child's general health worsen after receiving this medicine, please consult your doctor, pharmacist or other healthcare professional for advice.

72.

73. If any of the following happens, tell your doctor immediately or go to the casualty department at your nearest hospital:
74. - Allergic reactions – swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing
75. These are all very serious side effects. If you have them, you have had a serious allergic reaction to ONVARA. You may need urgent medical attention or hospitalization.
76.
77. Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:
78. - Bruising more easily than normal
79. - Red or purple, flat, pinhead spots under the skin
80. - Severe paleness
81. - Difficulty walking
82. - Inflammation of the brain (encephalitis) †
83. - Stroke (cerebrovascular accident)
84. - Seizures with or without fever
85. - Inflammation of the coverings of the brain and spinal cord (meningitis)†
86. - Inflammation of the lung (pneumonia/pneumonitis)
87. - Severe skin disorders
88. - Skin infection
89. These are all serious side effects. You may need urgent medical attention.
90.
91. Tell your doctor if you notice any of the following:
92. - Injection-site complaints such as pain, swelling, itching, and redness
93. - Fever
94. - Irritability
95. - Shingles (herpes zoster)†
96. - Chickenpox
97. - Chickenpox-like rash on the body or at the injection site
98. - Nausea
99. - Vomiting
100. †Can be from naturally occurring chickenpox or the vaccine in healthy individuals or individuals with lowered immunity.
101. If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.
102.

**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 "**6.04 Adverse Drug Reaction Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of ONVARA.

## 5. How to store ONVARA

Keep all medicines out of the reach and sight of children.

Store in a refrigerator at 2 °C to 8 °C.

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.**

## 6. Contents of the pack and other information

**What ONVARA contains**

The active substance is Varicella Virus Vaccine Live.

The other ingredients are anhydrous disodium phosphate, hydrolysed gelatine, monosodium L-glutamate, potassium dihydrogen phosphate, potassium chloride, sodium chloride, sucrose, and urea.

**What ONVARA looks like and contents of the pack**

Before reconstitution: White powder

After reconstitution: Clear, colourless to pale yellow liquid, free from visible particulate matter.

3 ml glass vial (with a grey rubber stopper and a silver aluminium cap with a blue plastic cap) containing powder together with a sterile vial with water for injection packed in a cardboard carton together with a package insert and patient information leaflet.

3 ml vial of ONVARA and 3 ml vial of water for injection is packed together in a cardboard carton with the package insert and patient information leaflet.

Pack sizes: 1 or 10 vials.

**Holder of Certificate of Registration**

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