POLIO SABIN™ (oral) MULTIDOSE PRODUCT INFORMATION
Live Oral Poliomyelitis Vaccine

DESCRIPTION
POLIO SABIN (oral) MULTIDOSE is a stabilised vaccine containing three antigenic types of live attenuated poliomyelitis viruses derived from Sabin strains: Type 1 (LS-c, 2ab), Type 2 (P712, Ch, 2ab), and Type 3 (Leon 12a,b). The viruses are propagated in human diploid cells (MRC5).

POLIO SABIN (oral) MULTIDOSE is supplied as a solution for direct oral administration. Each dose contains not less than: 1,000,000 CCID₅₀ Type 1; 100,000 CCID₅₀ Type 2; and 600,000 CCID₅₀ Type 3 viruses stabilised with 1M magnesium chloride. Other excipients include: L-arginine, neomycin B sulphate (trace amounts), polymyxin B sulfate (trace amounts), polysorbate 80, and purified water.

Due to minor variations of its pH the vaccine may vary in colour from light yellow to light red. Changes of the colour of the vaccine within these ranges do not signify deterioration of the product.

The manufacture of this product includes exposure to bovine derived materials. No evidence exists that any case of vCJD (considered to be the human form of bovine spongiform encephalopathy) has resulted from the administration of any vaccine product.

The use of POLIO SABIN (oral) MULTIDOSE vaccine has been approved by the National Health Authorities in the country of manufacture. Each lot of POLIO SABIN (oral) MULTIDOSE vaccine is tested according to the latest World Health Organisation requirements.

CLINICAL PHARMACOLOGY
POLIO SABIN (oral) MULTIDOSE induces an asymptomatic infection. The attenuated viruses replicate in the intestine, and confer protection by inducing antibodies to poliovirus Types 1, 2 and 3, both systemically and in the gut epithelium. The induction of local antibodies provides resistance against subsequent challenge with wild poliomyelitis viruses. This reduces the frequency of symptomless excretion of wild poliomyelitis virus within a community.

Vaccine strain poliomyelitis virus may persist in the faeces for up to 6 weeks after POLIO SABIN vaccination, and may lead to infection of unvaccinated contacts. Such infection may lead to protection of previously susceptible subjects. However, in immunosuppressed patients and their close contacts, such infection may lead to clinical illness. (see PRECAUTIONS)
This vaccine elicits type specific neutralising antibodies in over 90% of susceptible individuals when administered according to the recommended schedule. However, due to various non-specific factors, all three viruses may not multiply in the gut of all susceptible subjects and thus they may not acquire immunity against all three types of polio viruses, even after three doses of the vaccine.

Following a primary vaccination course of POLIO SABIN (oral) MULTIDOSE antibody titres decrease with time, and repeat doses as described under DOSAGE AND ADMINISTRATION are recommended to maintain protective immunity.

INDICATIONS
POLIO SABIN (oral) MULTIDOSE vaccine is indicated for active immunisation of infants, susceptible children and adults against poliomyelitis caused by poliovirus of Types 1, 2 and 3.

CONTRAINDICATIONS
In common with other vaccines, POLIO SABIN (oral) MULTIDOSE should not be administered to subjects suffering from acute severe febrile illnesses (temperature over 38°C), or persistent diarrhoea or vomiting. However, the presence of a trivial infection does not contraindicate vaccination.

POLIO SABIN (oral) MULTIDOSE should not be administered to subjects with known hypersensitivity to neomycin or polymyxin or to any other component of the vaccine, or to subjects having shown signs of hypersensitivity after previous administration of oral poliomyelitis vaccines. A history of contact dermatitis to neomycin or polymyxin is not a contraindication.

Since the vaccine contains live viruses it should not be administered to patients with impaired immune responses. Impaired immune responses occur in patients with hereditary cellular immune deficiencies, hypogammaglobulinaemias and dysgammaglobulinaemias and may be present in patients suffering from blood dyscrasias, leukaemias, all types of lymphoma, HIV infection, generalised malignancy and malignant neoplasms affecting the bone marrow or lymphatic system and in patients with altered immune state due to treatment with ACTH, corticosteroids, alkylating drugs and antimetabolites, or receiving irradiation. The NH&MRC* recommend that the inactivated polio vaccine (IPV) be used to vaccinate immunosuppressed subjects and their household contacts.
PRECAUTIONS

POLIO SABIN (oral) MULTIDOSE vaccine is **for oral use only; do not give parenterally.**

As with any vaccine, a solution of 1 in 1,000 adrenaline and other appropriate medical treatment should always be readily available for immediate use, in cases of a rare anaphylaxis or anaphylactoid reaction following administration of the vaccine. The vaccinee should remain under medical supervision for 30 minutes after immunisation.

It is good clinical practice that any vaccination be preceded by a review of medical history (especially with regard to previous vaccinations and possible adverse events) and a clinical examination.

Following a dose of POLIO SABIN, faecal excretion of the vaccine virus can last for 6 weeks. Contacts of recent vaccinees should be advised to observe strict personal hygiene. In particular, contacts of recently vaccinated babies should be advised of the need for thorough hand washing following nappy changes.

Because of the very small risk of vaccine-contact poliomyelitis (estimated to range from one case in one million to one in ten million vaccinées and susceptible close contacts), whenever the vaccine is given it is good practice to offer vaccination to presumably susceptible close contacts (such as unvaccinated parents) at the same time (see CLINICAL PHARMACOLOGY). The NH&MRC* recommend such contacts receive POLIO SABIN, as the risk of infection occurs before immunity develops in response to IPV (see DOSAGE AND ADMINISTRATION).

POLIO SABIN (oral) MULTIDOSE however is not recommended for siblings or other household contacts of immunosuppressed patients; such contacts should receive IPV.

Some authorities believe that in unvaccinated or incompletely vaccinated adults it is preferable to use the inactivated polio vaccine (IPV) because of some, though very small, risk of oral polio vaccine-induced poliomyelitis. However, the NH&MRC* advise immunocompetent adults should receive POLIO SABIN, as the very small risk of such disease is insufficient to warrant a change in immunisation policy.

Diarrhoea or vomiting may interfere with the immune response elicited to the vaccine (see CONTRAINDICATIONS). Vaccination should be avoided if there is a likelihood of infection with other enteroviruses since these may interfere with the immune response to the vaccine.

POLIO SABIN may be administered at birth, however the immunogenicity is likely to be reduced due to the presence of maternal antibodies. Therefore, the three dose primary vaccination schedule is required later in life to provide adequate protection.
Lower seroconversion rates have been observed in some populations and groups of vaccinees. (see CLINICAL PHARMACOLOGY).

Breast feeding does not interfere with the antibody response to POLIO SABIN, and vaccination of infants should not be delayed on this account.

POLIO SABIN (oral) MULTIDOSE vaccine can be used in the face of an epidemic, and in fact is particularly recommended to check the spread of polio virus in a community. However, the vaccine may not prevent or modify the disease in those already infected with a wild poliomyelitis virus (see CLINICAL PHARMACOLOGY).

Use in Pregnancy (Category B2)
Although there is no evidence that attenuated polio viruses have an adverse effect on the fetus, in accordance with general principles, the vaccine should not be given to pregnant women unless they are at a definite risk of infection from wild polioviruses.

Use in Lactation
The effect on breastfed infants of the administration of POLIO SABIN to their mothers has not been assessed in clinical studies. However, no contraindication for vaccination has been established.

Interactions
POLIO SABIN may be administered simultaneously with different live or inactivated vaccines, but concomitant administration with oral typhoid vaccine is not recommended.

Specifically, POLIO SABIN (oral) MULTIDOSE vaccine can be given at the same time as injectable trivalent diphtheria, tetanus and pertussis (DTP), BCG, haemophilus influenzae Type B (Hib) and hepatitis B vaccines It can also be orally administered simultaneously with the injectable measles, mumps and rubella vaccines if this fits conveniently in a vaccination schedule. Otherwise, there should be an interval of at least one month between the administration of two different live virus vaccines.

Recent administration of immunoglobulin is not a contraindication to administration of POLIO SABIN (oral) MULTIDOSE, however the immune response to the vaccine may be diminished.

Previous vaccination with a killed polio vaccine is not a contraindication for use of POLIO SABIN (oral) MULTIDOSE vaccine.
**Effects on the ability to drive and use machinery**
The vaccine is considered unlikely to affect the ability to drive and operate machinery.

**ADVERSE REACTIONS**
The attenuated viruses in the vaccine cause an asymptomatic infection in susceptible subjects. Although non-specific symptoms such as fever, malaise, headache, vomiting and diarrhoea have been described after vaccination, none have been recognised as caused by the vaccine.

Temporal association between vaccination with Sabin strain vaccines and paralytic poliomyelitis has been established in a few recipients or their close susceptible contacts. The frequency of this association is however extremely low. Estimates have varied from one case in one million to one in ten million vaccinees and susceptible close contacts.

Very rarely, allergic reactions including anaphylactoid reactions have been reported.

**DOSAGE AND ADMINISTRATION**
POLIO SABIN (oral) MULTIDOSE is a light yellow to light red solution for direct oral administration. Changes in colour within these ranges do not signify deterioration of the vaccine. Vaccines should be inspected visually for any particulate matter or discolouration prior to administration.

POLIO SABIN (oral) MULTIDOSE vaccine should under no circumstances be injected.

The vaccine is supplied in multidose glass vials with a special plastic dropper. To prepare the vial for oral use, remove the metal cap and rubber bung and place the dropper securely over the top of the vial.

**Dosage**
The recommended dose for immunocompetent infants, children and adults is 2 drops, as delivered from the special dropper supplied with the multidose glass vials.

It is recommended immunocompromised individuals be vaccinated with IPV.
**Administration**

The vaccine is usually administered directly into the mouth. Alternatively, the vaccine may be given on a lump of sugar. POLIO SABIN (oral) MULTIDOSE must not be mixed with foods or beverages containing substances, such as preservatives, that may inactivate the polioviruses.

During administration, care should be taken to avoid contamination of the multidose dropper with the saliva of a vaccinee.

If POLIO SABIN (oral) MULTIDOSE is regurgitated, it is recommended the vaccine dose be repeated.

POLIO SABIN (oral) MULTIDOSE should under no circumstances be injected.

**Vaccination Schedule**

**Infants and Children (Immunocompetent)**

**Primary Schedule**

POLIO SABIN (oral) MULTIDOSE vaccine is usually given to infants from 2 months of age upwards. Three successive doses of vaccine should be given separated by intervals of preferably 8 weeks for a complete schedule.

**Reinforcing Doses**

The NH&MRC* recommend one further reinforcing doses of POLIO SABIN be administered at age 4 years.

**Adults (Immunocompetent)**

**Primary Schedule**

Unvaccinated adults should receive a primary vaccination course of 3 doses of POLIO SABIN (oral) MULTIDOSE at intervals of 4-8 weeks.

Unvaccinated or incompletely vaccinated parents of children receiving POLIO SABIN (oral) MULTIDOSE should be offered a primary course of POLIO SABIN at the same time. (see PRECAUTIONS)

**Reinforcing Doses**

Reinforcing booster doses may not be necessary in previously immunised adults, unless there is a continued risk of exposure to infection, such as in:

- travellers to areas where poliomyelitis is epidemic or endemic
- or healthcare workers possibly exposed to poliomyelitis
In these groups, a single reinforcing dose of POLIO vaccine is recommended every 10 years.

**Because of the possibility of contamination, when the vaccine is kept at room temperature it should be used within 8 hours of opening or discarded. If necessary the vaccine may be kept in a refrigerator for up to 48 hours after opening, if contamination is avoided.** (see STORAGE AND SHIPMENT CONDITIONS)

**OVERDOSAGE**
No ill effects have occurred in the occasional reports of overdose.

**STORAGE AND SHIPMENT CONDITIONS**
The vaccine should be stored in a refrigerator between +2°C and +8°C or frozen at -20°C.

**Because of the possibility of contamination the vaccine should be used within 8 hours of opening or discarded. If necessary the vaccine may be kept in a refrigerator for up to 48 hours if contamination is avoided.**

Freezing at -20°C and thawing up to ten times does not affect the titre of the vaccine. Therefore after opening, incompletely used multidose vials of POLIO SABIN (oral) may be immediately frozen at -20°C. Frozen vials should be rapidly thawed and mixed by rolling the vial between the fingers, and the colour checked to ensure it is within the recommended range. After removal of the required doses, the vial and remaining contents should be promptly refrozen.

When distribution or administration is not imminent, it is advisable to store the vaccine, if possible, at temperatures of -20°C or less since this halts deterioration of its potency. Shipment should be done under refrigerated conditions, particularly in hot climates.

Exposure of the vaccine to ambient (non-refrigerated) temperatures should be kept to a minimum and exposure to sunlight should be avoided to preserve optimal potency of the vaccine.

**Stability**
The following experimental data give an indication of the stability of the vaccine and are not recommendations for storage.

Commercial preparations of POLIO SABIN (oral) MULTIDOSE are stabilised with a 1 M magnesium chloride solution. Extensive laboratory and field tests have shown that, in this form, there is no significant loss of virus titre after storage for 12 to 15 months in a refrigerator at temperatures of between +2°C to +8°C. When kept between +20°C to +25°C, potency is
maintained for one week, and at temperatures of +37°C there is no significant deterioration for one day.

The commercial vaccine will maintain its potency for at least 1 year when stored continuously at -20°C.

If the vaccine has been accidentally exposed to high environmental temperatures not exceeding the time and temperature limits indicated above, the expiry date indicated when storage is between +2°C and +8°C no longer applies. It should preferably either be used immediately or stored at -20°C until administration.

If it is thought that the thermal stability limits indicated above have been exceeded, the vaccine should, if economically justified, be re-tested for potency before use or discarded.

**EXPIRY DATES**
As indicated on packs and vaccine label, multidose packs show an expiry date of 1 year.

**PRESENTATIONS**
Multidose glass vials (with plastic dropper): 10 doses, in packs of 100

**MANUFACTURER**
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**DISTRIBUTED IN AUSTRALIA BY**
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* National Health & Medical Research Council, 8th Edition Australian Immunisation Procedures Handbook

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