PACKAGE INSERT

SMALLPOX VACCINE (DRIED)

Live Vaccinia Virus (Bovine Origin)

Powder for resuspension

(For active immunization against Smallpox disease)

ATC Code: J07BX Other Viral Vaccines

Sanofi Pasteur Limited

Toronto, Ontario, Canada

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SMALLPOX VACCINE (DRIED)
Live Vaccinia Virus (Bovine Origin)

SUMMARY PRODUCT INFORMATION

Route of Administration

Conventional smallpox vaccination with a bifurcated needle (scarification)

Dosage Form / Strength

Powder for resuspension

Each single dose after reconstitution contains:

Active Ingredients:

Live Vaccinia virus (bovine origin)

Clinically Relevant Nonmedicinal Ingredients

Excipients: Phenol, Glycerol, McIlvaine buffer

Manufacturing process residuals: neomycin and streptomycin may be present in trace amounts.

For a complete listing see DOSAGE FORMS, COMPOSITION AND PACKAGING *section.*

DESCRIPTION

Smallpox Vaccine (Dried) is prepared by Sanofi Pasteur Limited from partly purified suspensions of vaccinia virus prepared on calf skin by a process resulting in an extremely low bacterial content. The reconstituted vaccine is a cloudy, off-white to pale yellow suspension formulated to contain not less than 1 x 10^8 Pock Forming Units (PFU)/mL. The dry powder dissolves without difficulty in the diluent provided which consists of 40% glycerol in McIlvaine buffer containing 0.2% v/v phenol.

INDICATIONS AND CLINICAL USE

Smallpox Vaccine (Dried) is indicated for active immunization against smallpox disease. It may be used for primary vaccination and revaccination.

This vaccine is for emergency use in accordance with the National Advisory Committee on Immunization's (NACI) statement on Smallpox vaccination. (1)

The National Advisory Committee on Immunization recommends that smallpox vaccination be limited to groups at potential risk of exposure. (1)

Smallpox Vaccine (Dried) may be used for immunization of laboratory workers who handle or may handle smallpox virus or other orthopoxvirus specimens, (1) and for public health first responders to the scene of a potential smallpox case or outbreak. (1)

Immunization immediately after exposure and ≤4 days post-exposure to an infectious case of smallpox can prevent or decrease the severity of disease and the risk of mortality. (1)

Smallpox Vaccine (Dried) is not to be used for treatment of smallpox infections.

CONTRAINDICATIONS

In an emergency, if smallpox cases occur and a real risk of infection exists as determined by public health authorities, there are no absolute contraindications to smallpox vaccination. (1) If a relative contraindication exists (such as severe immunosuppression), the decision to vaccinate should be made in conjunction with public health authorities, weighing the risk of the disease in the circumstances and the relative risks and benefits of vaccination.

In the non-emergency situation (before the occurrence of a case of smallpox or if a less significant risk of infection exists as determined by public health authorities), or if the vaccine is to be given to laboratory personnel or others at potential risk of exposure (1) the following contraindications apply:

1. Known systemic hypersensitivity reaction to any component of Smallpox Vaccine (Dried) (or its container) or a life-threatening reaction after previous administration of the vaccine or a vaccine containing one or more of the same components are contraindications to vaccination. (2) (See SUMMARY PRODUCT INFORMATION.) Alternatively, such persons may be referred to an allergist for evaluation and desensitization to the implicated component, if immunization is deemed essential based on risk of exposure to smallpox.
2. Persons <18 years of age. Such persons are more likely to suffer from adverse reactions and cause inadvertent self-reinoculation and inoculation of others. (1)
3. Persons with active eczema, a history of eczema or other significant exfoliative skin conditions, including atopic dermatitis; (1) Persons with Darier's disease (keratosis follicularis) can develop eczema vaccinatum and therefore should not be vaccinated.(3) Persons with other active acute, chronic, or exfoliative conditions (e.g., burns, impetigo, varicella zoster, herpes, severe acne, or psoriasis) are at higher risk for clinically severe inadvertent inoculation and should not be vaccinated until the condition resolves. (3)
4. Persons who are immunosuppressed such as:
   - persons with leukemia, lymphoma, or a generalized malignancy,
   - persons on immunosuppressive therapies,
   - persons with hereditary immune deficiency disorders,
   - persons with HIV/AIDS; (1)
5. Pregnant women. Smallpox vaccine is not known to cause congenital malformations, but can very rarely lead to fetal vaccinia after primary immunization during pregnancy, resulting in neonatal death or stillbirth. (1)
6. Nursing women. The effect of administration of smallpox vaccine during lactation has not been assessed. The close physical contact that occurs during breastfeeding increases the chance of inadvertent inoculation. (3)

7. Persons with known underlying heart disease, with or without symptoms, or who have three or more known major cardiac risk factors (i.e., hypertension, diabetes, hypercholesterolemia, heart disease at age 50 years in a first-degree relative, and smoking). (3)
8. Persons who have household or other close contacts with active, or a history of eczema or other exfoliative skin conditions or who have household or close contacts to immunosuppressed or pregnant persons. If immunization of these individuals is required, they can be isolated from their household contacts until the vaccine scab falls off. (1)

WARNINGS AND PRECAUTIONS

General

Before administration of Smallpox Vaccine (Dried), health-care providers should inform the patient to be immunized of the benefits and risks of immunization, inquire about the recent health status of the patient, review the patient's history concerning possible hypersensitivity to the vaccine and its components or similar vaccine, previous immunization history, the presence of any contraindications to immunization and comply with any local requirements with respect to information to be provided before immunization.

As with any vaccine, immunization with Smallpox Vaccine (Dried) may not protect 100% of susceptible individuals.

It is extremely important that the vaccinee be educated to avoid contact transmission of the virus. (3) (See CONTRAINDICATIONS and ADVERSE REACTIONS.) The estimated risk of transmission of vaccinia virus to contacts is 27 infections per million vaccinees. (3)

Administration Route-Related Precautions

For conventional smallpox vaccination with a bifurcated needle (scarification). Do not inject intramuscularly, intravenously or subcutaneously.

Aseptic technique must be used for withdrawal of each dose. Use a separate, sterile bifurcated needle for each individual dose and for each entry into the multidose vial, to prevent disease transmission.

Febrile or Acute Disease

Elective vaccination should be postponed in cases of an acute or febrile disease. (2)

Cardiovascular

Persons receiving smallpox vaccine should be informed that myopericarditis (2) is a potential complication of smallpox vaccination and that they should seek medical attention if they develop symptoms of cardiac disease (e.g. chest pain, shortness of breath) after vaccination. (3)

Immune

The possibility of allergic reactions in persons sensitive to components of the vaccine should be evaluated. Allergic reactions may occur following the use of Smallpox Vaccine (Dried) even in persons with no prior history of hypersensitivity to the product components.

The stopper of the vial of the Smallpox Vaccine (Dried) vaccine contains latex (natural rubber).

The stoppers of the diluent and administration vials do not contain latex (natural rubber).

As with all other products, epinephrine hydrochloride solution (1:1,000) and other appropriate agents should be available for immediate use in case an anaphylactic or acute hypersensitivity reaction occurs. (4) Health-care providers should be familiar with current recommendations for the initial management of anaphylaxis in non-hospital settings including proper airway management. (4) For instructions on recognition and treatment of anaphylactic reactions, see the current edition of the Canadian Immunization Guide or visit the Health Canada website.

Ophthalmologic

Persons with inflammatory eye diseases may be at increased risk of inadvertent self re-inoculation by touching or rubbing of the eye. Therefore it may be prudent to defer vaccination of persons with inflammatory eye diseases requiring steroid treatment until the condition resolves and the course of therapy is complete. (3) (See CONTRAINDICATIONS.)

Pregnant Women

Smallpox immunization is contraindicated in pregnant women in non-emergency situations. (See CONTRAINDICATIONS.)

Nursing Women

Smallpox immunization is contraindicated in nursing women in non-emergency situations. (See CONTRAINDICATIONS.)

Pediatrics

Smallpox immunization is contraindicated in persons less than 18 years of age in non-emergency situations. (See CONTRAINDICATIONS.)

ADVERSE REACTIONS

Information on adverse events derived from published clinical trials and world-wide post-marketing experience with smallpox vaccines are provided below for reference.

The local lesion known as Jennerian vesicle is a sign of the replication of the vaccinia virus and of the corresponding inflammatory reaction; it indicates the take of the vaccination and is considered as normal. Normal progression of the local reaction results in a permanent scar at the administration site. (See DOSAGE AND ADMINISTRATION, Administration, Interpretation of Responses.)

Local Adverse Reactions

Primary vaccination can produce swelling and tenderness of regional lymph nodes beginning 3 to 10 days after vaccination and in some cases persisting up to 2 to 4 weeks after the skin lesion has healed. (3)

Other normal local reactions include: (3)

- local satellite lesions (which appear similar to the primary lesion),
- considerable local edema,
- intense local inflammation accompanying the vaccination (viral cellulitis) which may be confused with bacterial cellulitis

Administration site pruritus has been reported following smallpox vaccination.

Systemic Adverse Reactions

In a study using U.S. smallpox vaccine, 17% of adult primary vaccinees experienced fever of at least 37.7°C (100°F) within two weeks of vaccination; 7% had a fever of 38.3°C (101°F) or more, and 1.4% experienced a fever of 38.9°C (102°F) or more. Beyond two weeks, fever was recorded in 0.3% of vaccinees. In a study of adult primary vaccinees, 36% were sufficiently ill to miss work, school, or recreational activities or to have trouble sleeping. (3)

Children are more likely to suffer from adverse reactions and cause self inoculation and inoculation to others. Adverse events occur more frequently in infants than in children vaccinated after their first birthday.

In a 1968 study conducted in the U.S. involving over 14 million vaccinees, rates of post-vaccinial encephalitis were approximately four-fold higher in infants than those observed in older children (42.3 versus 9.5 cases per million vaccinations). In addition, infants were more likely to develop generalized vaccinia and erythema multiforme (394.4 versus 233.4 and 436.6 versus 157.7 cases per million, respectively).

Additional Adverse Reactions

Other adverse reactions to smallpox vaccine include non-specific reactions e.g., (bacterial superinfection of a local reaction, urticarial rash, anaphylaxis, erythema multiforme, and Stevens-Johnson syndrome) and specific smallpox vaccine reactions (local and systemic: see descriptions below). The rates of Vaccine Associated Adverse Events (VAAEs) are derived from a 1968 study conducted in the U.S. involving >14 million vaccinees. Overall, nine deaths associated with smallpox vaccine occurred in this population (one death per million primary immunizations and one death per four million reimmunizations). The reactions described below occur >10 times more frequently among first time vaccinees than revaccinees, and more frequently among infants than older children and adults. (1)

- **Inadvertent inoculation** is the transfer of the virus from the site of immunization to other body sites (eye, mouth, nose, face, genitalia) resulting in vaccinia lesions. This is the most

common adverse reaction, with rates approaching 600 cases per million doses administered. Most ensuing lesions heal spontaneously. (1) Lesions in eczematous skin, in disrupted skin and in the eye pose special hazards, as the infection can be extensive in skin lesions and a threat to eyesight. (3)

- **Generalized vaccinia** is a vesicular rash developing 6 to 9 days post-immunization in healthy vaccinees, occurring in approximately 80-250 cases per million. (1) However, generalized vaccinia has been less frequently reported after re-vaccination than after primary vaccination. In healthy individuals, the rash is self-limited. Individuals with underlying and unsuspected immunosuppressive illnesses may develop serious and severe forms of generalized vaccinia. (1)
- **Eczema vaccinatum** occurs in vaccinees or their unvaccinated contacts with active or healed eczema lesions or other exfoliative skin conditions. Vaccinial skin lesions appear on skin that is currently or was previously affected by eczema. This reaction occurs in 42 vaccinees per million. Usually the illness is mild and self-limited, but it can be severe and fatal. (1)
- **Progressive vaccinia (vaccinia necrosum)** is a severe, potentially fatal reaction characterised by progressive necrosis at the site of immunization and occasional secondary lesions elsewhere. This reaction occurs in 4.5 per million vaccinees and is fatal in a third of cases. It has occurred almost exclusively in persons with cellular immunodeficiency. (1)
- **Postvaccinial encephalitis**, the most serious complication, most frequently affects primary vaccinees (12 cases per million in primary vaccinees and 2 cases per million in revaccinees). Approximately 25% of cases with encephalitis develop permanent sequelae (both motor and/or intellectual impairment) and up to 35% die. (2)
- **Vaccinia Keratitis.** Lesions of the cornea secondary to implantation of vaccinia are potentially threatening to eyesight. Corneal abrasion, ulceration and subsequent clouding may result in significantly impaired vision. The frequency of vaccinia keratitis is unknown. From the experience of those who cared for patients with vaccinia keratitis and from published reports, it is not a common occurrence.
- **Cardiac Disease.** Data from a recent US smallpox vaccination program have been found to be consistent with a causal association between vaccination and myopericarditis, although this is not proven. (3) Myopericarditis occurred at a rate of about 1 in 10,000 vaccinees. Cases predominantly sought medical care after developing chest pain and there was a high rate of recovery. (5)

Vaccinia Immune Globulin (VIG) is recommended for the management of certain medical complications. VIG can be given in conjunction with smallpox vaccine to those individuals with underlying medical conditions that put them at increased risk for developing vaccinia-specific adverse reactions to the vaccine. (1) Refer to the VIG manufacturer's leaflet for further information.

Reporting Suspected Side Effects

For the general public: Should you experience a side effect following immunization, please report it to your doctor, nurse, pharmacist or immunization provider.

Should you require information related to the management of the side effect, please contact your healthcare provider. The Public Health Agency of Canada and Health Canada cannot provide medical advice.

For Healthcare professionals: If a patient experiences a side effect following immunization, please complete the Adverse Events Following Immunization (AEFI) Form appropriate for your province/territory (http://www.phac-aspc.gc.ca/im/aefi-essi-form-eng.php) and send it to your local Health Unit, or according to specified public health guidance.

DRUG INTERACTIONS

Concomitant Vaccine Administration

Persons scheduled to receive an annual purified protein derivative (PPD) skin test for tuberculosis screening should not receive the skin test until >1 month after smallpox vaccination.

Smallpox vaccine can be administered simultaneously with any inactivated vaccine. With the exception of varicella vaccine, smallpox vaccine can be administered simultaneously with other live-virus vaccines. (3) Varicella vaccine and smallpox vaccine should be administered at least 4 weeks apart, in order to avoid confusion in ascertaining which vaccine might have caused post-vaccination skin lesions or other adverse events. (2) Other live vaccines should be administered either on the same day or be separated by an interval of at least 1 month. (1) Separate injection sites must be used.

DOSAGE AND ADMINISTRATION

Recommended Dose

The recommended dose is defined by the droplet of reconstituted vaccine that forms between the prongs of the bifurcated needle.

Note: The original presentation of this vaccine has been updated to incorporate the use of bifurcated needles. Administration with bifurcated needles increases the number of doses in the vial from 10 (as indicated on the vaccine vial label) to approximately 100 (as indicated in this Product Insert). This update also requires unique reconstitution and immunization procedures, as described below.

In the non-emergency situation (i.e., before the occurrence of a case of smallpox anywhere in the world), one dose of smallpox vaccine is administered to recommended recipients >18 years of age. (1)

For the groups at risks identified in INDICATIONS AND CLINICAL USE, for whom smallpox immunization is recommended by NACI, immunization every 10 years is adequate. If smallpox

cases do occur and these individuals are at continuous risk, they should be reimmunized every 3 years. (1)

Administration

Ensure that you have completely read this document for Smallpox Vaccine (Dried) before proceeding with the directions below. For further information on vaccine administration contact the local public health authority.

Aseptic technique must be used for withdrawal of each dose. In order to prevent disease transmission, use a separate, sterile bifurcated needle for each individual patient, and for each entry into the multidose vial, even for administration to the same patient.

Persons administering the vaccine should wear gloves and eye protection. Gloves should preferably be changed between vaccinations and must be changed if they become contaminated with the vaccine. Refer to SPECIAL HANDLING INSTRUCTIONS for disposal of contaminated materials.

Before administration, ensure that the skin is clean. If obviously dirty, the skin over the administration site should be cleansed, preferably with a cloth moistened with water. If alcohol is used to cleanse the skin before immunization, the skin must be allowed to dry thoroughly before the vaccine is administered, to prevent inactivation of the vaccine by alcohol. (1)

The preferred site of vaccination is on the skin over the insertion of the deltoid muscle or on the posterior aspect of the arm over the triceps muscle.

1. **Reconstitution of Freeze-Dried Product and Withdrawal from Stoppered Vial**

   a. Lift up the plastic cap of the diluent and administration vials **but do not break or tear down aluminum seals.**
   b. Swab the surface of the vaccine, diluent and administration vial stoppers with an alcohol swab and allow to dry.
   c. Using a sterile disposable needle and syringe, aseptically withdraw 0.25 mL of the diluent and discard the diluent vial with the excess diluent.
   d. Holding the syringe containing the diluent steady, pierce the centre of the stopper in the vaccine vial containing the dried material and slowly inject the diluent. Shake the vial thoroughly until a uniform, cloudy, off-white to pale yellow suspension results.
   e. Inspect the vial of vaccine for extraneous particulate matter and/or discolouration before use. (See DESCRIPTION.) If these conditions exist, the product should not be administered.
   f. Using the same or a new needle and syringe than was used for diluent transfer, withdraw the entire contents of the vial and transfer the reconstituted vaccine into the administration vial provided by carefully piercing the centre of the stopper and slowly injecting the reconstituted vaccine into it. Discard the diluent transfer needle and syringe into a sharps biohazard waste container.

g. Record the lot number of the vaccine and the date of reconstitution on the label of the administration vial. Discard the empty vaccine vial into a biohazard waste container.

When the vaccine has been reconstituted, it should *preferably be used at once (See* STORAGE AND STABILITY *for storage information)*.

1. Administering with a Bifurcated Needle

a. Bending the plastic cap backwards and pulling counter-clockwise, tear away the aluminum seal of the administration vial containing the reconstituted vaccine and remove the entire seal.

b. Carefully remove the stopper from the administration vial of reconstituted vaccine-and aseptically retain the stopper (set aside inverted) for subsequent reuse. If the vial stopper is contaminated during the removal process, reseal the vial aseptically (e.g. with Parafilm®) for subsequent re-use.

Refer to SPECIAL HANDLING INSTRUCTIONS for disposal of contaminated materials.

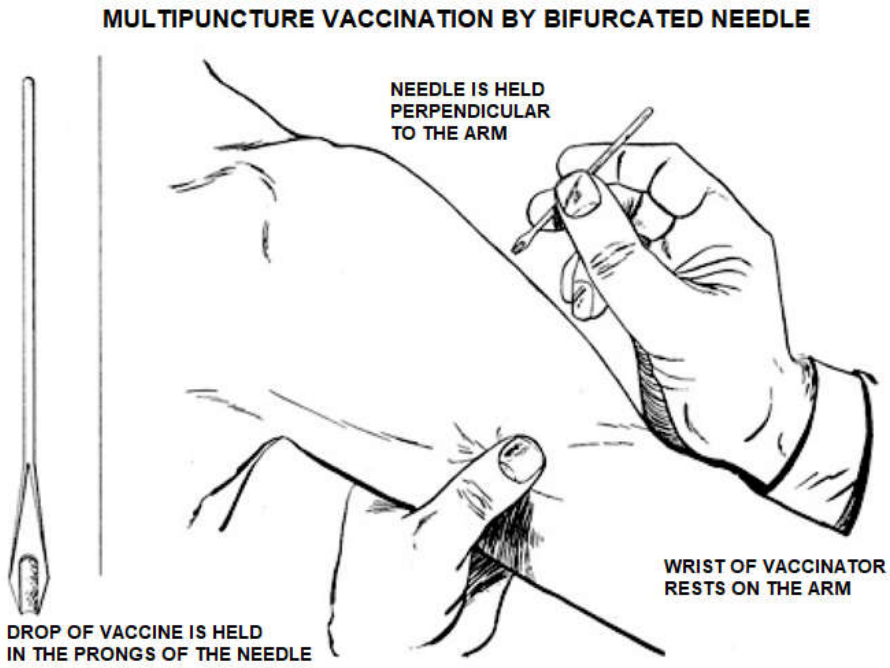
IMPORTANT: Vaccine that is or suspected to have been compromised must be discarded and not used for further vaccination. Examples of a compromised vial could include (but not be limited to) entry of the vial with a non-sterile bifurcated needle, re-entry with a previously used bifurcated needle.

c. Remove the bifurcated needle (supplied separately) from its package. DO NOT touch the pointed end of the needle. The multiple-puncture technique uses a pre-sterilized single use bifurcated needle that is inserted vertically into the vial of reconstituted vaccine, causing a droplet of vaccine to adhere between the prongs of the needle. The droplet contains the recommended dosage of vaccine, and its presence within the prongs of the bifurcated needle should be confirmed visually.

d. Holding the bifurcated needle perpendicular to the skin, 15 punctures are rapidly made with strokes vigorous enough to allow a trace of blood to appear after 15-20 seconds. (Refer to diagram below on multiple-puncture technique.) Any remaining vaccine should be blotted off with dry sterile gauze and the gauze disposed of in a biohazard waste container. Dispose of the needle in a biohazard waste sharps container.

Refer to SPECIAL HANDLING INSTRUCTIONS for disposal of contaminated materials.

Figure 1: (6)



After Care

The site can be left uncovered or a sterile piece of gauze can be used to loosely cover the vaccination site to deter the vaccinee from touching it. (1) Vaccinia virus can potentially be cultured from the vaccination site while the papule is forming until the scab separates from the skin (at least 14 to 21 days post-vaccination). During this period, care should be taken to prevent the transfer of virus to other parts of the body or to others, particularly those at high risk from vaccinia virus such as immunocompromised persons. If gauze is used as a loose dressing, then proper hand hygiene is essential following dressing changes. Contaminated bandages should be placed in sealed plastic bags before disposal in the garbage. Clothing or other cloth materials that have had contact with the site can be decontaminated with routine laundering in hot water with bleach. The vaccination site should be kept dry, although normal bathing can continue. (3)

Interpretation of Responses

Vaccinations should be examined and the response verified and documented at one week (6 - 8 days). If only one reading can be made it should be at 7 days. A “take” or “major reaction” is characterized by pustular lesion or an area of definite induration or congestion surrounding a central lesion, which can be either a scab or an ulcer. All other responses should be considered “non-takes”. (3) A person is considered immune if a “take” reaction occurs at the vaccination site. If a “take” reaction does not occur after seven days, the individual should be revaccinated using a different vaccine vial and at a different site (although the same arm can be used).

- The "Primary Take" shows the first sign of reaction about the 3rd or 4th day and reaches its maximum by the 10th or 12th day, with a typical Jennerian vesicle ("Jennerian" reaction - in which a papule, then vesicle, appears which progresses to a pustule, then a scab, then a scar). This reaction occurs in those individuals who have never been successfully vaccinated previously.

- "Vaccinoid" or "Accelerated Reaction" appears within 24 hours and usually reaches its maximum earlier than a "Primary Take." Examination one week after vaccination will show a vesicular or pustular lesion or an area of definite palpable induration or congestion surrounding a central lesion which may be a scab or ulcer. This reaction occurs in individuals who have been successfully vaccinated previously.
  Both the "Primary Take" and "Vaccinoid" or "Accelerated Reaction" indicate virus multiplication with consequent development or redevelopment of immunity.

- The "Early" or "Sensitivity" reaction appears within 24 hours and reaches its maximum by the 3rd day. It seldom leads to vesicle or pustule formation and simply shows a distinct redness and induration.

The "Early" (or "Sensitivity") reaction indicates a previous smallpox infection or vaccination. It may be the consequence of immunity adequate to prevent virus multiplication or may be an allergic skin response elicited by inactive vaccine or inadequate technique. Since these cannot be differentiated it is advisable to revaccinate with freshly prepared vaccine.

Give the patient a permanent personal immunization record. In addition, it is essential that the physician or nurse record the immunization history in the permanent medical record of each patient. This permanent office record should contain the name of the vaccine, date given, dose, manufacturer and lot number.

ACTION AND CLINICAL PHARMACOLOGY

Smallpox is caused by variola virus, a member of the orthopoxvirus genus, which is transmitted from person-to-person, mainly through respiratory droplets. Until the WHO declared smallpox globally eradicated in 1980, it was a highly communicable devastating disease with serious complications, including encephalitis and blindness, and a high mortality rate. (1)

Although vaccine efficacy has never been measured in a controlled trial, the eradication of smallpox is the best available evidence that the vaccine is effective.

Indicators of adequate vaccine response include:

1) *Vaccine "take" (Jennerian pustule)*: If a progressive reaction (see "Interpretation of Responses") consisting of a papule, vesicle, pustule, scab and, eventually, a characteristic scar develops at the site of immunization, the vaccinee is considered to have developed smallpox immunity. This will occur in both first-time vaccinees and revaccinated persons who have lost all or part of their original immunity. (See DOSAGE AND ADMINISTRATION - Administration.) This reaction is best observed 6 to 8 days post-immunization. A positive "take" indicates successful immunization. Clinical experience has shown that vaccine "take" is close to 100%. (1)

2) *Measurement of antibody titres:* The level of antibody necessary to protect against smallpox infection is unknown. However, over 95% of primary vaccinees experience a rise of antibody titre >1/10. (1)

STORAGE AND STABILITY

Store freeze-dried vaccine at <5°C (41°F).

The diluent and the reconstituted vaccine should be stored at 2° to 8°C (35° to 46°F). **Do not freeze.** Discard product if exposed to freezing.

If stored at 2° to 8°C (35° to 46°F), the reconstituted vaccine will retain its potency for up to 1 week, but it is preferable to use it at once.

Do not use vaccine after expiration date, which is indicated on materials supplied with the vaccine kit.

SPECIAL HANDLING INSTRUCTIONS

Dispose of all vaccine contaminated materials (e.g., swabs, gloves, empty or expired vaccine vials, compromised vaccine vials, stoppers, etc.) as biomedical waste. Such waste should be incinerated or autoclaved prior to general disposal.

DOSAGE FORMS, COMPOSITION AND PACKAGING

Dosage Forms

Smallpox Vaccine (Dried) is supplied as a sterile freeze-dried white powder supplied in a multidose vial (yielding approximately 100 doses/vial).

The diluent is a sterile clear colourless solution supplied separately in a vial containing a minimum fill volume of 0.25 mL. Only 0.25 ml is used to reconstitute one vial of Smallpox Vaccine (Dried).

After reconstitution, Smallpox Vaccine (Dried) is a cloudy, off-white to pale yellow suspension.

Composition

Each vial of reconstituted vaccine contains:

Active Ingredients

Live Vaccinia virus	1 x 10^8 PFU/mL

Other Ingredients
Excipients:

Phenol	0.2% v/v
Glycerol	40%
McIlvaine buffer	q.s. 0.25 mL

Neomycin and streptomycin	trace amounts

Packaging

For administration with bifurcated needles; Smallpox Vaccine (Dried) (multidose vials) for reconstitution with "Diluent for Smallpox Vaccine (Dried)", and administration vials.

The stopper of the vial of the Smallpox Vaccine (Dried) contains latex (natural rubber). The stoppers of the diluent and administration vials do not contain latex (natural rubber).

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Product information as of August 2020.

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