Smallpox Vaccine
Dried
Calf Lymph Type

Wyeth®

Dryvax®
dried smallpox vaccine

Description

Dryvax, SMALLPOX VACCINE, DRIED, is prepared from calf lymph. The calf lymph is purified, concentrated, and dried by lyophilization. During processing, not more than 100 units of polymyxin B sulfate, 200 micrograms of dihydrostreptomycin sulfate, 200 micrograms of chlorotetracycline hydrochloride, and 100 micrograms of neomycin sulfate per mL are added, and trace amounts of these antibiotics may be present in the final product. The reconstituted vaccine has been shown by appropriate test methods to contain not more than 200 viable bacterial organisms per mL. The Diluent for Dryvax, SMALLPOX VACCINE, DRIED, contains 50% glycerin, 0.25% phenol in Sterile Water for Injection, USP, with 0.005% brilliant green. The reconstituted vaccine which contains approximately 100-million living vaccinia viruses per mL, is intended only for multiple-pressure or multiple-puncture use.

Clinical Pharmacology

Introduction of potent smallpox vaccine containing living vaccinia viruses into the superficial layers of the skin results in viral multiplication, immunity, and cellular hypersensitivity. With the primary vaccination, a papule appears at the site of vaccination on about the third day. This becomes a vesicle on the fifth or sixth day, which becomes pustular, umbilicated, and surrounded by erythema and induration. The maximal area of erythema is attained between the eighth and twelfth day following vaccination (usually the tenth). The erythema and swelling then subside, and a crust forms which comes off about the twenty-first day. At the height of the primary reaction known as the Jennerian response, there is usually regional lymphadenopathy and there may be systemic manifestations of fever and malaise.

The primary vaccination elicits immunity, which wanes after several years, and an allergic sensitization to viral protein which persists. This allergy is manifested by the appearance of a papule and a small area of redness appearing within the first 24 hours after revaccination; this may be the maximum reaction but not infrequently vesicles appear in 24 to 48 hours with ultimate scabbing. The peak of this type of reaction is passed in three to five days.

Complications that may follow either primary or revaccination include: encephalitis, encephalopathy, transverse myelitis, acute infectious polyneuritis; generalized rashes (erythematous, urticarial, nonspecific); and/or death. Accidental infection (autoinoculation); generalized rashes (erythematous, urticarial, nonspecific); and secondary pyogenic infections at the site of vaccination. Such complications may result in severe disability, permanent neurological sequelae, and/or death.

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Indication and Usage

Smallpox vaccine is indicated for immunization against smallpox.

The judicious use of smallpox vaccine has been reported to have eradicated smallpox. At the World Health Assembly in May 1980, the World Health Organization (WHO) declared the world free of smallpox. Smallpox vaccination of civilians is now contraindicated.

Dosage and Administration

DIRECTIONS FOR RECONSTITUTION

Reconstitution of Dryvax utilizes the principle of transfer of diluent from its container to the vaccine vial by means of the vacuum present in the vaccine vial. Careful attention to the following directions will preserve the vacuum until needed for diluent transfer and will assure proper reconstitution of the lyophilized vaccine.

Precautions

GENERAL

After completion of the multiple-pressure or multiple-puncture vaccination, blot away any vaccine remaining on skin at vaccination site with clean, dry gauze or cotton.

The vaccine vial, its stopper, the diluent cartridge, the needle used for administration, and any gauze or cotton that came in contact with the vaccine should be burned, boiled, or autoclaved before disposal.

Individuals susceptible to adverse effects of vaccinia virus, e.g., those with eczema, other skin conditions, wounds, or burns and for siblings or other household contacts of such individuals.

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1. Lift up tab of aluminum seal on vaccine vial. DO NOT BREAK OFF OR TEAR DOWN TAB.
2. Wipe off vial stopper with an alcohol sponge and allow to dry.
3. Place vaccine vial upright on a hard, flat surface.
4. To reduce viscosity of cold diluent, warm by holding diluent-cartridge in palm of hand for a minute or so. Remove rubber needle cover from needle of diluent-cartridge with needle pointing UP to prevent accidental loss of diluent.
5. Turn diluent-cartridge so that needle is pointing down. If diluent has not moved to needle-end of diluent-cartridge, snap diluent-cartridge with finger. DILUENT MUST BE IN THE NEEDLE-END OF DILUENT-CARTRIDGE BEFORE CARRYING OUT STEP 6.
6. With a rapid, forceful motion, THRUST diluent-cartridge needle PERPENDICULARLY through stopper of vaccine vial (Fig. 2). The THRUST should be forceful enough to insert the needle to its full length—up to the hub. The vacuum present in vaccine vial will pull diluent from the cartridge into the vial.

NOTE: Should diluent fail to enter vaccine vial, withdraw diluent-cartridge from vaccine vial gently to effect complete reconstitution. Each vial is tested for presence of vacuum before shipment from the manufacturer. Therefore, prior to assuming loss of vacuum has occurred, make sure Reconstitution Steps 1 through 6 have been performed correctly.

7. Withdraw diluent-cartridge and discard.
8. Allow vaccine vial to stand undisturbed for 3 to 5 minutes. Then if necessary, swirl vial gently to effect complete reconstitution.
9. Record date of reconstitution in space provided on vaccine vial label.
10. Store reconstituted vaccine below 4°C (39°F), preferably below 0°C (32°F), when not in actual use.

DIRECTIONS FOR USE OF RECONSTITUTED VACCINE

1. Remove aluminum seal from vaccine vial by pulling down "tear off" tab.
2. Remove rubber stopper from vaccine vial and discard.
3. Remove white beaded foam platform from carton and break platform at its thinnest point. Discard larger portion of platform.
4. Place opened vial of vaccine upright in hole of remaining portion of platform. When so placed, the vaccine vial is at the proper angle for efficient dipping with the bifurcated needle.
5. Prepare site chosen for vaccination with suitable cleansing agent and allow to dry.
6. Remove plastic cap from needle-case.
7. Gently shake out (by wrist-rotating action rather than by vigorous vertical shaking) the butt-end of a sterile needle. Catch butt-end of needle and gently pull bifurcated point end free.
8. Dip bifurcated point of needle into vaccine. The needle will pick up a drip of vaccine in space between the two points.
9. Deposit the drop of vaccine onto clean, DRY site already prepared for vaccination. Do not drip needle into vaccine if needle has touched skin.
10. With the same needle, and using multiple-pressure or multiple-puncture technique, vaccinate through drop of vaccine. Only 2 or 3 needle pressures or punctures are recommended for primary vaccination; 15 for revaccination.
12. Repeat steps 7 through 11 for each individual to be vaccinated.
13. If vaccine is to be stored for subsequent use, push vial, neck-end first, into proximal, open end of needle-case cap. In so doing, the vial will engage a protective stopper-cap. Remove capped vial from needle-case cap and replace needle-case cap on needle-case. WITHOUT REMOVING FROM PLATFORM, store capped vial below 4°C (39°F), preferably below 0°C (32°F).
14. When next needed, remove vial from refrigerator or freezer and carefully take off stopper-cap.
15. Repeat Steps 5 through 11.
16. If vaccine is to be restored for subsequent use, replace stopper-cap and store below 4°C (39°F), preferably below 0°C (32°F).

Parenteral drug products should be inspected visually for particulate matter and dis- coloration prior to administration, whenever solution and container permit.

INTERPRETATION OF RESPONSES

The vaccination site should be inspected 6 to 8 days after vaccination. The response should be interpreted as follows:

Primary Vaccination

A primary vaccination which is successful should show a typical Jennerian vesicle (see "Clinical Pharmacology") and may be accompanied by fever, regional lymphadenopathy, and malaise persisting for a few days. If the typical vesicle is not observed, revaccination procedures should be checked and revaccination repeated with another lot of vaccine on a different area of skin until a successful result is obtained.

Revaccination

Following revaccination, two responses are defined by the WHO Expert Committee on Smallpox, eliminating use of older terms such as "accelerated," "vaccinoid," and "immune."

a. "Major Reaction"

A vesicular or pustular lesion or an area of definite palpable induration or congestion surrounding a central lesion which may be a crust or ulcer. This reaction indicates that virus multiplication has most likely taken place and that the revaccination is successful. Major reactions, especially when there has been an interval of many years since the last successful vaccination, may be accompanied by fever, regional lymphadenopathy, and malaise persisting for a few days.

b. "Equivoical Reaction"

Any other reaction should be regarded as equivocal. These responses may be the consequence of immunity adequate to suppress virus multiplication or may represent only allergic reactions to an inactive vaccine. If an equivocal reaction is observed, revaccination procedures should be checked and revaccination repeated with another lot of vaccine.

How Supplied

Combination package of 1 vial of Dried Smallpox Vaccine, 1 container of Diluent (0.25 mL sufficient for 100 vaccinations), and 100 sterile bifurcated needles.

Storage

Store DRYVAX in the refrigerator (2° to 8°C, 35° to 46°F). RECONSTITUTED DRYVAX may be used for 3 months if stored below 4°C (39°F), preferably below 0°C (32°F), when not in actual use. At time of reconstitution, record date in space provided on vial label. DRYVAX should not be used after the expiration date regardless of whether it is in the dry or reconstituted form.

References

2. MMWR 33:37, 1984.