INSTRUCTIONS FOR USE AND STORAGE OF LIVE ANTI-PLAGUE DRY VACCINE

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INSTRUCTIONS FOR USE AND STORAGE OF LIVE ANTI-PLAGUE DRY VACCINE

Translation from Russian [to Swedish]

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Address: Sundbyberg 4. Telephone 03/28 28 80
Label on Vaccinia Ampula

USER MINISTRY OF HEALTH

"Mikrob," Institute for Microbiology and Epidemiology of the Southwestern USSR

Dry, live anti-plague vaccine 1, 17

In the box _____ ampules In the ampule _____ doses

for intravenous use with ___ cm³ physiological salt solution

Dilution: for exterior use with ___ cm³ of physiological salt solution

for hypodermic use with ___ cm³ of physiological salt solution

To be stored in a dark place at a temperature not above +4°C

Series No...... Control No...... Usable until......19

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1) Stamped on

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INSTRUCTIONS FOR USE AND STORAGE OF
LIVE, DRY ANTI-PLAGUE VACCINE

1) Live, dry anti-plague vaccine is a suspension of
live bacteria vaccine strains of the plaque bacillus enroled
in a saccharose gelatin.

2) Live, dry anti-plague vaccine builds up active
immunity, lasting up to one year. When annual inoculations
of population groups are carried out, revaccination takes
place after 12 months.

In especially difficult epidemiological condi-
tions, revaccination is carried out after six months, pre-
ferably twice.

In places where inoculations are given for the
first time, or after a delay of some years, double vaccina-
tion should be done so that a basic immunity may be es-
ablished. In double inoculation, the interval between the
first and the second inoculations should be 20 to 25 days.
The dose for the second inoculation should be the same as
for the first.

3) The vaccine should be stored in a room where the
temperature is not above +4°C. (It can also be stored under
refrigeration, if it is not exposed to repeated thawing and
freezing). Under these conditions, the vaccine can be stored
for six months. After six months of storage, the vaccine
is again checked by the institute which produced it and, if
found usable, is used in accordance with instructions, by
the authorities which carry out the inoculations with the
vaccine series in question.

Installations unable to provide storage at the
proper temperature are prohibited from keeping vaccine sup-
plies for a longer period than 10 to 15 days.

4) Counterindications for inoculations are acute
diseases of the heart, uncompensated heart defects, severe
chronic diseases of liver, kidney, and other internal
organs, active forms of tuberculosis, severe cases of hyper-
tony and arteriosclerosis, cachexia, severe cases of furunc-
culosis, diabetes, and the second half of pregnancy.
For chronic or latent cases, the inoculation of vacci-
nae or guinea-pig to the inoculation is recom-
med. Persons suffering from acute diseases, in advanced and those
whose body temperature is high should be inoculated when
they have recovered and are able to do so.

5) Bayr. live vaccine may be applied
intracutaneously, intracutaneously, or even intravenously, and be
produced in swine or cattle of different breeds. Such settle-
ments may be used for subcutaneous, intracutaneous, or subcutaneous
inoculations, depending upon the method of injection.

6) When inoculation is carried out, the following
should be taken into consideration:

a) For increased immunity, intracutaneous inocu-
lation is to be preferred to subcutaneous inoculation, with
percutaneous next in the order of preference. Hence, healthy
population groups, in the seven to 70 age range showing no
contraindications are inoculated intracutaneously. Children
under seven, women in the first half of the pregnancy period,
and nursing children are inoculated percutaneously due to the
lesser reaction to this method. During a complicated
epidemiological situation, persons with relative counter-
indications are also inoculated percutaneously, namely those
who are weakened by previous illness and those who have mild
forms of the chronic illnesses listed above. Persons of
advanced age (over 50) may be inoculated intracutaneously or
percutaneously, according to the medical indications. Chi-
ldren under the age of two years are exempt from inoculation.

7) The ampules and their content are to be thoroughly
checked before and after the dilution. If there are cracks,
foreign matter, unbroken bumps, or uneven suspension present,
the vaccine should be discarded. The vaccine should be
diluted immediately prior to the inoculation. Vaccine which
has been diluted but not used within four hours is destroyed
through boiling or the addition of a sterilization liquid.
All handling of the vaccine as well as its application should
be done with observation of all sterilization rules. Before
the dilution the person who carries it and should wash his
hands with soap and rub them with alcohol. The ampule and
the file are also wiped with alcohol. The upper part of the
neck of the ampule is filed, wiped with alcohol and very care-
fully flamed, so that the ampule does not break. Then.
the neck of the ampule is broken and a sterile physiological salt solution in the amount required for the vaccination method in question is introduced into the ampule by means of a boiled syringe (see points 8, 11 and 14.) The opening in the ampule is temporarily covered with a sterile piece of cotton and the contents shaken, whereupon it is held in the hand for three to five minutes to warm it slightly and it is shaken once more until the dry vaccine is transformed into an even suspension. The obtained bacterial suspension is withdrawn from the ampule by means of a sterile pipette or syringe with a long cannula, and is transferred to a bottle containing the amount of physiological salt solution required for dilution of the vaccine.

8) The volume of physiological salt solution in which the vaccine must be diluted for intracutaneous inoculation is given on each ampule and on the label of the box. First, 1 to 3 cm³ of physiological salt solution is added to the ampule, and when the vaccine is completely dissolved, it is transferred, as described above, to the bottle containing the volume of physiological salt solution called for on the box label or on the ampule. An allowance should be made for the volume of salt solution introduced into the ampule to dissolve the vaccine.

After such dilution, one dose for intracutaneous inoculation of persons over the age of 14 is .2 cm³.

For inoculation of children under 14 years the vaccine is diluted with twice the amount of physiological salt solution called for on the label, which gives a dose of .15 cm³ for children 7 to 10 years of age, and .2 cm³ for children 10 to 14 years of age.

9) When the vaccine has been diluted for intracutaneous inoculation in accordance with the above, the injection is done, with all the rules of asepsis observed, strictly intracutaneously, preferably in the upper one-third of the shoulder, or in the upper part of the inside of the left arm.

The appearance of a whitish condensed blister ("lemon peel") at the place of vaccination indicates a correctly carried out inoculation. Cannulas and syringes are to be sterilized before all inoculations only by means of boiling.
10) One local and one general reaction can be observed in vaccinated persons:

a) The local reaction appears in almost all cases, in the form of swelling, reddening, condensation (constriction), and pain at the place of vaccination. Inoculations are often followed by a disturbance in the regional lymph glands and pain when they are touched, or tenderness in the armpit may be experienced, without a visible disturbance of the lymph glands. A papilla may form on the place of injection, which turns into a pustule. The pustule most often dissolves through the formation of a scab three to five days after the inoculation. All local symptoms begin to form 8-10-14 hours after the inoculation, reach full development toward the end of the first or the beginning of the second day, and gradually disappear after three to five days (more seldom after seven to eight days.)

b) The general reaction shows up in indisposition, chills, headaches, and fever, most often up to 37.5°C, less frequently up to 38°C, and very rarely up to 39°C. On occasion, nausea and vomiting occur. The general reaction appears during the first days, and disappears after one to two days. The general reaction fails to appear in some of those inoculated.

11) The amount of physiological salt solution required for dilution for percutaneous inoculation is given on the label of the box containing the vaccine. At such dilution, the dose for persons over 10 years of age is .15 cm³ (three drops from an eye pipette), for children from seven to ten .10 cm³ (two drops), and for children between two and seven years .05 cm³ (one drop). The vaccine diluted for percutaneous inoculation is left in the ampule.

12) Percutaneous inoculation against plague is done on the inside of the lower arm, or on the outside of the upper third of the shoulder, in the following manner:

The skin at the spot selected is carefully rubbed with a piece of cotton moistened with alcohol. The alcohol is let dry, whereupon the outer epidermic layer (horny layer) is lightly scraped with a sterile vaccination point or Huberts lancet, in three areas of the disinfected skin in the case of children over 10 and adults, in two areas in
children seven to 10, and in one area in children two to seven. The scraping is stopped as soon as the area red-
dens. Production of a much moistened area should not be
stirred for. The area should be 1½ to 2 cm², and the dis-
tance between areas should be 2 to 3 cm. To the area pre-
pared in this manner, drops of vaccine are added, whereupon
eight scratches are made, as in smallpox vaccination, four
lengthwise and four crosswise of the vaccine drops. The
vaccine is carefully rubbed in over the entire surface of
the prepared spot, let dry and become covered with a yellow-
ish crust. For this inoculation 10 to 15 minutes should be
reserved.

13) Percutaneous inoculation is followed by a plain
reaction, mainly local. In most cases, the general reaction
is unnoticeable or absent. Local reaction symptoms begin to
appear 8 to 14 hours after the inoculation and reach full
development after 20 to 30 hours, in rare cases after 48
hours.

The reaction is evidenced at the place of inocu-
ation by hyperemia, a small swelling, insignificant vesicles
in the scratches, and, on occasion, infiltration in the skin.
A general reaction in the form of fever or indisposition, and
enlargement or tenderness in the regional lymph glands is
seldom observed. If fever occurs, it is seldom above 37.5°C
and usually does not last over a few days.

14) For subcutaneous inoculation, the dry vaccine
contained in the ampules must be dissolved in the volume of
physiological cooking salt solution called for on the vaccine
label. Dilution of the vaccine is done according to the
method described for intracutaneous inoculation. The diluted
vaccine is injected, with observance of all the rules of
asepsis, under the skin at the lower corner of the shoulder
blade or under the skin of the shoulder, for adults and
children over 14 in the amount of 1 cm³, for children 10 to
14 in the amount of .5 cm³, and for children 7 to 10 in the
amount of .3 cm³.

15) After subcutaneous inoculation, a local and a
general reaction is observed:

a) The local reaction appears in almost all
cases, and is in the form of swelling, reddening, and pain at the place of inoculation. More rarely, the regional lymph glands show swelling. All of these symptoms begin developing 6 to 10 hours after the inoculation (more rarely after two or three days) and usually disappear after four to five days.

b) The general reaction is evidenced in indisposition, headaches, a rise in temperature up to 37.5°C, more rarely up to 38-39°C, and in rare cases up to over 39°C. On occasion, nausea and vomiting occurs. The symptoms begin to appear during the first days, and disappear after one to two days.

16) When inoculations are being carried out, the vaccine in the bottle or in the ampule should be shaken each time before filling the syringe or the pipette. The syringe or pipette must contain only one dose at a time.

17) Medical control is kept of the inoculated persons in accordance with general rules.

18) Before the inoculations are begun, those to be vaccinated are registered in a special journal according to the following formula:

<table>
<thead>
<tr>
<th>Last name</th>
<th>Age</th>
<th>Sex</th>
<th>Address</th>
<th>Previous Date</th>
<th>Dose and Inoc. of vaccine</th>
<th>Vac. series no.</th>
</tr>
</thead>
<tbody>
<tr>
<td>First name</td>
<td>Patronymic</td>
<td>Inoculation method</td>
<td>Character of the local &amp; general reactions</td>
<td>Remarks</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Without exception, all those subject to vaccination but not vaccinated are to be entered in another journal according to the same formula.

19) A certificate of vaccination must be issued for each vaccinated person.

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