BCG VACCINE

MÉRIEUX SEED DERIVED FROM STRAIN 1077 FOR INTRADERMAL USE

COMPOSITION

For 0.1 ml of reconstituted vaccine:

• Powder for suspension for injection:
– Revivable germs
(cultivable attenuated live bacillus particles, Mérieux seed)
(derived from strain 1077) . . . . . between 800 000 and 3 200 000 units
– Excipients:
Dextran - Glucose - Triton WR 1339 - Human albumin
• Diluent:
Water for injections . . . . . up to 0.1 ml

This vaccine conforms with the W.H.O. standards.

Freeze-dried live vaccine produced from an attenuated strain of *Mycobacterium bovis*.

PHARMACEUTICAL DOSAGE FORM

Injectable suspension, obtained by reconstituting the powder with the diluent.
– Vial of 10 doses (0.1 ml) for adults and children over one year or vial of 20 doses (0.05 ml) for children under one year, including the new-borns, to be reconstituted with 1 ampoule of 1 ml of diluent.
– Vial of 20 doses (0.1 ml) for adults and children over one year or vial of 40 doses (0.05 ml) for children under one year, including the new-borns, to be reconstituted with 1 ampoule of 2 ml of diluent.

MARKETING AUTHORIZATION HOLDER

Aventis Pasteur SA
2, avenue Pont Pasteur, F-69007 Lyon

INDICATION

This medicament is a VACCINE.

This medicament is recommended in the prevention of primary-tuberculosis, especially with the most serious manifestations.

CONTRAINDICATIONS

This medicinal product MUST NOT BE USED in the following cases:
– Congenital or acquired immunodeficiencies affecting cellular immunity.

SPECIAL CASE OF CHILDREN BORN TO HIV SEROPOSITIVE MOTHERS

The obligatory passage of maternal antibodies of the IgG type through the placenta makes it impossible to interpret the serology of the child until the age of about 9-10 months (persistence of the maternal antibodies has been detected up to 14 months).

It is therefore necessary to wait until the child has been found to be seronegative, as determined by immuno-transfer (Western Blot) with the support, if necessary, of techniques for detecting the viral genome, before confirming that the child is not infected.

1. If the child is not infected, BCG may be used in the normal manner (cf. PRECAUTIONS FOR USE).
2. If the child is infected, BCG vaccine is contraindicated irrespective of the child's condition, given the potential risk of development of "BCG-itis" in the vaccinated child. The advice of a specialized medical team is required.

– Temporary contraindications: extensive progressive dermatitis.

If there is any doubt, it is essential to consult your doctor or your pharmacist.

PRECAUTIONS FOR USE

Use this medicinal product with care in case of:
– In subjects who have suffered from a secondary reaction to a previous BCG vaccination (in particular a cheloid or lupoid local reaction), revaccination should be discussed in relation to the expected benefits.
– Immunodeficiency within the family circle of the vaccinated subject (in particular in the case of uninfected children born to HIV seropositive mothers): it is advisable to avoid any contact between cellularly immunodeficient individuals and the evolutive vaccinal lesion.
It is preferable to verify that tuberculin reactions are negative before vaccinating. A positive tuberculin reaction is confirmation of the vaccination; it is recommended to carry this out at the earliest 3 to 6 months after injection.
– The first vaccination is compulsory before 6 years of age. Vaccination may be performed from birth in the event of a risk of early exposure to the disease. For maximum protection, the vaccine should be administered as quickly as possibe after birth. The vaccination is compulsory at an earlier stage in public structures (crèches, nursery schools).
– A tuberculin screening skin test is not generally carried out before a BCG vaccination; if it is performed, a subject found to be positive does not need to be vaccinated.

If there is any doubt, do not hesitate to consult your doctor or your pharmacist.

Keep out of the reach of children.

DRUG INTERACTIONS AND OTHER INTERACTIONS

The BCG vaccine may be routinely given to any child exposed early to the risk of contact with the disease (tuberculosis). It may be given at the same time as vaccinations against Diphtheria - Tetanus - Whooping cough (DTP), Diphtheria - Tetanus (DT), Tetanus (TT), Measles, Poliomyelitis (Injectable Inactivated Vaccine = IPV or Oral Polio Vaccine = OPV), hepatitis B and yellow fever.

In order to avoid possible interactions between several medicinal products, any other ongoing treatment should be systematically reported to your doctor or to your pharmacist.

PREGNANCY - BREAST FEEDING

There is no indication to vaccinate women during pregnancy. If you find out that you are pregnant, consult your doctor.
Breast feeding can continue despite vaccination with BCG vaccine.

As a general rule, during pregnancy and breast feeding, it is always recommended to ask your doctor's or pharmacist's advice before using a medicinal product.

DOSAGE

The vaccinating dose is:

1 dose = 0.05 ml	For children under one year of age including the new-borns.
1 dose = 0.1 ml	For children over one year of age and adults.

PREPARATION OF A VACCINATING DOSE

1

For the reconstitution:
Transfer 1 or 2 ml of diluent (PHARMACEUTICAL DOSAGE FORM section) to the vial containing the vaccine with the aid of a sterile syringe fitted with a long needle.

2

Shake the vial gently and mix the ingredients by withdrawing the reconstituted vaccine into the syringe, once or twice, so as to make a fine and homogeneous suspension.

For the dose to be injected, see POSOLOGY section.
Use a short needle, see METHOD AND ROUTE OF ADMINISTRATION section.

10-dose vial + 1 ml diluent ampoule
10 doses for children over one year and adults,
20 doses for children under 1 year including new-borns.

20-dose vial + 2 ml diluent ampoule
20 doses for children over one year and adults,
40 doses for children under 1 year including new-borns.

MODE AND ROUTE OF ADMINISTRATION

Special care should be applied during the opening and reconstitution of the vaccine so that the vaccine does not spill from the vial.
Reconstitute the powder only with the diluent supplied by the manufacturer.

For the reconstitution: transfer the required quantity of diluent water for injections (1 or 2 ml) to the vial containing the vaccine with the aid of a sterile syringe fitted with a long needle. Shake the vial gently and mix the ingredients by withdrawing the reconstituted vaccine into the syringe, once or twice, so as to make a fine and homogeneous suspension.

While the doses are being withdrawn from the vial, the vaccine should be exposed to the light for the shortest period possible, and never for more than 4 hours. If it is not used immediately after reconstitution, the vaccine should be stored between + 2°C and + 8°C and protected from light, and any opened vial remaining at the end of a vaccination session (maximum 4 hours) should be destroyed.

The vaccine is intended to be injected strictly via the intradermal route, avoiding the subcutaneous route. The subject's skin must not be cleaned with an antiseptic.

For each injection, use one sterile syringe for intradermal use, fitted with a fine (5/10 mm) short (1 cm) bevelled sterile needle.
Hold the arm, and, stretching the skin, introduce the needle with the bevel upwards, completely tangentially to the skin. As soon as the bevel has penetrated the skin, push the plunger gently to introduce the liquid under the skin.
This injection, carried out in the deltoid region of the arm or on the external face of the upper thigh, should produce an orange-skin papule with a diameter of about 6 to 8 mm. It is recommended that the injection site should not be protected.

SIDE EFFECTS

Like any active product, this medicinal product may in certain children cause effects which are disturbing to a greater or lesser extent:

Local reactions:
It is quite normal to observe a local reaction after vaccination with BCG.
– A small, swollen and sensitive red spot appears at the injection point and gradually turns into a small vesicle and then into an ulcer in 2 to 4 weeks. The reaction generally persists for 2 to 5 months and leaves a superficial scar 2 to 10 mm in diameter in almost all children. Only dry dressings are recommended.
– In rare cases, an abscess may appear at the point of injection, or satellite adenitis, leading in exceptional cases to suppuration.
– Exceptional cases of lupus vulgaris at the injection point have been reported.

Systemic reactions:
– Some rare cases of anaphylactic reactions such as Quincke's oedema have been reported.
– Cases of infections related to the spreading of BCG in the body, such as osteitis, meningitis and "generalized infectious BCG-itis" have been reported in exceptional cases in literature.
– A risk of generalised reaction to BCG exists in immunodepressed individuals vaccinated with BCG or living in contact with a vaccinated individual.

Report to your doctor or your pharmacist any unwanted and disturbing effects which might not be mentioned in this leaflet.

STORAGE

Do not exceed the expiry date stated on the external packaging.

SPECIAL PRECAUTIONS FOR STORAGE

The BCG vaccine should be stored at a temperature of between + 2°C and + 8°C (in a refrigerator) and away from light. It is even more stable when it is stored at a temperature of – 20°C.

The diluent should not be frozen, but stored at low temperature.

Rev. 05/2000

Aventis Pasteur

Aventis