

MODULE 1.5.5.2

PATIENT INFORMATION LEAFLET (Clean Copy)

Read all of this leaflet carefully before you start using BCG VACCINE AJV freeze-dried powder for reconstitution for intradermal injection:

- keep this leaflet. You may need to read it again, and
- if you have further questions, please ask your doctor or your pharmacist.

BCG VACCINE AJV

Scheduling status

S2

Proprietary name and dosage form

BCG VACCINE AJV freeze-dried powder for reconstitution for intradermal injection.

WHAT BCG VACCINE AJV CONTAINS

- The active substance is: 0,75 mg Mycobacterium bovis (BCG), Danish 1331 and sodium glutamate as stabiliser per 1 ml of the reconstituted vaccine.
- The other ingredients are: The Reconstituting fluid for BCG VACCINE AJV contains: magnesium sulphate, dipotassium phosphate, citric acid monohydrate, L-asparagine monohydrate, ferric ammonium citrate, glycerol 85 %, ammonia solution 25 % and water for injection.

WHAT BCG VACCINE AJV IS USED FOR

This medicinal product is a vaccine and is used for the prevention of tuberculosis in infants, children and adults but does not ensure complete immunity. Babies should be immunised as soon as possible after birth.

BEFORE YOU ARE IMMUNISED WITH BCG VACCINE AJV

Do not use BCG VACCINE AJV:

- if you are hypersensitive (allergic) to any of the ingredients of BCG VACCINE AJV,
- if you have a weakened resistance towards infections due to a disease in/of your immune system,
- if you are receiving medical treatment that affects the immune response e.g. corticosteroids, radiotherapy or other immunosuppressive treatment; infants who are exposed to immunosuppressive therapy while in utero or via breastfeeding must not be vaccinated with BCG VACCINE AJV for as long as a postnatal influence of the immune status of the infant remains possible. (e.g. maternal treatment with TNF α antagonists),
- if your immune status is in question,
- if you are infected with HIV;

however, BCG VACCINE AJV may be given where benefits outweigh risks for vaccination such as infants born to HIV-infected women, but

- whose HIV infection is negative (i.e. laboratory confirmed), or
- whose HIV infection is unknown and demonstrate no clinical signs or symptoms suggestive of HIV infection;
- in patients suffering from an acute illness, high fever and in serous skin disease, vaccination should be postponed,
- if you are suffering from a malignant condition (e.g. lymphoma, leukaemia, Hodgkin's disease or other tumours of the reticulo-endothelial system),
- if you are already receiving medicines that are active against the bacteria that cause tuberculosis, and
- in infants who are born to mothers who are taking medicines that are active against the bacteria that cause tuberculosis.

Take special care with BCG VACCINE AJV:

- if BCG vaccination is deemed necessary after an individual has received immunosuppressive agents, such as antineoplastic chemotherapy for cancer or high dose systemic corticosteroid therapy, the advice of a specialist must be sought before the vaccination is performed due to the risk of a disseminated BCG infection,
- if you or your child has eczema. BCG VACCINE AJV can still be given into an area of normal skin if the eczema in other areas is not infected, and
- if you or your child had a skin test for Tuberculosis infection that has come up positive. BCG VACCINE AJV is not helpful in such people and there can be problems at the injection site if it is given.

Pregnancy and breast-feeding

If you are pregnant or breast feeding your baby, please consult your doctor, pharmacist or other health care professional for advice before being vaccinated.

Safety in pregnancy has not been established. BCG vaccination during lactation is believed to pose no risk to the breast-feeding child.

Important information about some of the ingredients of BCG VACCINE AJV:

Using other medicines with BCG VACCINE AJV:

Always tell your healthcare professional if you are taking any other medicine.

Other vaccines can be given at the same time as BCG VACCINE AJV, but must be given in different areas of the body. Other live vaccines must either be given at the same time or normally not less than 4 weeks after BCG vaccination.

No other vaccines should be injected into the arm or leg where BCG VACCINE AJV was given for 3 months afterwards.

HOW TO USE BCG VACCINE AJV:

Your doctor, pharmacist or other healthcare professional will immunise you as follows:

Children below 1 year of age: 0,05 ml of the reconstituted vaccine by intradermal injection.

0,1 ml of the reconstituted vaccine should be given to children 1 year or older, and adults.

The injection should be given slowly, strictly intradermally, into the upper layer of skin of the right arm in the region over the distal insertion of the deltoid muscle (about one-third down the upper arm). Use a sterile fine short needle for each injection (25 G/0,50 mm or 26 G/0,45 mm).

Alcohol or disinfectant used to clean the skin must be allowed to evaporate before injection to prevent inactivation of the vaccine.

Reconstitution:

Only Diluted Sauton Medium may be used for reconstitution of BCG VACCINE AJV.

The rubber stopper must not be wiped with antiseptic or detergent. If alcohol is used to swab the rubber stopper of the vial, it must be allowed to evaporate before the stopper is penetrated with the syringe needle.

The vaccine should be visually inspected before and after reconstitution for any foreign particles before administration.





The Reconstituting fluid for BCG VACCINE AJV must be cooled to $< 8^{\circ}\text{C}$ before use. Transfer 1 ml Reconstituting fluid for BCG VACCINE AJV with a sterile syringe with a long needle into the vial containing the vaccine. Carefully invert the vial a few times to resuspend the freeze-dried BCG thoroughly, which will produce a homogenous, slightly opaque and colourless suspension. Gently swirl the vial of resuspended vaccine before drawing up each subsequent dose. Avoid vigorous shaking. Thoroughly mixed the vaccine is a homogenous, slightly opaque and colourless suspension. For the multidose vial a separate sterile syringe and needle must be used for each injection.

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Vaccine Vial Monitor (Figure 1): A vaccine vial monitor (VVM) contains a heat-sensitive material that is printed on the vaccine vial product label or cap to register cumulative heat exposure over time.

Health workers must compare the colour of the heat sensitive square to a reference circle to determine whether or not a vial of vaccine should be discarded because it has been exposed to too much heat.

Figure 1: The Vaccine Vial Monitor

-  1. Inner square is lighter than the outer ring.
USE the vaccine, if expiry date not reached.
-  2. As time passes. Inner square is still lighter than the outer ring.
USE the vaccine, if expiry date not reached.
-  3. Discard point: Inner square matches the colour of outer ring.
DO NOT USE the vaccine.
-  4. Beyond the discard point: Inner square is darker than outer ring.
DO NOT USE the vaccine.

POSSIBLE SIDE EFFECTS

BCG VACCINE AJV can have side effects.

Not all side effects reported for this medicine are included in this leaflet. Should your general health worsen when immunised with this medicine or if you experience any untoward effects after vaccination, please consult your doctor, pharmacist or other health care professional for advice.

More frequent: A local reaction is normal after BCG. A small tender red swelling appears at the site of the injection which gradually changes to a small vesicle. An ulcer may appear 2 to 4 weeks after vaccination. An adherent dressing is not recommended. The reaction usually subsides within two to five months and in practically all children leaves a superficial scar 2-10 mm in diameter. In a minority of neonates, a scar may not be seen, due to the immaturity of the immune system.

Less frequent: Enlargement of the lymph nodes under your arms (< 1 cm) may appear following immunisation.

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If you have swelling at the injection site that does not settle or seems to be getting bigger, or an ulcer that gets bigger and seems very slow to heal, or if you notice swellings in your armpit that are larger than one centimeter across, you should tell your doctor or nurse. These are not normal reactions to the vaccine.

Other side effects

Less frequent: several allergic reactions (such as redness of the face and neck, swelling of the face, throat or neck, skin rash, breathing difficulties and collapse) can occur. These often start very soon after injection, and may happen while you are still in the clinic. If the symptoms start after leaving the clinic, it is important that you contact a doctor urgently or visit the nearest hospital emergency department.

Less frequent:

- headache,
- fever,
- swelling of gland in the armpit to more than 1 cm across, and
- an ulcer that lets out fluid at the injection site. If this happens, the ulcer should be allowed to dry and tight clothes should be avoided. If the ulcer seems very slow to heal, contact your doctor, pharmacist or nurse for advice.

Other less frequent side effects:

- inflammation of gland, sometimes with abscesses and release of fluid from the swellings; inadvertent subcutaneous injection produces abscess formation and may lead to ugly retracted scars,
- infection with the bacteria in the vaccine (*Mycobacterium bovis BCG*) can occur, that can spread through the body, including to the bones; this does not usually happen in people who are otherwise healthy but it has been reported. These infections need to be treated in a

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similar way to the treatment of TB,

- osteitis, lupus types of reaction and keloid formation may occur, and
- osteomyelitis.

STORING AND DISPOSING OF BCG VACCINE AJV

Keep all medicines out of the reach and sight of children.

During storage in refrigerator (between 2-8 °C) the product is stable until indicated date of expiration.

Reconstituted vaccine may be kept cold for up to six hours, protected from light.

Reconstituting fluid for BCG VACCINE AJV may be kept at room temperature or cold, but should not be frozen.

PRESENTATION OF BCG VACCINE AJV

Boxes containing 10 x 20 infant doses (0,05 ml for infants under 1 year of age).

10 brown vials BCG VACCINE AJV.

10 colourless vials Reconstituting fluid for BCG VACCINE AJV.

IDENTIFICATION OF BCG VACCINE AJV

Freeze-dried vaccine: A white powder or crust.

Reconstituting fluid: A clear colourless solution.

Reconstituted vaccine: Slightly opaque and colourless suspension.

REGISTRATION NUMBER

29/30.2/0643


**NAME, BUSINESS ADDRESS AND TELEPHONE NUMBER OF THE HOLDER OF THE
CERTIFICATE OF REGISTRATION**

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DATE OF PUBLICATION

- Date on the registration certificate of the medicine: 06 May 2011
- Date of the most recently revised patient information leaflet as approved by SAHPRA: November 2017