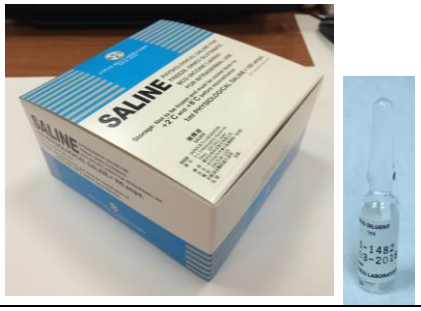
附件 1

國家衛生研究院製與日本製皮內注射型卡介苗相異處比較表

	國家衛生研究院製卡介苗	日本製皮內注射型卡介苗
單次接種之懸浮液體積	不論年齡均為 0.1 毫升(mL)	未滿 1 歲：0.05 毫升(mL) 1 歲以上：0.1 毫升(mL)
單次接種之懸浮液劑量	不論年齡均為 0.05 毫克(mg)	未滿 1 歲：0.025 毫克(mg) 1 歲以上：0.05 毫克(mg)
卡介苗	10 支安瓿/盒 1.5 毫克(mg)/安瓿 	100 支安瓿/盒 0.5 毫克(mg)/安瓿 
稀釋液	10 支安瓿/盒 10 毫升(mg)/安瓿 	100 支安瓿/盒 1 毫升(mL)/安瓿 
卡介苗撥瓶時是否需使用安瓿切割器	不需要	需要 
稀釋方式	抽 3 毫升(mL)稀釋液，先注入一半於卡介苗安瓿內，搖勻後再注入另一半	抽完瓶內 1 毫升(mL)稀釋液，全部注入卡介苗安瓿內搖勻
稀釋後懸浮液儲存時限	超過 2 小時未用完，需丟棄	超過 6 小時未用完，需丟棄

備註：未表列於本表者，則依現行(疾病管制署/國家衛生研究院製卡介苗)作業方式進行。

凍結乾燥卡介苗（日本）
Freeze-Dried Glutamate BCG Vaccine
（Japan）
皮內注射使用

【說明】

本品為由牛型結核分枝桿菌(*Mycobacterium bovis*)的減毒株製成之凍結乾燥卡介苗，用來預防結核病，並且符合世界衛生組織(WHO)之規格。

【成份】

1. Live Bacteria of Calmette and Guerin (as approximately 70% moist bacteria)…… 0.5mg/ampoule
2. Sodium Glutamate (as a stabilizer) …… 2.0mg/ampoule

【使用方法】

1. 該疫苗為皮內注射用，每次接種使用之卡介苗懸浮液劑量，依接種年齡說明如下：
   未滿 1 歲：0.05 毫升(mL)。
   1 歲以上：0.1 毫升(mL)。每次接種卡介苗須選用無菌且刻度精確的專用空針(註 1)。注射部位需以酒精進行消毒，待乾燥後再行接種。
2. 開啟安瓿時需特別注意以避免疫苗飄散出。由於本品對紫外線敏感，疫苗必須遮光保存。疫苗在開瓶稀釋後，如無法立即使用，必須保存於 2-8℃環境中；如超過 6 小時仍未用完，則必須丟棄。
3. 本品提供的稀釋液為本疫苗專用，唯有本疫苗所提供的稀釋液才能與本疫苗作搭配混合。不可使用其他種類疫苗之稀釋液或是其他廠牌之稀釋液。使用非指定之稀釋液會導致疫苗的損壞，或是在接種疫苗後造成更嚴重的反應。稀釋液不可結凍，且在與疫苗混合前必須將溫度維持在 2-8℃。
4. 在使用本品之前並不一定要執行結核菌素測驗，倘若執行測驗後呈現陽性反應者，則不宜接種(註 2)。

【稀釋與接種方法】

1. 本包裝內附安瓿切割器及滅菌膠紙，將安瓿頸部以安瓿切割器輕刮，因安瓿內部處於真空狀態，故應以滅菌膠紙緊密捲妥安瓿後，再折斷安瓿頸部，將滅菌膠紙取下使空氣緩慢入安瓿中，以避免瓿內粉末噴灑出來。
2. 以塑膠空針抽取 1 毫升(mL)稀釋液加入卡介苗安瓿中(稀釋液安瓿無須使用切割器即可折斷)。輕微的搖動以確保液體完全的混合，使之成為每毫升(mL)含 0.5 毫克(mg)之懸浮液。
3. 接種的部位為左上臂三角肌中點。不宜接種於肩膀，且不可重複接種。
4. 施打後安瓿內剩餘卡介苗懸浮液須丟棄(註 3)。

【接種期程】

1. 對於有早期暴露於結核病風險的嬰兒，應常規性地接種卡介苗。爲獲得最大的保護效果，該疫苗應於出生後及早接種 (註 4)。
   同時間亦可施打如白喉、破傷風與百日咳混合疫苗、麻疹疫苗、小兒麻痺疫苗、B 型肝炎疫苗、B 型嗜血桿菌疫苗、黃熱病疫苗以及補充維他命 A(註 5)。
2. 目前仍建議，若與其他活性減毒疫苗不同時間接種時，至少應間隔 4 週。

【接種後反應】

1. 在接種卡介苗後有局部的反應是正常的。在注射部位會出現小紅結節，在 2 到 4 週內逐漸會轉變為膿泡甚至潰爛。
2. 此種反應通常在 2 至 5 個月會逐漸消退，並在接種部位皮膚表面留下 2-10 毫米(mm)的結痂。
3. 少數情形小紅結節會持續甚至潰爛，極少數會在接種後的 2 至 4 個月出現腋窩的淋巴結腫大，其中少部分腫大的腋窩淋巴結會化膿。皮下注射可能造成潰瘍並留下疤痕。
4. 接種卡介苗可能會出現休克或過敏性反應。儘管過敏性反應是非常罕見的，但接種後仍需觀察。極少數情況有卡介苗全身性擴散感染，例如骨炎或骨髓炎，尤其是可能會出現在免疫缺陷之患者身上。對於系統性感染之抗結核菌藥物選擇，應尋求專家建議給予適當治療。

【禁忌】

凡有下列病症或體質者不宜注射(註 6):

1. 兒童接種卡介苗後，若於接種局部發生瘢瘤及狼瘡反應，則不應再行接種。
2. 孕婦不得使用。
3. 具有免疫缺陷者，包含細胞性免疫缺陷患者。
4. 人類免疫缺乏病毒者，無論是有無症狀，皆不得接受卡介苗接種。

【貯藏】

卡介苗之貯存及運送過程均應於 2-8℃。若可於攝氏零下 20℃低溫下會更穩定。稀釋液不得結凍。疫苗應遮光。疫苗及稀釋液應一起配送。疫苗效期標示於安瓿標籤上。

【包裝】

每支疫苗安瓿包含 0.5 毫克(mg)卡介苗（卡介苗菌濕重），每盒疫苗共 100 支安瓿。
每支稀釋液安瓿包含 1 毫升(mL)生理食鹽水，每盒稀釋液共 100 支安瓿。

【參考文獻】

1. Quality Control of freeze - dried BCG vaccine from Japan BCG Laboratory, Tokyo, Japan, 1994/1995, Dr. J. Milstien, WHO Vaccine Supply and Quality, 1996.
2. The Thermostability of Different BCG Products, K.Bunch - Christensen, Chief, BCG Department, Statens Seruminstitut, Copenhagen, WHO Collaborating Centre for BCG Vaccine; WHO/TB/81.118, 1981.

註1：注射時須選用無菌之卡介苗專用空針(0.5cc 附 28G 針頭)。
註2：工作結束，未用完之卡介苗，應加入等量 75%酒精後，以醫療廢棄物處理。
註3：接種卡介苗主要是為了避免幼童因感染結核菌發生嚴重結核病(例如：結核性腦膜炎等)，惟為減少卡介苗骨髓炎案例，我國之適合接種年齡為出生滿 5 個月(建議接種時間為出生滿 5-8 個月)。
註4：卡介苗為活性減毒疫苗，與其他疫苗接種的間隔，請參見疾病管制署全球資訊網(網址：www.cdc.gov.tw)「各項常規疫苗最小接種年齡與最短接種間隔」之相關規範。
註5：其他禁忌及注意事項:
禁忌：急性熱病、發燒、皮膚病、嚴重濕疹、免疫機能不全、麻疹及水痘感染及其復原期。
注意事項：
疑似結核病人及疑似被結核菌感染者，勿直接接種卡介苗。
發燒或正患有急性中重度疾病者，宜待病情穩定後再接種。
慢性疾病：如氣喘、肝臟病、心臟病、腎臟病等。
請父母確認父母雙方家人沒有疑似先天性免疫缺陷之家族史(如幼年因不明原因感染而死亡)。
生母為愛滋病毒感染者，其嬰幼兒應待追蹤滿 6 個月後，確定未受感染。
提早接種者，須注意體重應達 2,500 公克以上。

【製造商】
JAPAN BCG LABORATORY
公司地址: 1-5- 21 Otsuka, Bunkyo - ku, Tokyo 112 - 0012, Japan
生產廠址: 3-1-5 Matsuyama, Kiyose-shi, Tokyo 204-0022, Japan

【藥商】
國光生物科技股份有限公司
台中市潭子區潭興路一段 3 號

FREEZE-DRIED GLUTAMATE BCG VACCINE (JAPAN) FOR INTRADERMAL USE

DESCRIPTION

It is a live freeze-dried vaccine made from an attenuated strain of *Mycobacterium bovis*.
It is used for the prevention of tuberculosis. The vaccine fulfils WHO requirements for BCG vaccine.

COMPOSITION OF VACCINE

(a) Live Bacteria of Calmette and Guerin (as approximately 70% moist bacteria) ····· 0.5mg/ampoule
(b) Sodium Glutamate (as a stabilizer) ····· 2.0mg/ampoule

ADMINISTRATION

For children under one year 0.05ml and for others 0.1ml of reconstituted vaccine is given intradermally. Special syringes allow administration of the exact dose. A sterile syringe and a sterile needle should be used for each injection. The skin should not be cleaned with antiseptic. Special care is needed in opening the ampoule so that the vaccine is not blown out. Because of sensitivity to ultraviolet light, the vaccine must be protected from sunlight. If not used immediately after reconstitution, the vaccine should be kept on ice to maintain its temperature between +2℃ and +8℃. Any opened container remaining at the end of a session (within **six hours** of reconstitution) must be discarded.

The diluent supplied is specially designed for use with this vaccine. Only this diluent may be used to reconstitute the vaccine. Do not use diluents from other types of vaccine or from other manufacturers. Water for injection may NOT be used for this purpose. **Using an incorrect diluent may result in damage to the vaccine and/or serious reactions to those receiving the vaccine**. Diluent must not be frozen but must be cooled between +2℃ and +8℃ before reconstitution.

Skin testing with tuberculin is not generally carried out before giving BCG, but when performed, those who are found to be positive reactors need not be immunized.

RECONSTITUTION AND VACCINATION

File the neck part of the BCG ampoule with the file provided with the pack for cutting the ampoule. Wrap the filed site with the sheet provided with the pack to prevent the vaccine from blowing out of the ampoule as the interior of the ampoule is kept vacuum, and then snap to break off the ampoule at the filed site. With a syringe, add the whole amount of saline diluent into the BCG ampoule (A file is not needed to break off the diluent ampoule). Give a few gentle shakes to the ampoule to ensure homogeneity of the suspension. A homogeneous suspension in a concentration of 0.5mg per ml is now obtained. The vaccination site is about half way down the outer aspect of the upper arm. Do not vaccinate at the shoulder, nor revaccinate at a previously vaccinated site. Any volume of vaccine remaining in the container must be discarded.

IMMUNIZATION SCHEDULE

BCG should be given routinely to all infants at risk of early exposure to the disease. For maximum protection, this vaccine should be given as soon after birth as possible. It can be given at the same time as DTP, measles, polio (OPV and IPV), hepatitis B, Haemophilus influenzae type b, and yellow fever vaccines and vitamin A supplementation. Many countries still recommend not to give BCG within 4 weeks of another live vaccine.

SIDE EFFECTS

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 and then an ulcer in 2-4 weeks. The reaction usually subsides within two to five months and in practically all children leaves a superficial scar 2-10 mm in diameter. Rarely, the nodule may persist and ulcerate. Occasionally, enlargement of axillary lymph nodes may appear in 2-4 months following immunization. Very rarely, enlarged lymph nodes can suppurate. Inadvertent subcutaneous injection may produce abscess formation and may lead to scarring.

Shock or anaphylaxis may appear. Although anaphylaxis is very rare, the subjects should be observed for an allergic reaction after BCG. Very rarely, systemic disseminated BCG-infection, including osteitis or osteomyelitis, may appear, especially in persons with primary or secondary immunodeficiencies. Expert advice should be sought regarding the appropriate treatment regimen with selected anti-tuberculosis drugs for the management of systemic infections.

CONTRAINDICATIONS

Keloid and lupoid reactions may also occur at the site of injection and children experiencing such reactions should not be revaccinated.

Do not give in pregnancy.

Immune deficiency

The vaccine is contraindicated in individuals with cell-mediated immune deficiency.

Individuals known to be infected with human immunodeficiency virus (HIV), either non-symptomatic or symptomatic, should <u>NOT</u> receive BCG vaccine.

STORAGE

BCG vaccine should be stored and transported between +2℃ and +8℃. It is even more stable if stored in temperatures as low as -20℃. The diluent should not be frozen. The vaccine should be protected from the light. Vaccine ampoules and diluents should be transported together. The expiry is specified on the BCG ampoule label.

PRESENTATION

The vaccine comes in boxes of 100 ampoules each containing 0.5mg BCG (moisture weight).

The diluent in boxes of 100 ampoules each containing 1.0ml physiological saline accompanies all orders.

REFERENCES

1. Quality Control of freeze-dried BCG vaccine from Japan BCG Laboratory, Tokyo, Japan, 1994/1995, Dr. J. Milstien, WHO Vaccine Supply and Quality, 1996.
2. The Thermostability of Different BCG Products, K.Bunch-Christensen, Chief, BCG Department, Statens Seruminstitut, Copenhagen, WHO Collaborating Centre for BCG Vaccine; WHO/TB/81.118, 1981.

JAPAN BCG LABORATORY

HEAD OFFICE : 1-5-21 Otsuka, Bunkyo-ku, Tokyo 112-0012, Japan
Tel : +81 - 3 - 5395 - 5583
Fax : +81 - 3 - 5395 - 5580

KIYOSE PLANT : 3-1-5 Matsuyama, Kiyose-shi, Tokyo 204-0022, Japan

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