

(/drug-shortages/519)BCG Vaccine



AHFS Class: 80:12 – Vaccines (tofc-80)

BCG Vaccine (AHFS DI)

BCG Vaccine

Introduction

BCG vaccine is a lyophilized preparation of live, attenuated organisms of the Calmette-Guérin strain of *Mycobacterium bovis* that is used to stimulate active immunity to tuberculosis infection.¹

Uses

■ Tuberculosis Prevention

BCG vaccine is used for the prevention of tuberculosis (TB) in individuals not previously infected with *M. tuberculosis* who are at high risk for exposure.^{1,110} The manufacturer states that BCG vaccine is only recommended for individuals who have tested negative to a recent tuberculin skin test with 5 TU.¹

BCG vaccine is particularly effective in preventing severe forms of TB disease such as disseminated and meningeal TB in young children, with protective efficacy rates as high as >80%; however, efficacy of the vaccine in preventing pulmonary TB disease in adults and adolescents has been more variable.^{1,111,112} While BCG vaccine is used routinely outside the US, particularly in countries where TB is endemic, use of the vaccine in the US is limited because of the low risk of *M. tuberculosis* infection in the overall US population, the variable effectiveness of the vaccine against pulmonary TB in adults, and the vaccine's potential to cause a false-positive TB skin test reaction, which can complicate the management of individuals who may be infected with *M. tuberculosis*.^{1,110,111} Additionally, widespread implementation of TB infection control measures in the US has successfully decreased the number of outbreaks in the healthcare setting and decreased healthcare-associated transmission of *M. tuberculosis* to patients and healthcare workers.¹¹¹

The US Centers for Disease Control and Prevention (CDC) provides recommendations for the use of BCG vaccination in the US.¹¹⁰ The most current CDC guidelines recommend the use of BCG vaccine only in selected individuals who meet specific criteria and in consultation with a TB expert.¹¹⁰ CDC states that BCG vaccination should only be considered for children who have a negative TB test who are continuously exposed and cannot be separated from adults who are untreated or ineffectively treated for TB disease and who cannot be given long-term primary preventive treatment for TB infection; or have isoniazid- and rifampin-resistant strains of TB.¹¹⁰ BCG vaccination also should be considered in certain healthcare personnel on an individual basis in settings where the likelihood of transmission and subsequent infection with drug-resistant strains of *M. tuberculosis* is high and comprehensive TB infection control precautions in the workplace have been unsuccessful.¹¹⁰ Healthcare providers can consult their state or local TB control program for additional information regarding BCG vaccination for patients.¹¹⁰

Dosage and Administration

■ General

Pretreatment Screening

Prior to administration, review a patient's immunization records for a history of vaccine hypersensitivity and assess the possibility of experiencing an allergic reaction to BCG vaccine.¹

A Mantoux skin test is recommended prior to BCG vaccination to demonstrate the absence of tuberculous infection.¹

Dispensing and Administration Precautions

BCG vaccine contains live organisms.¹ All equipment and supplies in contact with the vaccine should be handled and disposed of properly in biohazardous containers.¹

Individuals who prepare the vaccine should take necessary precautions to minimize the risk of spreading disease including wearing gloves and avoiding contact of BCG with broken skin.¹ If vaccine preparation cannot be performed in a biocontainment hood, then a mask and gown should be worn to avoid inhalation of BCG organisms and inadvertent exposure to broken skin.¹

Ensure that epinephrine injection (1:1000) is readily available in the event of an acute anaphylactic reaction.¹

■ Administration

BCG vaccine is administered percutaneously in the deltoid region using a sterile, single-use, multiple-puncture device; the vaccine should *not* be administered IV, intramuscularly, subcutaneously, or intradermally.¹

BCG vaccine for percutaneous administration is commercially available as a lyophilized powder; the powder should be reconstituted prior to administration.¹ To prepare an adult dose, reconstitute the vaccine by adding 1 mL of sterile water for injection to one single-dose vial of the vaccine.¹ To prepare a pediatric dose, reconstitute the vaccine by adding 2 mL of sterile water for injection to one single-dose vial of the vaccine.¹ Gently swirl the vial until a homogenous suspension is obtained; avoid forceful agitation of the vial.¹ Do not filter the contents of the vial.¹ The reconstituted vaccine should be kept refrigerated (do not freeze), protected from direct sunlight, and used within 2 hours.¹ Discard any unused portions.¹

To administer the vaccine, prepare and clean the skin.¹ Drop the immunizing dose (0.2–0.3 mL) of BCG onto the surface of the skin and spread over a 1 by 2 inch area using the multiple-puncture device.¹ An additional 1–2 drops of the vaccine may be added to ensure a very wet vaccination site.¹ Loosely cover the site and keep dry for 24 hours after administration.¹

Store intact vials of BCG vaccine refrigerated (2–8°C) and protect from direct sunlight.¹

■ Dosage

Prevention of Tuberculosis (TB)

For the prevention of TB, the usual dosage of BCG vaccine in adults and children 1 month of age or older is 0.2–0.3 mL.¹ In neonates younger than 1 month of age, the dosage of BCG vaccine should be decreased by 50% by reconstituting the vaccine with 2 mL instead of 1 mL of sterile water for injection without preservatives; if indications for BCG vaccine persist and the neonate has an insignificant reaction to the tuberculin skin test, a full dose of the vaccine should be given after 1 year of age.¹

Tuberculin reactivity resulting from BCG vaccination should be documented.¹ A tuberculin skin test should be performed in a vaccinated individual 2–3 months after BCG administration, and the test results (in mm of induration) should be recorded in the medical record.¹ Repeat vaccination for those who remain tuberculin negative to 5 TU of tuberculin after 2–3 months.¹

Cautions

■ Contraindications

Individuals with impaired immunologic responses because of HIV infection, congenital immunodeficiency (e.g., chronic granulomatous disease or interferon gamma receptor deficiency), leukemia, lymphoma, or generalized malignancy.¹

Individuals who are immunosuppressed as a result of steroid use or treatment with alkylating agents, antimetabolites, or radiation.¹

HIV-infected or immunocompromised infants, children, or adults.¹

Individuals with allergies to any component of the vaccine or an anaphylactic or allergic reaction to a previous dose.¹

Individuals with active tuberculosis (TB).¹

Infants, children, or adults with severe immune deficiency syndromes, and children with a family history of immune deficiency disease.¹

■ Warnings/Precautions

Administration Precautions

BCG vaccine should be administered by the percutaneous route with the multiple-puncture device as described in the manufacturer's prescribing information.¹ The vaccine should not be injected IV, subcutaneously, intramuscularly, or intradermally.¹ BCG vaccine preparation contains live bacteria; therefore, special precautions including aseptic technique should be used when preparing the vaccine.¹ All equipment and supplies used in vaccine preparation should be disposed of properly in biohazardous containers.¹ Parenteral drugs should not be prepared in areas where BCG has been handled to avoid cross-contamination.¹

Local Effects

Local effects may occur after vaccination with BCG vaccine and include moderate axillary or cervical lymphadenopathy and induration and subsequent pustule formation at the injection site; these reactions can persist for as long as 3 months after vaccination.¹ More severe local reactions may occur up to 5 months after vaccination and persist for several weeks including ulceration at the vaccination site, regional suppurative lymphadenitis with draining sinuses, and caseous lesions or purulent drainage at the puncture site.¹

The intensity and duration of local reactions depend on the depth of penetration of the multiple-puncture device and individual patient response.¹ Slight tenderness at the puncture site may be encountered as well as some itching.¹ The initial skin lesions usually appear within 10–14 days and consist of small red papules at the site.¹ The papules reach maximum diameter (about 3 mm) after 4 to 6 weeks, after which they may scale and then slowly subside.¹

Systemic Effects

Systemic signs and symptoms consistent with a "flu-like" syndrome (e.g., fever, anorexia, myalgia, neuralgia) have occurred for 24 to 48 hours following administration of BCG vaccine; these effects are generally consistent with hypersensitivity reactions.¹ However, a fever ($\geq 103^{\circ}\text{F}$) or acute localized inflammation persisting for longer than 2–3 days may be suggestive of active infections.¹ If an active infection is suspected, further evaluate the patient and consult with an infectious disease specialist.¹

Treatment with antimycobacterial agents should not be delayed while the diagnostic evaluation, including cultures, is being conducted.¹ Negative cultures do not necessarily rule out infection.¹

Disseminated BCG Infection

Disseminated BCG infection, which can be fatal, has occurred following administration of BCG vaccine; most reported cases have occurred in immunocompromised individuals.¹ The most frequent disseminated infection is BCG osteomyelitis.¹ Disseminated and/or localized BCG infections have been reported following administration of BCG vaccine to patients with *symptomatic* HIV infection who are immunosuppressed in association with acquired immunodeficiency syndrome (AIDS) or other clinical manifestations of HIV infection.^{100,105,120} In at least one infant with *asymptomatic* HIV infection who received BCG vaccine, a possible disseminated BCG infection occurred since the BCG strain of *M. bovis* was isolated from the lymph node and CSF several months after vaccination.¹¹³ Disseminated BCG infections also have been attributed to previous vaccination in several patients who subsequently manifested symptomatic HIV infection.^{120,121} If systemic BCG infection occurs, consult an infectious disease expert and initiate appropriate anti-tuberculosis therapy.¹

Individuals with Altered Immunocompetence

BCG vaccine is contraindicated in individuals with conditions that can cause immunodeficiency (HIV infection, congenital immunodeficiency, leukemia, lymphomas, generalized malignancy) and those receiving immunosuppressant agents (e.g., steroids, alkylating agents, antimetabolites, radiation therapy).¹ BCG vaccine should be administered with caution to individuals at high risk for HIV infection.¹

Laboratory Test Interferences

Following administration of BCG vaccine, it is usually impossible to distinguish between tuberculin sensitivity caused by *M. tuberculosis* infection and tuberculin sensitivity resulting from the vaccine; therefore, caution should be exercised in interpreting tuberculin skin test reactions in patients who have received BCG vaccine and these patients should be further evaluated for latent TB infection or TB disease as if they were not vaccinated with BCG.^{1,110} CDC states that TB blood tests (interferon-gamma release assay [IGRA]) are preferred for individuals who have received the BCG vaccine, including children, since the BCG vaccine does not induce positive results when these tests are used.¹¹⁰

Specific Populations

Pregnancy.

It is not known whether BCG vaccine can cause fetal harm if administered during pregnancy.¹ Animal reproduction studies have not been conducted with the vaccine.¹ CDC recommends that pregnant women not receive BCG vaccination pending further studies to support safety in this population.¹¹⁰

Lactation.

It is not known whether BCG vaccine is excreted in human milk.¹ Because many drugs are excreted in human milk and because of the potential for serious adverse reactions from BCG in nursing infants, a decision should be made whether to discontinue nursing or not to vaccinate, taking into account the importance of tuberculosis vaccination to the mother.¹

Females and Males of Reproductive Potential.

It is not known whether BCG vaccine can affect reproductive capacity.¹

Pediatric Use.

BCG vaccine is used in pediatric patients.¹ Infants younger than 1 month of age should receive 1/2 of the usual dose.¹

Geriatric Use.

Clinical studies did not include sufficient numbers of patients ≥65 years of age to determine whether they respond differently from younger patients.¹ Other reported clinical experience has not identified differences in response between elderly and younger patients.¹ An intact immune system is a prerequisite for BCG vaccination.¹ If the immune status of an elderly patient, or any patient, is in question, withhold BCG vaccination until immune status has been evaluated.¹

■ Common Adverse Effects

Local reactions are common after BCG vaccination.¹

Drug Interactions

■ Antimicrobial Agents

Antimicrobial agents may interfere with the development of immune response to BCG vaccine and should only be used under medical supervision.¹

■ Immunosuppressive Agents

Immunosuppressive agents may interfere with the development of immune response to BCG vaccine and should only be used under medical supervision.¹

■ Live Vaccines

Since BCG is a live vaccine, the immune response to the vaccine may be impaired if administered within 30 days of another live vaccine.¹ However, there is no evidence currently available to support this concern.¹ Whenever possible, the manufacturer states that live vaccines administered on different days should be administered at least 30 days apart.¹

Description

BCG vaccine is a lyophilized preparation of live, attenuated organisms of the Calmette-Guérin strain of *Mycobacterium bovis*.¹ BCG vaccine commercially available in the US contains the TICE substrain of BCG and is administered by percutaneous administration via a multiple-puncture device.¹

Vaccination with BCG promotes trained immunity mediated by innate immune cells such as monocytes, macrophages, and natural killer cells.¹²⁵

Advice to Patients

The following information contains important points for the clinician to discuss with patients during counseling. For more comprehensive monographs suitable for distribution to the patient, please refer to the *AHFS Patient Medication Information* monographs available from MedlinePlus (<https://vsearch.nlm.nih.gov/vivisimo/cgi-bin/query-meta?v:project=medlineplus>) (in English and Spanish; written at a 6th- to 8th-grade reading level).

Before administering BCG vaccine, inform patients and/or caregivers of the benefits and risks of immunization and inquire about the health status of the patient.¹ Inform patients that the efficacy of BCG vaccination has been variable and that BCG vaccination may interfere with the diagnosis of newly acquired *M. tuberculosis* infections; also inform patients about potential serious complications associated with BCG vaccination in immunocompromised individuals.¹

Advise patients that following BCG vaccination, no dressing is required; however, it is recommended that the site be loosely covered and kept dry for 24 hours.¹ The vaccination site should be kept clean until the local reaction has disappeared.¹

Advise patients that BCG vaccine contains live organisms.¹ Although the vaccine will not survive in a dry state for long, infection of others is possible.¹

Advise patients that following BCG vaccination, initial skin lesions usually appear within 10–14 days and consist of small red papules at the vaccination site.¹ The papules reach a maximum diameter (about 3 mm) after 4 to 6 weeks, after which they may scale and slowly subside.¹ There is usually no visible sign of the vaccination at 6 months, although on occasion, a faintly discernible pattern of the points from the multiple puncture device may be visible.¹ Individuals with a predisposition to keloid formation may have more visible evidence of the vaccination.¹ Advise patients to report any unusual adverse reactions to their clinician.¹

Advise patients that they may experience "flu-like" symptoms for 24–48 hours following BCG vaccination.¹ Patients should consult their physician immediately if they experience a fever of 103°F or greater, or acute local reactions persisting longer than 2–3 days.¹

Advise patients to inform their clinician if they are or plan to become pregnant or plan to breast-feed.¹

Advise patients to inform their clinician of existing or contemplated concomitant therapy, including prescription and OTC drugs and dietary or herbal supplements, as well as any concomitant illnesses.¹

Inform patients of other important precautionary information.¹

Additional Information

The American Society of Health-System Pharmacists, Inc. represents that the information provided in the accompanying monograph was formulated with a reasonable standard of care, and in conformity with professional standards in the field. Readers are advised that decisions regarding use of drugs are complex medical decisions requiring the independent, informed decision of an appropriate health care professional, and that the information contained in the monograph is provided for informational purposes only. The manufacturer's labeling should be consulted for more detailed information. The American Society of Health-System Pharmacists, Inc. does not endorse or recommend the use of any drug. The information contained in the monograph is not a substitute for medical care.

Preparations

Excipients in commercially available drug preparations may have clinically important effects in some individuals; consult specific product labeling for details.

BCG Vaccine (<https://www.accessdata.fda.gov/scripts/cder/ndc/default.cfm?sugg=NonProprietaryName&ApptName=BCG+Vaccine&collapse=1>)

Parenteral

For injection, for percutaneous use

1–8 × 10⁸ CFU of BCG bacillus

BCG Vaccine[®], Merck Sharp and Dohme (<https://www.accessdata.fda.gov/scripts/cder/ndc/default.cfm?sugg=LabelerName&ApptName=Merck+Sharp+and+Dohme&collapse=1>)

Related Resources

AHFS Patient Medication Information (<https://vsearch.nlm.nih.gov/vivisimo/cgi-bin/query-meta?v:project=medlineplus&query=BCG%20Vaccine>) and other related patient health topics (MedlinePlus)

ASHP Drug Shortages Resource Center (<https://www.ashp.org/Drug-Shortages>)

CCRIS (<https://toxnet.nlm.nih.gov/cgi-bin/sis/search2/r?db=crris:%22BCG%20Vaccine%22>) (Chemical Carcinogenesis Research Information System)

ChemIDplus (<https://chem.nlm.nih.gov/chemidplus/name/BCG%20Vaccine>)

Biochemical Data Summary ([http://www.drugbank.ca/unearth/q?](http://www.drugbank.ca/unearth/q?utf8=%E2%9C%93&query=BCG%20Vaccine&searcher=drugs&approved=1&vet_approved=1&nutraceutical=1&illicit=1&withdrawn=1&investigational=1&)

[utf8=%E2%9C%93&query=BCG%20Vaccine&searcher=drugs&approved=1&vet_approved=1&nutraceutical=1&illicit=1&withdrawn=1&investigational=1&](http://www.drugbank.ca/unearth/q?utf8=%E2%9C%93&query=BCG%20Vaccine&searcher=drugs&approved=1&vet_approved=1&nutraceutical=1&illicit=1&withdrawn=1&investigational=1&) (US and Canada)

Clinical Trials (<https://www.clinicaltrials.gov/ct/search?submit=Search&term=BCG%20Vaccine>)

DailyMed (<https://dailymed.nlm.nih.gov/dailymed/search.cfm?query=BCG%20Vaccine>) (drug labels)
 DART (<https://toxnet.nlm.nih.gov/cgi-bin/sis/search2/r?dbs+dart:%22BCG%20Vaccine%22>) (Developmental and Reproductive Toxicology Database)
 Drugs@FDA (<https://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Search.SearchAction&SearchType=BasicSearch&SearchTerm=BCG%20Vaccine>) (approval information)
 European Medicines Agency (https://www.ema.europa.eu/en/search/search?search_api_views_fulltext=BCG%20Vaccine)
 FDA National Drug Code Directory (<https://www.accessdata.fda.gov/scripts/cder/ndc/default.cfm?sugg=NonProprietaryName&ApptName=BCG%20Vaccine&collapse=1>)
 FDA Recalls, Market Withdrawals, and Safety Alerts (<https://www.fda.gov/Safety/Recalls/default.htm>)
 HSDB (<https://toxnet.nlm.nih.gov/cgi-bin/sis/search2/r?dbs+hsdb:%22BCG%20Vaccine%22>) (Hazardous Substances Data Bank)
 Inxight Drugs (<https://drugs.ncats.io/substances?q=%22BCG%20Vaccine%22>) (National Center for Advancing Translational Sciences)
 LactMed (drug effects on breastfeeding) (<https://toxnet.nlm.nih.gov/cgi-bin/sis/search2/r?dbs+lactmed:@or+%28na+%22BCG%20Vaccine%22+%29>)
 New Drug Approvals (<https://ahfs.ashp.org/drug-assignments.aspx>)
 Orange Book (<https://www.accessdata.fda.gov/scripts/cder/ob/default.cfm?panel=0&drugname=BCG%20Vaccine>) (therapeutic equivalence)
 PharmGKB (<https://www.pharmgkb.org/search?connections&gaSearch=BCG%20Vaccine&query=BCG%20Vaccine&type=chemical>) (Pharmacogenomic data from PharmGKB)
 Pillbox (*beta*) (https://pillbox.nlm.nih.gov/pillimage/search_results.php?submit=Search&splid=&getingredient=BCG%20Vaccine) (drug identification and images)
 PubMed (<https://www.ncbi.nlm.nih.gov/pubmed?DB=pubmed&term=BCG%20Vaccine%5BALL+Fields%5D>) (scientific journals)
 Safety-related Labeling Changes (<https://www.accessdata.fda.gov/scripts/cder/safetylabelingchanges>) (FDA/CDER)
 ToxLine (<https://toxnet.nlm.nih.gov/cgi-bin/sis/search2/r?dbs+toxline:%22BCG%20Vaccine%22>) (Toxicology Literature Online)

† Use is not currently included in the labeling approved by the US Food and Drug Administration.

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About ASHP

ASHP represents pharmacists who serve as patient care providers in acute and ambulatory settings. The organization's nearly 55,000 members include pharmacists, student pharmacists, and pharmacy technicians. For more than 75 years, ASHP has been at the forefront of efforts to improve medication use and enhance patient safety. For more information about the wide array of ASHP activities and the many ways in which pharmacists advance healthcare, visit ASHP's website (<https://www.ashp.org>), or its consumer website (<https://www.safemedication.com>).

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