

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

BadgerBCG

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Live *Mycobacterium bovis* BCG for the active immunisation of badgers to reduce lesions of tuberculosis caused by *Mycobacterium bovis*.

3. PHARMACEUTICAL FORM

Lyophilisate for suspension for injection.

4. PACKAGE SIZE

10 vials

1 vial contains 1 dose of $2-8 \times 10^6$ colony forming units when reconstituted with 1 ml Sauton diluent.

5. TARGET SPECIES

As part of TB control measures BadgerBCG should only be used in badgers. In the UK badgers are protected species and any intervention, including trapping and vaccinating, will require licensing by the relevant authorities in England, Scotland, Wales or Northern Ireland.

6. INDICATION(S)

For the active immunisation of badgers to reduce lesions of tuberculosis caused by *Mycobacterium bovis*.

This is a Limited Marketing Authorisation.

Duration of immunity is unknown.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Administration is by intramuscular injection.

Reconstitution:

Only Sauton diluent provided with BadgerBCG should be used for reconstitution. The rubber stopper must not be wiped with any 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.

Syringes and needles should be sterile before use.

The vaccine should be visually inspected both before and after reconstitution for any foreign particulate matter prior to the administration.

Using a syringe fitted with a suitable needle, transfer 1 ml of Sauton diluent to the vial.

Carefully invert the vial a few times to resuspend the lyophilised vaccine completely. Gently swirl the vial of resuspend vaccine before drawing up the contents of the vial which constitute one dose.

When drawn up into the syringe the vaccine suspension should appear homogeneous, slightly opaque and colourless.

8. WITHDRAWAL PERIOD

Blank

9. SPECIAL WARNING(S), IF NECESSARY

See package leaflet for warnings.

DO NOT SHAKE.

10. EXPIRY DATE

EXP: Month/Year

11. SPECIAL STORAGE CONDITIONS

Store and transport refrigerated (2°C – 8°C).
Once opened and reconstituted, use within 4 hours.

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Blank

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

[Distribution category]

For animal treatment only. To be supplied only on veterinary prescription.

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14. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Animal & Plant Health Agency (APHA), New Haw, Addlestone, Surrey, KT15 3NB,
UK

Telephone number: 03300416578

Fax number: +44(0)1932347046

e-mail: salesdesk@apha.gov.uk

Manufactured for APHA by AJ Vaccines A/S, Copenhagen, Denmark

16. MARKETING AUTHORISATION NUMBER(S)

Vm 03326/4021

17. MANUFACTURER'S BATCH NUMBER

Lot: { number }

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Sauton Diluent

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Sauton Diluent contains:

Magnesium sulphate heptahydrate, dipotassium phosphate,
L-asparagine monohydrate, ferric ammonium citrate, glycerol (85%), citric acid
monohydrate, water for injections.

3. PHARMACEUTICAL FORM

Solvent for BadgerBCG
(refer to BadgerBCG package leaflet)

4. PACKAGE SIZE

10 vials

5. TARGET SPECIES

Blank

6. INDICATION(S)

Blank

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Blank

8. WITHDRAWAL PERIOD

Blank

9. SPECIAL WARNING(S), IF NECESSARY

Blank

10. EXPIRY DATE

EXP: Month/Year

11. SPECIAL STORAGE CONDITIONS

Do not freeze.

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Blank

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE
[Distribution category]

For animal use only.

14. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Marketing authorisation holder:
Animal & Plant Health Agency (APHA)
New Haw, Addlestone,
Surrey, KT15 3NB, UK
Telephone number: 03300416578
Fax number: +44(0)1932347046
e-mail: salesdesk@apha.gov.uk

16. MARKETING AUTHORISATION NUMBER

Vm 03326/4021

17. MANUFACTURER’S BATCH NUMBER

Lot:

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING
UNITS {NATURE/TYPE}**

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

BadgerBCG

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Live *M. bovis* BCG for the immunisation of badgers against tuberculosis.

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

1 vial contains 1 dose of $2-8 \times 10^6$ colony forming units when reconstituted with 1 ml Sauton diluent.

4. ROUTE(S) OF ADMINISTRATION

For intramuscular use.

5. WITHDRAWAL PERIOD

Refer to the package leaflet for warnings

6. BATCH NUMBER

Lot: { number }

7. EXPIRY DATE

EXP: Month/Year

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

Keep the container in the outer carton. This is a limited marketing authorisation.

Duration of immunity is unknown

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PARTICULARS TO APPEAR ON THE IMMEDIATE DILUENT LABEL

1. NAME OF THE DILUENT

Sauton diluent
Solvent diluent for BadgerBCG

2. CONTENT BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

1 ml

3. ROUTES OF ADMINISTRATION

Blank

4. STORAGE CONDITIONS

Do not freeze

5. BATCH NUMBER

Lot: {number}

6. EXPIRY DATE

EXP: {month/year}

7. THE WORDS "FOR ANIMAL TREATMENT ONLY"

Blank

**[Include information under these headings as it appears in the SPC]
PACKAGE LEAFLET FOR:**

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Animal & Plant Health Agency
Woodham Lane
New Haw
Addlestone
Surrey
KT15 3NB
UK

Telephone number: 03300416578
e-mail: salesdesk@apha.gov.uk

AJ Vaccines A/S
5, Artillerivej
DK-2300 Copenhagen S
Denmark

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

BadgerBCG Lyophilisate of BCG for suspension for injection of badgers.

3. STATEMENT OF THE ACTIVE SUBSTANCE (S) AND OTHER INGREDIENTS

Live attenuated *Mycobacterium bovis* Bacille Calmette Guerin (BCG) Danish Strain 1331.

1 vial contains 2-8 x 10⁶ colony forming units (cfu) when reconstituted with 1 ml Sauton Diluent.

4. INDICATION(S)

For the active immunisation of badgers to reduce lesions of tuberculosis caused by *Mycobacterium bovis*.

For use in badgers from the age at which they emerge from the sett.

Onset of immunity is 17 weeks. This is a Limited Marketing Authorisation. Duration of immunity is unknown.

However, annual vaccination on a population basis is recommended in view of the estimated 30% rate of turnover including new cubs and badger movement.

5. CONTRAINDICATIONS

None.

6. ADVERSE REACTIONS

Palpable small swellings (maximum 30 mm) at the injection site are common observations. On rare occasions, swelling at the injection site may persist for at least 2 years, although in most cases they resolve within 8 months.

7. TARGET SPECIES

Eurasian Badgers (*Meles meles*).

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

For use in badgers from the age at which they emerge from the sett.
1 ml reconstituted vaccine containing $2-8 \times 10^6$ colony forming units by intramuscular injection.

9. ADVICE ON CORRECT ADMINISTRATION

For use in badgers from the age at which they emerge from the sett: 1 ml reconstituted vaccine containing $2-8 \times 10^6$ colony forming units.

Reconstitution:

Only Sauton diluent provided with BadgerBCG should be used for reconstitution. The rubber stopper must not be wiped with any 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. Syringes and needles should be sterile before use.

The vaccine should be visually inspected both before and after reconstitution for any foreign particulate matter prior to the administration. Using a syringe fitted with a suitable needle, transfer 1 ml of Sauton diluent to the vial. Carefully invert the vial a few times to resuspend the lyophilised vaccine completely. **DO NOT SHAKE.** Gently swirl the vial of resuspended vaccine before drawing up the contents of the vial which constitute one dose. When drawn up into the syringe the vaccine suspension should appear homogeneous, slightly opaque and colourless.

Administration is by intramuscular injection.

10. WITHDRAWAL PERIOD(S)

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the reach and sight of children.

Store and transport refrigerated ($2^{\circ}\text{C} - 8^{\circ}\text{C}$).
and protect from light.

Do not use after the expiry date stated on the label. The expiry date refers to the last day of the month.

Shelf-life after reconstitution according to directions is 4 hours.

12. SPECIAL WARNING(S)

i. Special precautions for use in animals

None.

ii. Special precautions to be taken by the person administering the veterinary medicinal product to animals

BadgerBCG should not be handled by persons receiving systemic corticosteroids or immunosuppressive treatment including radiotherapy, those suffering from malignant conditions (e.g., lymphoma, leukaemia, Hodgkin's disease or other tumours of the reticulo-endothelial system), those with primary or secondary immunodeficiencies, those with HIV-infection. The reaction to self injection and infection with Bacille Calmette Guérin (BCG) may be exaggerated in these persons, and a generalised BCG-infection is possible.

In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

To the physician:

BadgerBCG is a 1 ml dose of the identical AJ Vaccines BCG product which is licensed for human use at a dose of 0.1 ml. Overdose above 0.1 ml increases the risk of suppurative lymphadenitis and may lead to excessive scar formation. Gross overdosage increases the risk of undesirable BCG complications. Expert advice, including that of a chest physician, should be sought regarding the appropriate treatment regimen for the management or prophylaxis of systemic infections or persistent local infections following self injection with BCG.

Antibiotic sensitivity of the BCG strain:

Minimum inhibitory concentrations (MIC) for selected anti-tuberculous drugs for the BCG Danish strain 1331 (as determined by Bactec 460).

Drug	Minimum Inhibitory Concentration (MIC)
Isoniazid	0.4 mg/l
Streptomycin	2.0 mg/l
Rifampicin	2.0 mg/l
Ethambutol	2.5 mg/l

The MIC for isoniazid is 0.4 mg/l. There is no consensus as to whether *Mycobacterium bovis* should be classified as susceptible, intermediately susceptible or resistant to isoniazid when the MIC is 0.4 mg/l. However, based on criteria set for *Mycobacterium tuberculosis*, the strain could be considered to be of intermediate susceptibility.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Any unused product or waste materials derived from such products should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

February 2021

15. OTHER INFORMATION

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Vm 03326/4021

Approved: 15/02/21

