SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

BadgerBCG

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Lyophilised vaccine:

Active substance:

Mycobacterium bovis Bacille Calmette Guérin (BCG) Danish Strain 1331	2-8 × 10^6 colony forming units (cfu)

Diluent:

Sauton diluent	1 mL

For full list of excipients, see Section 6.1.

3. PHARMACEUTICAL FORM

Lyophilisate and solvent for suspension for injection.

4. CLINICAL PARTICULARS

4.1 Target species

Eurasian Badgers (*Meles meles*)

4.2 Indications for use, specifying the target species

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.

4.3 Contraindications

None

4.4 Special warnings

None

4.5 Special precautions for use

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 1ml dose of the identical AJ Vaccines BCG product which is licensed for human use at a dose of 0.1ml. Overdose above 0.1ml 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.

4.6 Adverse reactions (frequency and seriousness)

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.

4.7 Use during pregnancy or lactation

No information is available.

4.8 Interaction with other medicinal products and other forms of interaction

No information is available on the compatibility of this vaccine with any other. Therefore the safety and efficacy of this product when used with any other (either when used on the same day or at different times) has not been demonstrated.

4.9 Amounts to be administered and administration route

For use in badgers from the age at which they emerge from the sett: 1 ml reconstituted vaccine containing 2-8 × 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 1ml 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.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

No adverse reactions other than those already noted under 4.6.

4.11 Withdrawal period(s)

Not applicable.

5. IMMUNOLOGICAL PROPERTIES

To stimulate active immunity against *Mycobacterium bovis.*

ATCvet code: QI20XE01

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lyophilised vaccine:

Sodium L-glutamate monohydrate

Sauton diluent:

Magnesium sulphate heptahydrate
Dipotassium phosphate
Citric acid, monohydrate
L-Asparagine monohydrate
Ferric ammonium citrate
Glycerol
Water for injections

6.2 Incompatibilities

Do not mix with any other medicinal product except the diluent supplied for use with the product.

6.3 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale is 2 years.
Shelf-life after reconstitution according to directions is 4 hours.

6.4 Special precautions for storage

Store and transport refrigerated (2°C – 8°C).
Store and transport in the original package in order to protect from light.

6.5 Nature and composition of immediate packaging

Amber Type I glass vial with bromobutyl stopper and aluminium cap; Type I glass vial with a chlorbutyl stopper and an aluminium cap.

Cardboard box with 10 vials of a 1 dose per vial presentation.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

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

7. MARKETING AUTHORISATION HOLDER

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

8. MARKETING AUTHORISATION NUMBER

Vm 03326/4021

9. DATE OF FIRST AUTHORISATION

24 March 2010

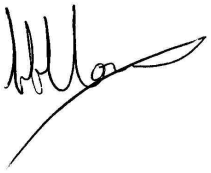
10. DATE OF REVISION OF THE TEXT

October 2020

PROHIBITION OF SALE, SUPPLY AND/OR USE

As part of TB control measures BadgerBCG should only be used in badgers.

In the UK badgers are a protected species and any intervention, involving trapping and vaccinating, will require licensing by the relevant authorities in England, Scotland, Wales or Northern Ireland.



Approved 06 October 2020