PARTICULARS TO APPEAR ON THE OUTER PACKAGE {Cardboard box}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

CZV Avian Tuberculin PPD, solution for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each mL of solution contains:

Active substance:

Purified protein derivative from culture

of Mycobacterium avium, subsp. avium strain D4 ER …… 25 000 IU

Contains phenol and Ponceau red (E124)

3. PACKAGE SIZE

25 x 5 mL

10 x 5 mL

1 x 5 mL

25 x 2 mL

10 x 2 mL

1 x 2 mL

4. TARGET SPECIES

Cattle

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Intradermal use.

7. WITHDRAWAL PERIODS

Withdrawal period: zero days

8. EXPIRY DATE

Exp. {mm/yyyy}

Once opened use immediately.

9. SPECIAL STORAGE PRECAUTIONS

Store and transport refrigerated (2 ºC – 8 ºC)
Do not freeze.
Protect from light.

May be stored and transported up to a maximum of +37 ºC for a period not longer than 14 days.

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

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

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

CZ Vaccines S.A.U.

14. MARKETING AUTHORISATION NUMBERS

Vm 30824/4000

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS {20 doses vials/50 doses vials}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

CZV Avian Tuberculin PPD

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Each mL of solution contains:

Active substance:

Purified protein derivative from culture

of Mycobacterium avium, subsp. avium strain D4 ER …… 25 000 IU

Contains phenol and Ponceau red (E124)

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

Once opened use immediately.

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

CZV Avian Tuberculin PPD, solution for injection

2. Composition

Each mL of solution contains:

Active substance:
Purified protein derivative from culture
of *Mycobacterium avium*, subsp. avium strain D4 ER ……. 25 000 IU

Excipients:

Qualitative composition of excipients and other constituents
Phenol
Glycerol
Ponceau red (E124)
Phosphate buffered saline: Sodium chloride Disodium phosphate Potassium phosphate

Clear pinkish-red solution

3. Target species

Cattle.

4. Indications for use

Single intradermal test
For use in bovine animals from 6 weeks of age or older where, as a consequence of exposure to slow growing mycobacteria in the environment, cross sensitisation to bovine tuberculin is suspected.

Intradermal comparative test
When used together with CZV Bovine Tuberculin PPD, in vivo diagnosis of cattle from 6 weeks of age that have generated an immune response against *M. bovis*, differentiating animals reacting to *M. bovis* from those that have become sensitised

to bovine tuberculin as a result of exposure to other mycobacteria or related genera (single intradermal comparative tuberculin test).

5. Contraindications

None.

6. Special warnings

Special warnings:
Although field experience suggests that there may be no adverse effect when the product is used in cattle sensitised to M. avium subsp. avium, safety in such animals has not been specifically tested and established, therefore careful monitoring should be done.

It is not recommended to repeat the test until at least 42 days have passed since the previous test in order to avoid false negatives due to a loss of skin responsiveness during a period of post-test desensitization.

When used in chronically infected animals with severe pathology, the tuberculin test may be unresponsive.

Newly infected animals may not react to the tuberculin test until the cell mediated immune response has developed (for most animals this is between 3 – 6 weeks post-infection).

Post-partum immunosuppression may give rise to false negative results in cattle that have recently calved. A lack of sensitivity to the test can occur in cattle that were recently or concurrently treated with immunosuppressive agents.

Special precautions for safe use in the target species:
The results obtained with this test should be interpreted by taking into account others result obtained in the herd and the clinical and epidemiological factors which have led to the use of this test.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Accidental self-injection may cause an area of intense irritation, especially in tuberculin-sensitised individuals. It is recommended that, in such an event, seek medical advice immediately and show the package leaflet or label to the physician.

Pregnancy and lactation:
The safety of the veterinary medicinal product has not been established during pregnancy and lactation.

Interaction with other medicinal products and other forms of interaction:
No information is available on the safety and efficacy of this immunological veterinary medicinal product when used with any other veterinary medicinal product except CZV Bovine Tuberculin PPD. A decision to use this immunological veterinary

medicinal product before or after any other veterinary medicinal product therefore needs to be made on a case by case basis.

Care should be taken in the interpretation of tests carried out in cattle which have been previously vaccinated against bovine tuberculosis or Johne's disease (paratuberculosis) because such vaccinations may cause false positive or false negative results in the tuberculin skin tests N.B. Vaccination of cattle against bovine tuberculosis is currently forbidden in the EU. Vaccination of cattle against paratuberculosis may be forbidden in some EU Member States.

Overdose:
No local or systemic reactions are observed after administration of an overdose (double dose).

Special restrictions for use and special conditions for use:
Any person intending to manufacture, import, possess, distribute, sell, supply and use this veterinary medicinal product must first consult the relevant Member State's competent authority on the current vaccination policies, as these activities may be prohibited in a Member State on the whole or part of its territory pursuant to national legislation.

Major incompatibilities:
Do not mix with any other veterinary medicinal product.

7. Adverse events

Bovine:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):
Hyperthermia[1]

[1]Transitory,up to a maximum of 41.4 ºC and, within 3 days after injection.

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system at:

Website: https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine

e-mail: adverse.events@vmd.gov.uk

8. Dosage for each species, routes and method of administration

Dose
0.1 mL

Administration
Injection site shall be clipped and cleansed. A fold of skin within clipped area shall be taken between the forefinger and thumb and measured with callipers and recorded. The dose of CZV Avian tuberculin PPD shall then be injected by the intradermal route into the deeper layers of the skin, in a defined area between the first and second third of the neck. A correct injection shall be confirmed by palpating a small pea-like swelling at each site of injection.

The distance between the two injections (CZV Avian Tuberculin PPD and CZV Bovine Tuberculin PPD) in the comparative intradermal test should be approximately 12 – 15 cm. In young animals in which there is no room to separate the sites sufficiently on one side of the neck, one injection must be made on each side of the neck at identical sites in the centre of the middle third of the neck.

The skin-fold thickness of each injection site shall be remeasured 72 ± 4 hours after injection and recorded.

Interpretation of the results:

Avian single intradermal test
The interpretation of reactions shall be based on clinical observations and the recorded increase in skin-fold thickness at the site of injection 72 hours after injection of tuberculin.

a) Negative reaction: if only limited swelling is observed, with an increase of not more than 2 mm in the thickness of the fold of skin without clinical signs such as diffuse or extensive oedema, exudation, necrosis, pain or inflammation of the lymphatic ducts in that region or of the lymph nodes.

b) Inconclusive reaction: if no clinical signs such as mentioned in a) are observed and if the increase in skin-fold thickness is more than 2 mm and less than 4 mm.

c) Positive reaction: if clinical signs such as mentioned in a) are observed and/or there is an increase of 4 mm or more in the thickness of the fold of skin at the injection site.

Intradermal comparative test when CZV Avian Tuberculin PPD and CZV Bovine Tuberculin PPD are used together:

a) Positive: a positive bovine PPD reaction which is more than 4 mm greater than the avian reaction and/or the presence of clinical signs diffuse or extensive oedema, exudation, necrosis, pain or inflammation of the lymphatic ducts in that region or of the lymph nodes.

b) Inconclusive: a positive or inconclusive bovine PPD reaction which is from 1 to 4 mm greater than the avian reaction, and absence of clinical signs.

c) Negative: a negative bovine PPD reaction, or a positive or inconclusive bovine PPD reaction but which is equal to or less than a positive or inconclusive avian PPD reaction and the absence of clinical signs in both cases.

No other products except CZV Bovine Tuberculin PPD should be administered before, at the same time or after the intradermal test near to the injection site.

Animals inconclusive to intradermal comparative test that are not removed as reactors by the competent authority shall be subjected to another test after a minimum of 42 days. Animals which are not negative to this second test shall be deemed positive to the test under EU legislation.

Different criteria for interpretation of results may be applied in accordance with national requirements for bovine TB eradication schemes

9. Advice on correct administration

Shake well before use.

10. Withdrawal periods

Zero days.

11. Special storage precautions

Keep out of the sight and reach of children.

Store and transport refrigerated (2 °C – 8 °C).
Do not freeze.

Protect from light.
May be stored and transported up to a maximum of +37 ºC for a period not longer than 14 days.
Do not use this veterinary medicinal product after the expiry date which is stated on the label
Exp: The expiry dates refers to the last day of month

Shelf life after first opening the immediate packaging: use immediately

12. Special precautions for disposal

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 30824/4000

Pack sizes

Type I hydrolytic glass vials containing 50 doses (5 mL), with a rubber-butyl stopper and aluminium seal or red flip-off aluminium seal.

Type I hydrolytic glass vials containing 20 doses (2 mL) with rubber-butyl stopper and aluminium seal or red flip-off aluminium seal.

Sales presentation:

Cardboard boxes with 1 vial of 2 mL (20 doses)

Cardboard boxes with 10 vials of 2 mL (20 doses)

Cardboard boxes with 25 vials of 2 mL (20 doses)

Cardboard boxes with 1 vial of 5 mL (50 doses)

Cardboard boxes with 10 vials of 5 mL (50 doses)

Cardboard boxes with 25 vials of 5 mL (50 doses)

Not all pack sizes may be marketed.

15. PID link (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

16. Contact details

Marketing authorisation holder and manufacturer responsible for batch release:and contact details to report suspected adverse reactions:

CZ Vaccines S.A.U.
A Relva s/n – Torneiros
36410 O Porriño
Pontevedra
Spain
+34 986 33 04 00

17. Other information

POM-V

Gavin Hall
Approved: 03 March 2025