PARTICULARS TO APPEAR ON THE OUTER PACKAGE: CARDBOX OF 1250 DOSES WITH 25 VIALS OF 5 ML, CARDBOX OF 500 DOSES WITH 10 VIALS OF 5 ML, CARDBOX OF 50 DOSES WITH 1 VIAL OF 5 ML,

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

CZV Bovine Tuberculin PPD, solution for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each dose of 0.1 ml contains:

Active substances:
Purified protein derivative from culture of *Mycobacterium bovis*, strain AN-5
……..... 2,500 IU*
*IU: International units

3. PACKAGE SIZE

5 ml
10 vials of 5 ml
25 vials of 5 ml
2ml
10 vial of 2 ml
25 vial of 2 ml

4. TARGET SPECIES

Cattle

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Intradermal

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.
Do not freeze.
Protect from light.

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 NUMBER

Vm 30824/4001

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS 5- AND 2-ML VIALS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

CZV Bovine Tuberculin PPD

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Each dose of 0.1 ml contains:

Active substance:
Purified protein derivative from culture of *Mycobacterium bovis*, strain AN-5
……..... 2,500 IU*
*IU: International units

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 Bovine Tuberculin PPD solution for injection

2. Composition

Each dose of 0.1 ml contains:

Active substances:

Purified protein derivative from culture of *Mycobacterium bovis*, strain AN-5 ……..... 2,500 IU*
*IU: International units

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Phenol	0.5 mg
Glycerine	
Phosphate buffered saline: Sodium chloride Disodium phosphate Potassium phosphate	
Water for injection	

Transparent colourless or yellowish solution, free of particles

3. Target species

Cattle.

4. Indications for use

In vivo diagnosis of cattle from 6 weeks of age that have generated an immune response against *Mycobacterium bovis*, the causative agent of bovine tuberculosis (single intradermal tuberculin test).

When used together with CZV Avian PPD Tuberculin, 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:
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 desensitisation.
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 the test should be interpreted by taking into account other results obtained in the herd and the clinical and epidemiological factors which have led to the use of this test.

Special precautions for the protection of the environment:
None.

Pregnancy and lactation:
Although no specific laboratory safety tests were done in pregnant or lactating cattle, experience from field use indicate that the administration of CZV Bovine Tuberculin PPD does not have a negative effect on reproductive performance or lactation.

Interaction with other medicinal products and other forms of interaction:
Safety and efficacy data are available which demonstrate that this immunological veterinary medicinal product can be administered on the same day but not mixed with CZV Avian Tuberculin PPD.

No information is available on the safety and efficacy of this product when used with any other veterinary medicinal product. A decision to use this 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 other than those mentioned in section on Adverse events are observed after administration of an overdose.

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.

For administration only by a veterinarian.

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

7. Adverse events

Cattle

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

[1]Up to 41.4°C 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 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: 0.1ml

Age of administration: From 6 weeks

Route of administration: Intradermal

Administration Shake well before use.

Injection sites shall be clipped and cleansed. A fold of skin within each clipped area shall be taken between the forefinger and thumb and measured with callipers and recorded. The dose of CZV Bovine Tuberculin PPD shall then be injected intradermally 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 Bovine Tuberculin PPD and CZV Avian Tuber-culin 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
Single intradermal test

a) Positive: if it is observed an increase of 4 mm or more in the thickness of the fold of the skin at the injection site or 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: if no clinical signs such as mentioned above are observed and if the increase in skin-fold thickness is more than 2 mm and less than 4 mm.

c) Negative: Increase of not more than 2 mm in the thickness of the fold of skin without clinical signs.

Animals inconclusive to the single intradermal test shall be subjected to another test after a minimum of 42 days.

Animals which are not negative to this second test shall be deemed to be positive to the test.

Animals positive to the single intradermal test may be subjected to an intradermal comparative test if false positive reaction or interference reaction is suspected.

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

a) Positive: a positive bovine PPD reaction which is more than 4 mm greater than the avian reaction 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 Avian 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 tuberculosis 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 carton after Exp. The expiry date refers to the last day of that month.

Shelf life after first opening the immediate packaging: use immediately.

12. Special precautions for disposal

Medicines should not be disposed of via wastewater.

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 30824/4001

Pack sizes:
Cardboard box of 1,250 doses with 25 vials of 5 ml.
Cardboard box of 500 doses with 10 vials of 5 ml
Cardboard box of 50 doses with 1 vial of 5 ml.
Cardboard box of 500 doses with 25 vials of 2 ml
Cardboard box of 200 doses with 10 vials of 2 ml
Cardboard box of 20 doses with 1 vial of 2 ml

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

Tel: +34 986 33 04 00

17. Other information

POM-V

Gavin Hall
Approved: 12 September 2025