1. NAME OF THE VETERINARY MEDICINAL PRODUCT

CZV Bovine Tuberculin PPD solution for injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 0.1 ml dose contains:

Active substances:

Mycobacterium bovis, strain AN5, bovine tuberculin purified protein derivative……..…..... 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. CLINICAL INFORMATION

3.1 Target species

Cattle

3.2 Indications for use for each target species

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).

3.3 Contraindications

None.

3.4 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.

3.5 Special precautions for use

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 to be taken by the person administering the veterinary medicinal product to animals:
In case of accidental self-injection, persons who have been exposed to tuberculin protein, either from a previous tuberculosis vaccination, or from environmental exposure may develop a reaction within 48 to 72 hours, consisting of a skin reaction of a hard, dense wheal. Mild itching, swelling, or irritation at the site of the injection are frequent reactions. If a strong reaction or systemic symptoms occur, seek medical advice immediately and show the package leaflet or the label to the physician.

Special precautions for the protection of the environment:
Not applicable.

3.6 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 veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

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.

3.8 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.

3.9 Administration routes and dosage

Dose: 0.1ml

Age of administration: From 6 weeks

Route of administration: Intradermal use

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 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) Negative: Increase of not more than 2 mm in the thickness of the fold of skin without clinical signs.
c) 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 4mm.
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:

The distance between the two injections 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

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.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

No local or systemic reactions other than those mentioned in section 3.6 are observed after administration of an overdose.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

For administration only by a veterinarian.

3.12 Withdrawal periods

Zero days.

4. IMMUNOLOGICAL INFORMATION

4.1 ATCvet code: QI02AR01

In vivo diagnosis of the immune status of cattle against *Mycobacterium bovis*

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Do not mix with any other veterinary medicinal product.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years
Shelf life after first opening the immediate packaging: use immediately.

5.3 Special precautions for storage

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.

5.4 Nature and composition of immediate packaging

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

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

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.

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

Medicines should not be disposed of via wastewater or household waste. *<to be completed nationally>*
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 national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

CZ Vaccines S.A.U.

7. MARKETING AUTHORISATION NUMBER(S)

VPA10784/002/001

8. DATE OF FIRST AUTHORISATION

28/10/2011

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

17/06/2025

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).