SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

CZV Avian Tuberculin PPD, solution for injection

2. QUALITATIVE AND QUANTITATIVE 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	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Phenol	5 mg
Glycerol	
Ponceau red (E124)	0,05 mg
Phosphate buffered saline: Sodium chloride Disodium phosphate Potassium phosphate	

Clear pinkish-red solution

3. CLINICAL INFORMATION

3.1 Target species

Cattle

3.2 Indications for use for each target species

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).

3.3 Contraindications

None.

3.4 Special warnings

Vaccinate healthy animals only.

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 immunosuppresion 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 this test should be interpreted by taking into account other resultsobtained in the herd together with 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. If pain persists for more than 12 hours after medical examination, seek medical advice again

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] Transitory increase of the temperature 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 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

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

3.8 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.

3.9 Administration routes and dosage

Dose
0.1 mL
Shake well before use

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 ± 4 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 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 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 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

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

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

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: QI02AR02

It is used to detect sensitisation to avian tuberculin

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.

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 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.

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

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 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)

Vm 30824/4000

8. DATE OF FIRST AUTHORISATION

24 July 2007

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

November 2024

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product subject to prescription.

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

Gavin Hall

Approved 22 January 2025