SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

AVITUBAL 28 000 ***solution for injection***
Avian tuberculin – 28 000 IU

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Composition - 1 ml:
Active substance:*Proteinum tuberculini Mycobacterii avium* (strain D 4 ER) – 28 000 IU
Excipients: Phenolum
Solutio stabilisata purificata

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Injection.

4. CLINICAL PARTICULARS

4.1 Target species

Poultry, cattle, pigs.

4.2 Indications for use, specifying the target species

For simple tuberculization of poultry and pigs and for comparative tuberculization of cattle.

4.3 Contraindications

None.

4.4 Special warnings for each target species

Tuberculization can be repeated no sooner than 42 days after preceding tuberculization.

4.5 Special precautions for use

Special precautions for use in animals
Not applicable.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
Not applicable.

4.6 Adverse reactions (frequency and seriousness)

None known.

4.7 Use during pregnancy, lactation or lay

The administered preparation has no impact either on egg laying or the quality of laid eggs. Application of the preparation has no influence on gravidity and lactation.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

Apply 0.1 ml dose intradermally.

Poultry tuberculization:
Apply a 0.1 ml dose intradermally to the auricle, preferably to its lower edge, while the second auricle is used as a control. Use only thin needles without a lateral orifice. A lentil-shaped swelling appears at the site of puncture after a properly performed inoculation.

Evaluation: Evaluate the reaction 48 hours after the application. Inflammatory auricle swelling (an apparent difference in comparison with the control auricle) means a positive.

Cattle tuberculization:
In the case of comparable intradermal tuberculization bovine tuberculin and avian tuberculin are applied simultaneously. The test is carried out not earlier than 42 days after the evaluation of the results obtained from the simple tuberculinization. It is intended for verification of preceding results obtained with the simple tuberculinization. 0.1 ml of tuberculins are applied intradermally. The site for injection of avian tuberculins shall be about 10 cm from the crest of the neck and the site for the injection of bovine tuberculin about 12.5 cm lower on a line roughly parallel with the line of the shoulder or on different sides of the neck; in young animals in which there is not room to separate the sites sufficiently on one side of the neck, one injection shall be made on each side of the neck at identical sites in the centre of the middle third of the neck.

The technique of tuberculin testing and interpretation of reactions:
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. A short sterile needle, bevel edge outwards, with graduated syringe charged with tuberculin, inserted obliquely into the deeper layers of the skin may be used. A correct injection shall be confirmed by palpating a small pea-like swelling at each site of injection.

Evaluation:
Comparable tuberculinization shall be evaluated 72 (± 4) hours after the tuberculin application. Both tuberculins are evaluated according to the special table used for simple tuberculinization with bovine tuberculin.

The interpretation of the tuberculinization results in the case of Mycobact. bovis infection:

Positive: Reaction number to bovine tuberculin exceeds the reaction to avian tuberculin by more than 4 mm; or, clinical symptoms, such as diffuse or extensive oedema, exudation, necrosis, soreness or inflammatory reaction of relevant lymphatics or lymph-nodes, are discovered in the application place of bovine tuberculin.
Dubious: Positive or dubious reactions to the bovine tuberculin, reaction number is from 1 to 4 mm greater than the reaction to avian tuberculin, no clinical symptoms are discovered.
Negative: Positive, dubious or negative reactions to bovine tuberculin, but reaction number is the same or lower than for avian tuberculin, no clinical symptoms are discovered in either case.
A further allergic examination should be carried out a minimum of 42 days after the first examination in those animals showing dubious results after comparable tuberculinization. Animals for which the results of the second tuberculinization are not negative are considered to react positively to bovine tuberculin.
Control (diagnostic) slaughter and the laboratory examination of the relevant organs and lymph-nodes or further examination should be carried out in disputable cases.

Pigs tuberculization:

Intradermal tuberculization is carried out on the dorsal side of the auricle, at the point where the head turns into the auricle, namely, approx. 2 - 3 cm from the auricle base.
Dosage – 0.1 ml.

Evaluation:
Evaluation is carried out 48 hours after application. Characteristic inflammatory swelling often accompanied by erythema and sometimes even with central necrosis in the site of puncture is apparent when the reaction is positive. Skin swelling accompanied by necrosis in some cases shall be considered as the main symptom of the inflammatory reaction in pigmented pigs. In breedings free of tuberculosis, swellings of a diameter exceeding 20 mm mean a positive reaction whereas with swellings of a diameter of 10 - 20 mm the reaction is dubious. In those breedings where tuberculosis has been diagnosed, inflammatory changes in diameter exceeding 10 mm are considered as positive reactions and changes up to 10 mm in diameter to be dubious.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary
A double preparation dose has no side effects on target animals.

4.11 Withdrawal period(s)
Zero days.

5. IMMUNOLOGICAL PROPERTIES
Pharmacotherapeutic group: Veterinaria - immunopraeparata
ATCvet code: QV04CF01

The preparation is obtained from the heat-treated product of growth and lysis of *Mycobacterium avium* capable of revealing a delayed hypersensitivity in an animal sensitised to micro-organisms of the same species.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients
Phenolum, Solutio stabilisata purificata

6.2 Incompatibilities
Not applicable.

6.3 Shelf life
Shelf life after the first opening – 10 hours.
2 years.

6.4 Special precautions for storage
Store in a refrigerator (2 °C – 8 °C).
Store in a dry place.
Protect from light.

6.5 Nature and composition of immediate packaging

The preparation is dispatched in 3 ml, 9 ml (6R) and 10 ml with neck 13 mm or 20 mm and 20 ml glass vials airtightly closed with rubber piercing stoppers and equipped with aluminium caps.
The product is delivered in the following packaging:
Cardboard box: 1×5 ml, 5×5 ml, 10×5 ml, 1×10 ml, 1×20 ml, 5×20 ml, 10×20 ml
Plastic box: 2×1 ml, 5×1 ml, 10×1 ml, 2×2 ml, 5×2 ml, 10×2 ml, 20 ×2 ml, 5×10 ml, 10×10ml

Package: 2 × 1 ml, 5 × 1 ml, 10 × 1 ml
2 × 2 ml, 5 × 2 ml, 10 × 2 ml, 20 × 2 ml
1 × 5 ml, 5 × 5 ml, 10 × 5 ml
1 × 10 ml, 5 × 10 ml, 10 × 10 ml
1 × 20 ml, 5 × 20 ml, 10 × 20 ml

Each package is equipped with an approved Package Insert.

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

8. MARKETING AUTHORISATION NUMBER(S)

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

10. DATE OF REVISION OF THE TEXT