# PACKAGE LEAFLET FOR
# Artuvetrin Test

## 1. NAME AND ADDRESS OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE

Nextmune b.v.
Vijzelweg 11
8243 PM Lelystad (NL)

## 2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Artuvetrin Test

## 3. STATEMENT OF THE ACTIVE SUBSTANCES AND OTHER INGREDIENTS

Active substance(s):
Allergen extracts from pollen, mites and insects, epithelia, yeast and moulds:
See vial label.

Per ml:

| | |
|---|---|
| Concentration per pollen extract/allergen(mixture) | 1000 NU*/ml |
| Concentration per epithelium extract/allergen(mixture) | 100 µg/ml |
| Except for sheep epithelium | 10 µg/ml |
| Concentration per yeast-/mould extract/allergen | 100 µg/ml |
| Concentration per mite-/insect extract/allergeen | 100 NU/ml |
| Except for aedis, flea, culex, tabanus, culicoides<br>Except for housefly | 1000 NU/ml<br>10 NU/ml |

*NU=Noon Unit, defined as follows: the amount of allergen extract obtained from 1 gram raw material is by definition equivalent to $10^6$ Noon Units.

Vial with negative control solution:
Physiological saline solution

Vial with positive control solution:
Histamine phosphate: 0.1 mg/ml

## 4. INDICATION(S)

Diagnosis of atopy.
The veterinary medicinal product is indicated for the diagnosis of atopic hypersensitivity reactions in dogs. For the correct diagnostic assessment, a proper anamnesis must be done along with an IgE-specific test like the skin test.

## 5. CONTRAINDICATIONS

- Skin changes in and around the test area.
- Conditions reducing the dog’s general state of health.

## 6. ADVERSE REACTIONS

Slight itching after injection.
In sporadic cases anaphylactic shock can occur after injections with allergens with symptoms like lethargy, oedema of the head, pruritus, dyspnea, vomiting, diarrhea or fainting. In such cases intravenous treatment with 1 to 5 milliliter (until effective, inject slowly) of an adrenaline solution (1:1000) is indicated.
If you notice any serious effects or other effects not mentioned in this package leaflet, please inform your veterinary surgeon.

## 7. TARGET SPECIES

Dog

## 8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

One 0.05 ml per allergen extract administered intracutaneously in the lateral thorax wall.

## 9. ADVICE ON CORRECT ADMINISTRATION

Instructions for correct administration and conduct of the test

- Carefully shave the dog's lateral thorax wall, the test must be administered on intact skin.
- Number the injection sites on the dog's skin with a marker or pen at intervals of 2.5 cm.
- Fill the syringes with the different allergen and control solutions.
- Administer 0.05 ml of each allergen and control solution intracutaneously (a bubble will appear after injection) with the number on the holder corresponding to the number written on the skin.
- Read the skin reaction after 15-20 minutes by labelling the increase in the wheal with a marker or pen.

Interpretation of the skin test
The response to the negative control is usually zero. The response to the allergen solution with a wheal diameter greater than half the wheal produced by the positive control solution (or larger than half of the difference in diameter of the positive and negative controls) is considered positive.

False-positive reactions can be caused by:

- Solutions being injected too close together.
- Damaged skin caused by the shaving or injection in irritated skin.
- The dog scratching the injection site(s) in the period between the intracutaneous injection and the reading of the test.
- Sedation with morphine. This substance leads to a release of histamine which produces the wheal.

False-negative reactions can be caused by:

- Subcutaneous injection instead of intracutaneous injection.
- Testing outside the relevant season (if applicable).
- Interaction with certain medicines, see under 12 Special Warning(s)
- The dog lies on the tested side on a cold surface, which reduces the evident increase in a wheal.
- The dog is greatly stressed.

## 10. WITHDRAWAL PERIOD

Not applicable.

## 11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Store in a refrigerator (2 °C - 8 °C).
Do not freeze.
Store in the original package.

Do not use after the expiry date which is stated on the label after EXP:

## 12. SPECIAL WARNING(S)

Special precautions to be taken by the person administering the veterinary medicinal product to animals.
In case of accidental self-injection, consult a doctor immediately and show him/her the leaflet or the label.
People with a known hypersensitivity to mite/insect allergens or one of the excipients must avoid contact with the veterinary medicinal product.

Use during pregnancy, lactation or lay
The safety of the veterinary medicinal product has not been proven during pregnancy or lactation.

Interaction(s) with other medicinal products and other forms of interaction
The immunological veterinary medicinal product must be administered at different sites.

Corticosteroids, tranquillizers, immunosuppressant's and antihistamines can interfere with the allergy test. Therefore, these veterinary medicinal products must be stopped at least two weeks (depot preparations 6 weeks) prior to the allergy test.

Available safety and efficacy data show that this immunological veterinary medicinal product can be administered on the same day but not mixed with other Artuvetrin Test preparations.

There is no information available about the safety and effectiveness of this immunological veterinary medicinal product with any other veterinary medicinal product, except the above-mentioned veterinary medicinal products. Regarding the use of this immunological veterinary medicinal product before or after any other veterinary medicinal product, a decision should be made in each individual case.

Overdose (symptoms, emergency procedures, antidotes)
No other adverse effects are known with overdose than those listed under section 6.

Incompatibilities
As no research has been done into compatibility, the veterinary medicinal product must not be mixed with other veterinary medicinal products.

## 13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Unused veterinary medicinal product or waste materials should be disposed of in accordance with the national regulations.
Ask your veterinary doctor about how to dispose of medicines no longer required. These measures should help to protect the environment.

## 14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

25 March 2021

## 15. OTHER INFORMATION

Glass 3-ml vial with a rubber stopper and aluminum cap.

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For any information about this veterinary medicinal product, please contact:
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