PACKAGE LEAFLET FOR
Artuvetrin Therapy

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

Artuvet Animal Health b.v.
Vijzelweg 11
8243 PM Lelystad (NL)

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Artuvetrin Therapy

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

Active substances:
Allergen extracts from pollen, mites and insects, epithelia, yeast and moulds:
See vial label.

The veterinary medicinal product prescribed by a veterinary doctor is individually prepared for a dog and contains at most eight (8) allergens or mixtures of allergens.

1 ml contains:

	Artuvetrin Therapy				**Artuvetrin Therapy Forte**			
Number of extracts (allergens)	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**
Concentration per pollen extract/ allergen(mixture)	1000 NU/ml	500 NU/ml	333 NU/ml	250 NU/ml	400 NU/ml	333 NU/ml	286 NU/ml	250 NU/ml
Concentration per epithelium extract/ allergen(mixture)	100 µg/ml	50 µg/ml	33 µg/ml	25 µg/ml	40 µg/ml	33 µg/ml	29 µg/ml	25 µg/ml
Except for sheep epithelium	10 µg/ml	5 µg/ml	4 µg/ml	3 µg/ml	4 µg/ml	3 µg/ml	3 µg/ml	3 µg/ml
Concentration per yeast/mould extract/ allergen	100 µg/ml	50 µg/ml	33 µg/ml	25 µg/ml	40 µg/ml	33 µg/ml	29 µg/ml	25 µg/ml
Concentration per mite/insect extract/ allergen	100 NU/ml	50 NU/ml	33 NU/ml	25 NU/ml	40 NU/ml	33 NU/ml	29 NU/ml	25 NU/ml
Except for flea, culex, tabanus, culicoides	10 NU/ml	5 NU/ml	3 NU/ml	3 NU/ml	4 NU/ml	3 NU/ml	3 NU/ml	3 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.

Adjuvant:
Aluminium hydroxide
Artuvetrin Therapy : 0.3 mg
Artuvetrin Therapy forte : 0.5 mg

4. INDICATION(S)

Treatment of allergen-specific atopy in dogs.
For the correct diagnostic assessment, a proper anamnesis must be done along with an IgE-specific test.

5. CONTRAINDICATIONS

Do not use with:
-Disorders affecting the working of the immune system (e.g. immunodeficiencies, malignities and auto-immune diseases).
-Renal function disorders
-Hypersensitivity to the adjuvant or one of the excipients.

6. ADVERSE REACTIONS

A slight worsening of pruritus can be noted after the allergen injection.
In sporadic cases anaphylactic shock can occur after injections with allergens with symptoms like lethargy, oedema of the head, pruritus, dyspnea, vomiting, diarrhoea 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

The veterinary medicinal product is administered subcutaneously according to the following dosage schedule.

Adjustment period:

Week number	Day	Dosage (in ml)
1	**1**	**0.2**
3	**15**	**0.4**
5	**29**	**0.6**
7	**43**	**0.8**
10	**64**	**1.0**
13	**85**	**1.0**

Maintenance period:

Week number	Day	Dosage (in ml)
17	**113**	**1.0**
21	**141**	**1.0**
Etc.		

The maintenance treatment (1.0 ml) is continued after an interval of at least 4 weeks and lasts for life in principle.

The effect of the treatment can be judged by the improvement in the clinical picture.
If no improvement is evident by 8 months after the start of the treatment, it can be concluded that further treatment with the allergens in question will not have any effect.

In periods of high concentrations of an allergen in the air (for example during the flowering season of grasses) to which the dog is allergic, there may occasionally be brief relapses in the symptoms. It is recommended to reduce the dose during these periods.
In consultation with the treating veterinary doctor, deviations may be made in the dosing schedule.

9. ADVICE ON CORRECT ADMINISTRATION

The veterinary medicinal product prescribed by a veterinary doctor is individually prepared for a patient. Check that the vial contains the therapy prepared for the patient before drawing it up into the syringe. The allergens are listed on the vial's label.
Check the quantity of suspension to be administered, following the dosage schedule.
Shake the vial before use. Then insert the needle of the syringe through the rubber cap and withdraw the required quantity of suspension. Hold the syringe vertical with the needle upwards and remove any bubbles by tapping the syringe. Press carefully on the plunger until the first drop appears.
Pull up a fold of skin and form a depression with your index finger. Place the needle in the depression and push it slowly through the skin. Let go of the skin. Press down on the plunger slowly and smoothly until the syringe is empty.

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 for use in animals
It is recommended to reduce as much as possible or even stop the dose of any current treatment with corticosteroids or immunosuppressants two weeks before starting the adjustment period for the veterinary medicinal product.

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 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.

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 Therapy 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 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

23 december 2015

15. OTHER INFORMATION

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