# APiTHER DEPOT

**Personalised Subcutaneous Allergen Immunotherapy**

***APPLICATION CARD FOR CONTINUATION TREATMENT APITHER DEPOT***

## WARNINGS

*This application card should be signed by your Doctor, and should be process in a pharmacy.

*It is recommended to make the request one month before de ending, to avoid the treatment stopping.

*In case you stop the treatment, talk to your Doctor to establish a new dose regimen.



In case of any of these more serious symptoms, talk to your doctor inmmediately.

### Precautions:

In exceptional cases, this treatment can pose a risk of generalised and sometimes severe reactions (hives, asthma, anaphylactic shock, etc.). The following rules therefore should be followed throughout the period of the treatment:

1. It is paramount for the healthcare personnel to carefully read the administration requirements before applying the extract.
2. The allergen extract should always be administered under medical supervision.
3. Allergenic extracts should only be administered when immediate treatment is available to the patient if he/she suffers a generalised reaction (hives, asthma, anaphylactic shock, etc.), such as subcutaneous adrenaline or others. For this reason, these treatments must be administered in a properly equipped medical setting, primary care centres, medical specialist centres or hospitals. Under no circumstances should they be administered in the patient's home.
4. After the administration of every single dose, the patient must remain for at least 30 minutes in the centre where the medicinal product has been administered.
5. In the event of any side effect, and before proceeding with the treatment, talk to the prescribing doctor.
6. Guideline for the correct adrenaline administration.

Subcutaneous adrenaline 1/1,000 wil be administered at dose 0.01 mL/kg of weight/ 20 minutes.

The approximate doses for correct adrenaline administration are:

- Children under 6 years: 0,2 ml.
- Children 6 to 12 years: 0,4 ml.
- Adults: 0,5 – 0,8 ml

If the generalised reaction persists, these doses can be repeated every 15 minutes for a maximum of 3 times. If necessary, transfer the patient to a hospital emergency room.

Regular monitoring of the patient must be carried out by the prescribing doctor, who undertakes to carry out the appropriate dilutions of the extract and any other modifications to the treatment the patient may require.

The redness at the injection site is normal, as long as it does not exceed 5 cm in diameter. If a major reaction occurs, the medication or measures that the doctor has prescribed for that reaction should be taken.

### 5. How to store Apither Depot

Keep this medicine out of sight and reach of children.

Store in a refrigerator (between 2 and 8°C).

Do not freeze.

Store in original packaging.

Do not use Apither Depot after the expiry date which is stated on the label after exp. date. The expiry date refers to the last day of that month.

Do not use Apither Depot if the vial has lost some of its contents or if the packaging has been damaged.

### 6. Contents of the pack and other information

### What Apither Depot contains

- The active substance of Apither Depot are allergen extracts to which the patient is sensitised which has been prescribed by the specialist.
- The other ingredients are the depot diluent, composed of aluminum hydroxide in physiological saline solution.

### What Apither Depot looks like and contents of the pack

Apither Depot is supplied as injection vials for subcutaneous administration.

Apither Depot consists of two presentations or containers corresponding to initiation and maintenance treatment, as follows:

***Initiation treatment:***

- The pack may contain, three or two vials, identified with numbers and colours at the following concentrations. This treatment can be started with any of the vials depending on the rate of administration scheduled by your doctor.
- Vial 1 – concentration 1/100 of vial 3, green label, total volume 3,6 ml.
- Vial 2 – concentration 1/10 of vial 3, yellow label, total volume 3,6 ml.
- Vial 3 – maximum concentration, red label, total volume 4,5 ml.

***Maintenance treatment:***

- The presentation pack may contain one or two vials 3, red label, maximum concentration and volume of 4,5 ml.

In both packs 1 ml single use syringes are included to facilitate proper dosage and administration conditions.

### Marketing authorisation holder and manufacturer

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Teléfono:+34 965.28.67.00 - Fax: +34 965.28.64.34
Email: prospectos@asac.net

### Manufactured by:

Laboratorios Diater S.A.
Avda Gregorio Peces Barba,2
Parque Tecnológico de Leganés
28918 Leganés (Madrid)

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ASAC Pharmaceutical Immunology

# APiTHER DEPOT

**Personalised Subcutaneous Allergen Immunotherapy**

**Package leaflet: Information for the user**
**Apither Depot subcutaneous personalized allergenic Immunotherapy**

**Read all of this leaflet carefully before you start using this medicine because it contains important information for you.**
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

### What is in this leaflet



### 1. What Apither Depot is and what it is used for

Apither Depot is an immunotherapy treatment (vaccine), composed of allergen extracts to which the patient is sensitised, adsorbed in an aluminum hydroxide gel, which serves to reduce the antigen in the body. It is supplied as injectable suspension for subcutaneous administration.

Apither Depot is prepared on an individual basis for each patient since each patient has a different sensitivity to certain substances called allergens. The doctor therefore should decide the composition of Apither Depot suited to each case. Apither Depot is used for the treatment of allergic diseases associated with rhinitis, rhinoconjunctivitis or seasonal or perennial bronchial asthma.

## 2. What you need to know before you use Apither Depot

### Do not use Apither Depot:

- If you are allergic to any other ingredients of this medicine (listed in section 6).
- If you have a severe immune deficiency or active autoimmune disease.
- If you have diseases that severely affect your immunity.
- If you have fever.

### Warnings and precautions

Talk to your doctor or pharmacist before using Apither Depot.
Apither Depot should be administered subcutaneously, make sure not to administrate it intramuscular or intravenous route.

### Other medicines and Apither Depot

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines. Tell your doctor or pharmacist if you are in treatment with β-blockers, medicines using to treat specific heart diseases or high blood pressure.

### Apither Depot with food, drink and alcohol

No interactions with food, drink or alcohol have been described.

### Pregnancy, breast-feeding and fertility

No information is available on the safety of this vaccine during pregnancy or breast-feeding. If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

### Driving and using machines

No effects on the ability to drive and handle tools or machines have been described and therefore no special precautions are required.

### Apither Depot contains sodium chloride, phenol and sodium chloride.

## 3. How to use Apither Depot

They should be administered in medical consultations, primary care centers, outpatient clinics or hospitals suitably equipped for the treatment of potential adverse reactions. It should not be administered in any case in the patient's home.
Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.
Remember that this treatment should be administered under medical supervision, where measures are available to deal with a possible anaphylactic reaction.
The dosage regimen described in this leaflet is a guidance and may be changed by your doctor. Your doctor will indicate the duration of your treatment with Apither Depot. Do not discontinue the treatment before the time indicated by your doctor.
It is very important for you to follow the instruction before use Apither Depot:
- Start to administer the treatment with the lowest numbered vial which corresponds to the lowest concentration.
- Shake the vial gently before each dose.
- Extract the dosage of the treatment.
- Ensure that the administration route is subcutaneous. The injection will be administered in the dorsal upper arm, 20 cm above the elbow, alternating arms in each administration. Care is taken to ensure it is not administered intravenously.
- The treatment will continue in the same way with the next vials, in ascending numerical order (according to the numbering of label).
You must avoid brusque movements or strenuous exercise for the first few hours after administration

### Administration schedule:

- The specific schedule is a guidance and may changed as your doctor sees fit.
- The injection will be given at weekly intervals and then the maximum dose will be given once a month over a long period of time ranging from 3 to 5 years. Your doctor will determine the duration of treatment in each case.
- The blank spaces on the administration card (tables of this leaflet) are intended to record possible dose repetition or changes to the dosage or the schedule prescribed by your doctor.

Treatment is carried out in two phases, an initial phase, which consists of a gradual increase in the allergenic dose administered until the maximum tolerated dose is administered, and afterwards, a continuation phase, which the maximum dose is administrideed on a monthly basis for at least 3-5 years.

### Conventional schedule

### Starting Treatment

It is important to note the date of each dose in the corresponding administration card box (tables of this leaflet).

| VIAL Nº | VOLUME TO BE INJECTED | INTERVAL BETWEEN ADMINISTRATIONS | DATE | COMMENTS |
|---|---|---|---|---|
| **1 Green Label** | 0,1 mL | 1 week | | |
| | 0,2 mL | 1 week | | |
| | | | | |
| | 0,4 mL | 1 week | | |
| | | | | |
| | 0,8 mL | 1 week | | |
| | | | | |

| VIAL Nº | VOLUME TO BE INJECTED | INTERVAL BETWEEN ADMINISTRATIONS | DATE | COMMENTS |
|---|---|---|---|---|
| **2 Yellow Label** | 0,1 mL | 1 week | | |
| | 0,2 mL | 1 week | | |
| | | | | |
| | 0,4 mL | 1 week | | |
| | | | | |
| | 0,8 mL | 1 week | | |
| | | | | |

| VIAL Nº | VOLUME TO BE INJECTED | INTERVAL BETWEEN ADMINISTRATIONS | DATE | COMMENTS |
|---|---|---|---|---|
| **3 Red Label** | 0,1 mL | 1 week | | |
| | 0,2 mL | 1 week | | |
| | | | | |
| | 0,4 mL | 1 week | | |
| | | | | |
| | 0,6 mL | 1 week | | |
| | | | | |
| | 0,8 mL | 1 week | | |
| | Maximum dose | 2 weeks | | Request maintenance treatment |

### Maintenance treatment:

| VIAL Nº | VOLUME TO BE INJECTED | INTERVAL BETWEEN ADMINISTRATIONS | DATE | COMMENTS |
|---|---|---|---|---|
| **3 Red Lable** | | | | |
| | Maximum dose | 1 month | | |
| | | | | |
| | Maximum dose | 1 month | | |
| | | | | |
| | Maximum dose | 1 month | | Request next maintenance treatment |
| | | | | |
| | Maximum dose | 1 month | | |

A slight opacity can be presented after shake the vial.

### If you use more Apither Depot than you should

If you use more Apither Depot than you should, talk to your doctor inmediately.

### If you forget to use Apither Depot

Do not take a double dose to make up for a forgotten one.
In order for the treatment to be effective, Apither Depot must be used regularly throught the treatment period.

### If you stop using Apither Depot

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.
Your doctor will determine the duration of the treatment for each case.

## 4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.
Most side effects are due to improper administration of the allergen extract. For this reason we recommend you to read this leaflet carefully.
The most common local reactions are redness, oedema or inflammation at the injection site; these side effects normally occur between 10-60 minutes after the injection and may persist for several hours and disappear without treatment.
Systemic reactions (asthma, generalized hives, laryngeal oedema) are less common and may require treatment with antihistamines, bronchodilators or injectable corticosteroids while maintaining the patient under medical observation. Occasionally headache, dizziness or discomfort may occur.

## PHARMACY DATA

Pharmacy ..... N.I.F. .....

Address ..... P.C. .....

City ..... Country .....

Phone .....

**COMMENTS** .....

.....

SEND THIS CARD COMPLETED TO API S.A., POSTAL CODE Nº 5427, ALICANTE.
Nº FAX 96 528 62 45
***TICK WITH A CROSS IF YOU HAVE SENT THE FAX PREVIOUSLY*** ☐

## MEDICAL DATA

Dr. .....

Nº association .....

Date .....

☐ 1 VIAL Nº 3
☐ 2 VIALS Nº 3

The minor presentation will be send in case no treatment reflected.

Signature

Label with barcode