APiTHER POLYMERIZED

Personalised Subcutaneous Allergen Immunotherapy

APPLICATION CARD FOR CONTINUATION TREATMENT APITHER POLYMERIZED

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.

We inform you that the personal data consigned in this document, will be included in a file whose ownership corresponds to ASAC PHARMACEUTICAL IMMUNOLOGY, S.A., in order to manage and control the prescription of the requested products, and make the appropriate communications. ASAC PHARMACEUTICAL IMMUNOLOGY, S.A. also informs you that these data will be handle according to the provisions of the current legislation on the subject of protection of personal data and, especially, in the Regulation (UE) 2016/679 and "*Ley Orgánica 3/2018*" of December 5, Protection of Personal Data and guarantee of the digital rights.

The data will be kept as long as it is necessary to keep them in accordance with the aforementioned purpose, and when it is no longer necessary, they will be blocked and / or deleted with the application of adequate security measures and in accordance with the types of data processed. Personal data will not be communicated to third parties, except legal obligation.

The interested party has the right to exercise, with respect to the data requested, the following rights:

- Withdraw consent at any time;
- Right of access, rectification, portability and deletion of your data, as well as limitation or opposition to its processing;
- Right to submit a claim with the Control Authority (Spanish Agency for Data Protection: https://www.aepd.es/) if you consider that the treatment does not comply with current regulations.

Contact details to exercise your rigths: ASAC PHARMACEUTICAL IMMUNOLOGY, S.A. C/ Capricornio, 5 – 03006 - Fax: +34 965 286 434 – Email: apipedidos@asac.net

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 allergenic extract.

For this reason we recommend you read this leaflet carefully.

The most common local reactions are redness, oedema or inflammation at the injection site, they are normal but not exceeding 5 cm diameter. These side effects normally occur between 10-60 minutes after the injection and persist for several hours and disappear without medical treatment. If biggest local reaction occur, you may need medication or other measures prescribed by your doctor.

Systemic reactions (asthma, hives, laryngeal oedema), are less common and may require treatment with antihistamines, bronchodilators or injectable corticosteroids while maintaining the patient under medical observation.

Anaphylactic reactions require urgent administration of a subcutaneous or intramuscular 1/1000 adrenaline injection, which can be repeated if necessary. The recommended dose in children is 0.01 ml/kg body weight, without exceeding 0.5 ml.

The approximate doses for correct adrenaline administration are:

- Children up to 6 years: 0.2 ml
- Children aged 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.

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

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

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 treatment:

1. It is paramount for the healthcare personnel to carefully read the administration requirements before applying the extract.

2. The allergen vaccine 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 adrenaline or others. For this reason, these treatments must be administered in a properly equipped medical setting, primary care centers, medical specialist centers 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.

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.

5. How to store Apither Polymerized

Keep this medicine out of the sight and reach of children.

Store in the refrigerator (between 2-8°C).

Do not freeze.

Store in original packaging.

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

Do not throw away any medicines via wastewater. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Apither Polymerized contains

- The active substance is modified allergen extracts to which the patient is sensitized, which has been prescribed by the specialist.
- The other ingredients are saline solution and phenol.

What Apither Polymerized looks like and contents of the pack

Apither Polymerized is supplied as injection vials for subcutaneous administration.

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

Initiation treatment:

- The pack can contain, three, two or one vials, identified with numbers and colours and the following concentrations:
- Vial 1 - concentration 1/100 of vial 3, green label, total volume of 3ml.
- Vial 2 - concentration 1/10 of vial 3, yellow label, total volume of 3 ml
- Vial 3 - maximum concentration, red label, total volume of 3 ml.

This treatment can be started with any of the vials depending on the rate of administration scheduled by your doctor.

Continuation treatment:

- The presentation pack may contain one or two vials 3, red label, maximum concentration and volume of 3 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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Telephone: +34 965 28 67 00 - Fax: +34 965 28 64 34

E-mail: prospectos@asac.net

Manufactured by:

Laboratorios Diater S.A.

Avda Gregorio Peces Barba,2

Parque Tecnológico de Leganés

28918 Leganés (Madrid)

This leaflet was last revised in:

July 2019

ASAC Pharmaceutical Immunology

APiTHER POLYMERIZED

Personalised Subcutaneous Allergen Immunotherapy

Package leaflet: Information for the user

Apither Polymerized 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 Polymerized is and what it is used for

Apither Polymerized is an immunotherapy treatment (vaccine), composed of allergen extracts to which the patient is sensitised. It is administered via subcutaneous route for the treatment of allergic diseases.

The allergenic extracts of Apither Polymerized are extracts that have been modified with the aim of reducing the capacity to produce adverse reactions while maintaining the ability to induce an adequate immune response.

Apither Polymerized is prepared on an individualised basis for each patient since each patient has a different sensitivity to certain substances called allergen. The doctor therefore should decide the composition of Apither Polymerized suited to each case.

Apither Polymerized is used for the treatment of allergic diseases associated with rhinitis, rhino-conjunctivitis or seasonal or perennial bronchial asthma.

Pharmacoterapeutic group: Allergen Extracts. V01 AA Code.

2. What you need to know before you use Apither Polymerized

Do not use Apither Polymerized:

- If you are allergic to any of the other ingredients of this medicine (listed in section 6).
- If you have severe immune deficiency or active autoimmune disease.
- If you have severe or poorly controlled asthma.
- If you can not be administered adrenaline.
- If you are receiving treatment with beta-blocker agents.
- If you have fever.
- If you have AIDS.
- If you have cancer.
- Children less than 2 years old.
- If you are pregnant.

Warnings and precautions

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

Other medicines and Apither Polymerized

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines, including other vaccines.

Talk to your doctor or pharmacist if you are in treatment with beta-blockers (medicines to treat high blood pressure or some heart diseases or immunosuppresant).

Apither Polymerized with food, drink and alcohol

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

Pregnancy, breast-feeding and fertility

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.
No information is available on the safety of this vaccine during pregnancy or breast-feeding.

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 Polymerized contains phenol and sodium chloride.

3. How to use Apither Polymerized

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 Polymerized. Do not discontinue the treatment before the time indicated by your doctor.
It is very important for you to follow the instructions for use, unless your doctor has given you others:
- 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.
- Proceed in the same way with the following vials, in ascending numerical order (according to the numbering of label).

You must avoid violent movements, exercise or hot bath 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 for any repetition of a dose or for any changes in the volumes to be injected, or to the administration intervals your doctor may have prescribed.

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

Starting treatment:

Conventional schedule

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

A slight opacity can be presented after shake the vial.

VIAL	VOLUME TO BE INJECTED	INTERVAL BETWEEN ADMINISTRATIONS	DATE	COMMENTS
1 Green label				
	0.5 ml	1 week		

VIAL	VOLUME TO BE INJECTED	INTERVAL BETWEEN ADMINISTRATIONS	DATE	COMMENTS
2 Yellow label				
				Request maintenance treatment
	0.5 ml	1 week		

VIAL	VOLUME TO BE INJECTED	INTERVAL BETWEEN ADMINISTRATIONS	DATE	COMMENTS
3 Red label				
	0.5 ml	1 week		
	0.5 ml	1 month		
	0.5 ml	1 month		
	0.5 ml	1 month		
	0.5 ml	1 month		
	0.5 ml	1 month		

Initiation treatment:

Cluster schedule

VIAL	VOLUME TO BE INJECTED	INTERVAL BETWEEN ADMINISTRATIONS	DATE	COMMENTS
3 Red label	0.2 + 0.3 ml*	30- 45 minutes		
	0.5 ml	Month 1		
	0.5 ml	Month 2		
	0.5 ml	Monthly until vial finalisation.		

*Doses separated by 30-45 minutes

Continuation treatment

VIAL	VOLUME TO BE INJECTED	INTERVAL BETWEEN ADMINISTRATIONS	DATE	COMMENTS
3 Red label				
	0.5 ml	1 month		
	0.5 ml	1 month		
				Request next maintenance treatment
	0.5 ml	1 month		
	0.5 ml	1 month		

If you use more Apither Polymerized than you should

If you use a higher dose than the recommended one the risk of side effects can increase. In this case the treatment should be suspended as your doctor determines.

If you forget to use Apither Polymerized

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

If you stop using Apither Polymerized

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

If you stop using Apither Polymerized

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.

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