APiTHER

Personalised Sublingual Spray Allergenic Immunotherapy

APPLICATION CARD FOR CONTINUATION TREATMENT APITHER SUBLINGUAL SPRAY

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

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 allergenic extract.

For this reason we recommend you read this leaflet carefully.

The most common local reactions affect the oral cavity and are classified as oral allergy syndrome (itching, swelling, oedema, etc.). If a stronger local reaction arises, the medicine or measures the doctor has prescribed for the reaction must be taken.

Systemic reactions such as rhinitis, conjunctivitis, asthma and urticaria are less common. If any of these adverse reactions occur, antihistamines, bronchodilators or even corticosteroid injections must be administered and the patient is to remain under medical monitoring.

Serious generalised respiratory reactions, severe itching of the palms of the hands or soles of the feet, nausea, headache, bronchospasm, angioedema or shock rarely occur.

These more serious symptoms require emergency treatment. If you notice any of these symptoms, report to the nearest medical centre immediately.

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 of age: 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.

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 (urticaria, asthma, anaphylactic shock, etc.). The following rules therefore should be followed throughout the period of treatment:

In the event of the onset of any adverse reaction, ask the prescribing doctor before continuing with treatment.

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 modification to the treatment the patient may require.

Reporting of side effects

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

By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Apither Sublingual Spray

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

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

Do not freeze.

Keep in the original package.

Do not use this medicine after the expiry date which is stated on the container after "EXP". The expiry date refers to the last day of that month.

Do not use this medicine if you notice that the vials have leaked or if the container has been damaged.

Do not throw away any medicines via wastewater or household waste.

Ask your pharmacist how to throw away medicines and packages you no longer use. These measures will help to protect environment.

6. Contents of the pack and other information

What Apither Sublingual Spray contains

- The active substances are allergenic extracts to which the patient is sensitised, and which have been prescribed by the specialist.
- The other ingredients are sodium chloride, phenol, glycerol and phosphates.

What Apither Sublingual Spray looks like and contents of the pack

Apither Sublingual Spray is supplied in vials for oral administration.

Apither Sublingual Spray is supplied in two containers corresponding to the starting treatment and continuation treatment:

Starting treatment:

3 different presentations that can contain one, two or three vials of allergenic extract, identified by letters and colours, at the following concentrations:

- Kit 1: 1 vial C and 2 vials D.
- Kit 2: 1 vial D.
- Kit 3: 2 vials D.

Where:

Vial C - 1/5 concentration of vial D, yellow label, with total volume 3 ml.

Vial D - maximum concentration (1/1), red label, with total volume 9 ml.

Continuation treatment:

3 different presentations that can contain one, two or three vials of allergenic extract, identified by letters and colours, at the maximum concentration:

- Kit 1: 1 vial D (red label) 9 ml.
- Kit 2: 2 vials D (red label) 9 ml.
- Kit 3: 3 vials D (red label) 9 ml.

Marketing authorisation holder and manufacturer

ASAC Pharmaceutical Immunology, S.A.

C/ Capricornio 5, 03006 - Alicante (Spain)

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:

June 2019

ASAC Pharmaceutical Immunology

APiTHER

Personalised Sublingual Spray Allergenic Immunotherapy

Package leaflet: Information for the user
Personalised Sublingual Spray Allergenic Immunotherapy

Read all of this leaflet carefully before you start taking 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 Sublingual Spray is and what it is used for

Apither Sublingual Spray is a treatment of immunotherapy (vaccine) composed of allergenic extracts to which the patient is sensitised. It is administered via sublingual route for the treatment of allergic diseases.

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

Pharmacotherapeutic group: Allergenic extracts. Code V01 AA.

2. What you need to know before you take Apither Sublingual Spray

Do not take Apither Sublingual Spray:

- 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 cancer.
- If you have severe or poorly controlled asthma.
- If you cannot be administered adrenaline.
- If you are receiving treatment with beta-blocker drugs.
- If you have fever.
- If you have psychiatric disorders.
- If you have difficulties that prevent an adequate treatment adherence.

Warnings and precautions

Talk to your doctor or pharmacist before taking Apither Sublingual Spray.
Apither Sublingual Spray is administered via the oral route.
Before taking Apither Sublingual Spray, the patient symptoms must be controlled, with the help of appropriate treatment if necessary.
In the event of onset of any adverse reaction, ask the prescribing doctor before continuing with treatment.
If necessary, transfer the patient to a hospital emergency room. Regular follow-up by the specialist, who is responsible for making any changes to the treatment required by the patient, is essential.

Children and adolescents

As a general rule, Apither Sublingual Spray should not be used in children under 2 years of age.

Other medicines and Apither Sublingual Spray

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, specially β-blockers or antihistamine.

Apither Sublingual Spray 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. It is therefore advisable not to use the product in such situations.

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 Sublingual Spray contains glycerol and phenol.

This medicine contains glycerol and phenol and therefore may cause headache, stomach discomfort and diarrhoea.

3. How to take Apither Sublingual Spray

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.
1 puff of Apither Sublingual Spray is equivalent to 0.1 ml.
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 Sublingual Spray. 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:
- Administration preferably should be under fasting conditions or before meals.
- Before increasing the dose, make sure that the previous dose has caused no adverse reactions.
- When your starting treatment contains vials C and D, always start administration with vial C, which contains the lowest concentration.
- Shake the vial gently before each dose.
- The vial has to be in an upright position, without invert it.
- Before the first administration 3 or 4 puffs of air should be conducted to fully fill the valve and circuit.
- Administer via sublingual route. Place the appropriate dose under the tongue and allow it to act for 2-3 minutes until fully absorbed. Immediately afterwards, swallow any amount of the product remaining under the tongue.
- It is normal that some liquid left in the vial C. This is in case of a possible repetition or change of the dose by your Doctor.
- Proceed in the same way with the following vials, until the end of treatment.

Administration schedule:

- The specified schedule is a guidance and may be changed as your doctor sees fit.
- 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 tolerated dose is reached; and a continuation phase, in which the maximum dose is administered on a daily basis.
The duration of treatment will be established by the specialist.
In general, treatments of this kind are usually administered for at least 2-3 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).
- Starting treatment (1 vial C and 2 vials D, 1 vial D or 2 vials D)
- **Vial C:** this vial lasts 4 days, after which it is discarded. Administration starts with 1 puff, followed by daily increments (see dosing schedule).
- **Vial D:** administration begins on day 5 after the start of the treatment with vial C or directly with this vial, 1 puff until the vial/s are empty.

VIAL	DAY	DOSE (no. puffs)	DATE	COMMENTS
C Yellow label Dil. 1:5 of Vial D Volume: 3 ml	1	1		
	2	2		
	3	3		
	4	4		
D Red label Max. conc. Volume: 9 ml	5	1		
	6	1		
	7	1		
	8	1		
	9	1		
	10	1		
	Administer 1 puff a day until the vial is empty			

Pauta Rush:

VIAL	DOSE	INTERVAL OF DAILY ADMINISTRATION	DATE	COMMENTS
D Red label	1 puff	1 once a day until the vials are empty.		

Continuation treatment:

- Maintenance treatment (1, 2 or 3 vials D).
The recommended dose is 1 puff a day. The mean duration of each vial according to the recommended dosage is 3 months (see dosing schedule).
The doctor may modify the dose and schedule according to medical criterion.

VIAL	DAY	RECOMMENDED DOSE (no. puffs)	Date/dose administered (puffs)		
			Vial D	Vial D	Vial D
D Red label Max. conc. Vol.: 9 ml	1	1			
	2	1			
	3	1			
	4	1			
	5	1			
	6	1			
	7	1			
	8	1			
	9	1			
	10	1			
	11	1			
	12	1			
	13	1			
	14	1			
	15	1			

If you take more Apither Sublingual Spray than you should

Talk to your Doctor immediately if you take more Apither Sublingual Spray than you should.

If you forget to take Apither Sublingual Spray

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 taking Apither Sublingual Spray

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

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 D
☐ 2 vial D
☐ 3 vial D

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

Signature

Label with barcode