

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 bacterial vaccine is and what it is used for.
2. What you need to know before you take Apither bacterial vaccine.
3. How to take Apither bacterial vaccine.
4. Possible side effects.
5. How to store Apither bacterial vaccine.
6. Contents of the pack and other information.

1. What Apither personalised sublingual spray bacterial vaccine is and what it is used for

Apither bacterial vaccine is an inactivated bacteria suspension for immunotherapy, which is administered

via sublingual. Apither bacterial vaccine belongs to a group of medicines (inactivated bacteria vaccines) that stimulate the activity of the immune system against infectious agents, increasing the ability to limit its proliferation and the derived complications, in patients with aggravated chronic respiratory disease from recurring infections.

According to medical criteria, this vaccine may be prescribed for the prevention of recurrent respiratory diseases and urinary tract infections.

2. What you need to know before you take Apither bacterial vaccine

Do not take Apither bacterial vaccine:

- if you are allergic to the active substance or any of the other ingredients of this medicine (listed in section 6).
- if you have immune deficiency or severe autoimmune disease, or if you are being treated with immunosuppressants.

Warnings and precautions

Talk to your doctor or pharmacist before taking Apither bacterial vaccine.

The administration of the product is not recommended when you are suffering from an acute febrile episode or an active infection of the respiratory tract. In this case, you must stop the treatment and restart it when the process is resolved, unless your doctor tells you otherwise.

Children and adolescents

There is no information about the safety of Apither bacterial vaccine in children or adolescents.

Other medicines and Apither bacterial vaccine

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

No interactions between Apither bacterial vaccine and other medicines have been reported. Treatment with Apither bacterial vaccine does not replace treatment with any other medicine. Unless the doctor indicates, the administration of antibiotics or symptomatic medication should not be suspended.

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.

Although the administration of bacterial vaccines containing inactivated micro-organisms is not formally contraindicated during pregnancy and breast-feeding, no information is available on the use of Apither bacterial vaccine in these situations (pregnancy and breast-feeding). Before start the treatment, talk to your doctor if you are pregnant, or you may be pregnant, or if you are breast-feeding. Your doctor will assess whether or not to use this medicine.

Driving and using machines

No effects on driving or using machines have been reported.

3. How to take Apither bacterial vaccine

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Remember to take your medicine.

Apither bacterial vaccine is administered via sublingual. Do not inject.

Shake the vial before each application to ensure homogeneity of the bacterial suspension.

The first time you use the vial, press the dosing mechanism into the air 2-3 times to allow the spray to gain pressure. The treatment should preferably be administered under fasting conditions.

Method of administration

Place the dose under the tongue and allow it to act for 2 minutes. Then swallow the rest of the amount that has not been absorbed.

Dose and posology

Apither bacterial vaccine is an individualised treatment, so the dose will be established by the doctor. As a general rule, 2 puffs of the vaccine should be

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 the ending, to avoid the treatment stopping.

*Strictly follow the administration guideline received by your specialist.

*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 rights: ASAC PHARMACEUTICAL IMMUNOLOGY, S.A. C/ Capricornio, 5 – 03006 - Fax: +34 965 286 434 – Email: apipedidos@asac.net



Manufacturer

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away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Apither bacterial vaccine contains

The active substances are a suspension of 2600 million bacteria per each mL of product. The bacterial species found in the composition are established by the doctor on the basis of the patient diagnosis, with specification on the pack label.

The other ingredients are phenol, sodium chloride and purified water.

What Apither bacterial vaccine looks like and contents of the pack

Apither bacterial vaccine is supplied as vial for sublingual administration.

The package contains 2 vials of whitish bacterial suspension of equal concentration, 2,600 millions of bacteria per ml.

Each vial contains a total volume of 9.5 mL provided with a dispenser.

Apither Bacterial Vaccine presents turbidity due to bacteria in suspension.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Some patients have reported mild reactions at the application site, such as local irritation or sneezing, which subside spontaneously. More rarely, mild reactions elsewhere, such as increased body temperature, nasal and ocular congestion or urticaria-type reactions, may occur. Worsening of the clinical condition or the onset of an asthma attack have rarely been reported.

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 bacterial vaccine

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

Store in a refrigerator (2°C – 8°C). Do not freeze.

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

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw

administered daily as a single dose. The dose should be reduced by half (1 puff) in children under 12 years of age. The dose should be repeated every day until the treatment cycle of 3 months has been completed.

Carefully follow the instructions of your doctor, who will indicate the treatment plan and duration, as well as the best dosing regimen for you.

If you take more Apither bacterial vaccine than you should

Apither bacterial vaccine is a treatment that has shown an excellent tolerability.

In case of overdose or accidental intake talk immediately with your doctor or pharmacist.

If you forget to take Apither bacterial vaccine

Do not take a double dose to make up for a forgotten dose.

If you forget to use a dose, administer it as soon as possible. Then continue the next day as indicated by your doctor.

If you stop taking Apither bacterial vaccine

Unless undesirable effects occur, or where indicated by your doctor, do not discontinue the treatment, since the expected benefits would not be obtained.

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



APITHER

Personalised Sublingual Spray
Bacterial Vaccine

Doctor

Dr. _____

Association No _____

Date _____

Barcode label



Stamp, sign, associate n° and date

2 Vials presentation

SEND THIS CARD DULY COMPLETED TO: ASAC PHARMACEUTICAL IMMUNOLOGY S.A. (API)
TO POSTAL CODE 5427 03080 ALICANTE, apipedidos@asac.net

Pharmacy

Address _____ e-mail _____ Phone _____

City _____ Province _____ Postal code _____

C.I.F./N.I. _____ Date of order _____

If a new container is required by your doctor, please use this form as a letter-request.

IMPORTANT NOTE: before process the continuation treatment in your pharmacy, is a legal indispensable requirement, that is authorized with a doctor signature.

Please, mark this box if the order was sent by e-mail or fax