PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986

The medicine is dispensed with a physician's prescription only

Arexvy

Powder and suspension for suspension for injection

Before preparation, the powder vial (antigen) contains:

RSVPreF3[1] antigen	163 micrograms

After reconstitution, each dose (0.5 mL) contains:

RSVPreF3[1] antigen	120 micrograms

[1]Respiratory Syncytial Virus recombinant glycoprotein F stabilized in the pre-fusion conformation

For the list of inactive and allergenic ingredients in the preparation, see section 2 - "Important information regarding some of the ingredients of the medicine" and section 6 "Additional information".

Read the leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the physician or pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar.

1. WHAT IS THE MEDICINE INTENDED FOR?

Arexvy is indicated for active immunization for the prevention of lower respiratory tract disease (LRTD) caused by respiratory syncytial virus (RSV) in adults 60 years of age and older.

Therapeutic group: Anti-respiratory syncytial virus vaccines.

RSV is a respiratory virus that spreads very easily.

- RSV can cause lower respiratory tract disease – infection of the lungs and other parts of the body that help you breathe.

RSV infection can happen at any age, and usually causes mild, cold-like signs in adults. But it can also:

- cause more serious respiratory illness in infants and older adults.
- make some illnesses worse, such as long-term respiratory or heart diseases.

How does Arexvy work?

Arexvy helps your body's natural immune system produce antibodies and special white blood cells. These protect you against RSV.

Arexvy does not contain the virus. This means it cannot cause infection.

2. BEFORE USING THE MEDICINE

Do not use the medicine if:

- you are sensitive (allergic) to the active ingredient or any of the other ingredients contained in the vaccine (listed in section 6 “Additional information”).

If you are not sure if the above applies to you, talk to the physician or pharmacist.

Special warnings regarding use of the medicine

Before you receive Arexvy, tell the physician or pharmacist if:

- you have ever had a severe allergic reaction after the injection of any other vaccine.
- you have a severe infection with a high temperature (fever). If this happens, the vaccination may be delayed until you feel better. A minor infection, such as a cold, should not be a problem, but talk to the physician first.
- you have a bleeding problem or bruise easily.
- you have fainted with a previous injection – fainting can happen before or after any needle injection.

If any of the above apply to you, or you are not sure, talk to the physician or pharmacist before you receive Arexvy.

As with other vaccines, Arexvy may not fully protect all people who are vaccinated.

Drug interactions

If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, inform the physician or pharmacist.

Tell the physician or pharmacist if you have recently received any other vaccine.

Arexvy may be given at the same time as a flu vaccine.

If Arexvy is given at the same time as another injectable vaccine, a different injection site will be used for each vaccine, which means a different arm for each injection.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to become pregnant, consult the physician or pharmacist before being vaccinated with this vaccine.

Arexvy is not recommended during pregnancy or when breastfeeding.

Driving and operating machinery

Some of the effects listed in section 4 “Side effects” (such as feeling tired) may temporarily affect your ability to drive or operate machinery. Do not drive or operate machinery or use tools if you are feeling unwell.

Important information regarding some of the ingredients of the medicine

Arexvy contains sodium and potassium

The preparation contains less than 1 mmol sodium (23 mg) per dose, that is, it is considered “sodium-free”.

The preparation contains less than 1 mmol potassium (39 mg) per dose, that is, it is considered “potassium-free”.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use the preparation according to the physician’s instructions.
Check with the physician or pharmacist if you are uncertain about the dosage and treatment regimen of the preparation.
The dosage and treatment regimen will be determined by the physician only.

The usual dosage is generally:
Arexvy is given as a single dose injection of 0.5 mL into a muscle, usually into the upper arm.

Do not exceed the recommended dose.

Adhere to the treatment regimen as recommended by the physician.
Do not take medicines in the dark! Check the label and the dose each time you take medicine. Wear glasses if you need them.
If you have further questions regarding use of the medicine, consult the physician or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Arexvy may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

Very common side effects (may occur in more than 1 in 10 doses of the vaccine)
- pain at the injection site
- feeling tired (fatigue)
- headache
- muscle pain (myalgia)
- joint pain (arthralgia).

Common side effects (may occur in up to 1 in 10 doses of the vaccine)
- redness and swelling at the injection site
- fever
- chills.

Uncommon side effects (may occur in up to 1 in 100 doses of vaccine)
- itching at the injection site
- pain
- generally feeling unwell (malaise)
- enlarged lymph nodes, or swollen glands in the neck, armpit or groin (lymphadenopathy)
- allergic reactions, such as rash
- feeling sick (nausea)

- vomiting
- stomach pain.

Tell the physician or pharmacist if you experience any of the side effects listed above. Most of these side effects are mild to moderate in intensity and do not last long.

If a side effect occurs, if one of the side effects worsens, or if you are suffering from a side effect not mentioned in the leaflet, consult the physician.

Reporting side effects

Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage (http://www.health.gov.il), which directs you to the online form for reporting side effects or by entering the link: https://sideeffects.health.gov.il/

5. HOW TO STORE THE MEDICINE?

Avoid poisoning! This medicine and any other medicine must be kept in a safe place out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the physician.

Do not use the medicine after the expiry date (exp. date) that appears on the label and carton. The expiry date refers to the last day of that month.

Storage conditions

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

Store in the original package to protect from light.

Do not dispose of any medicine via the wastewater or household waste. Ask the pharmacist how to dispose of medicines that are not being used. These measures will help protect the environment.

6. ADDITIONAL INFORMATION

In addition to the active ingredients, the medicine also contains:

Powder:

◦ Trehalose dihydrate, Potassium dihydrogen phosphate, Dipotassium phosphate, Polysorbate 80.

Suspension:

◦ Sodium chloride, Potassium dihydrogen phosphate, Dioleoyl phosphatidylcholine, Disodium phosphate anhydrous, Cholesterol, 3-O-desacyl-4'-monophosphoryl lipid A, Purified Quillaja saponin, Water for injection.

What the medicine looks like and the contents of the package:

- powder and suspension for preparation of a suspension for injection.
- the powder is white.
- the suspension is an opalescent, colorless to pale brownish liquid.

One package of Arexvy contains:

- powder (antigen) for one dose, in a vial.

- suspension (adjuvant) for one dose, in a vial.

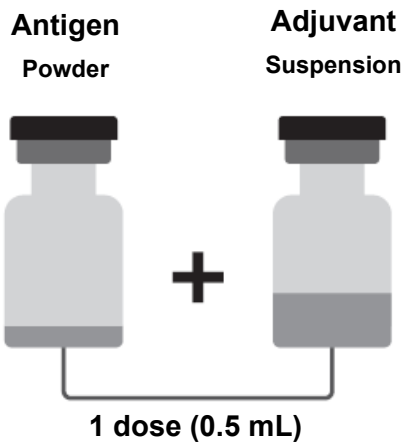
Arexvy is available in packages of one powder vial with one suspension vial or in packages of 10 powder vials with 10 suspension vials.
Not all package sizes may be marketed.

- License Holder: GlaxoSmithKline (Israel) Ltd., 25 Basel St., Petach Tikva.
- Manufacturer: GlaxoSmithKline Biologicals S.A., Rixensart, Belgium.
- Registration number of the medicine in the National Drug Registry of the Ministry of Health: 175-37-37768-00

This leaflet was checked and approved by the Ministry of Health in January 2024.

Arexvy PIL v1C

<u>The following information is intended for healthcare professionals only</u>:
Arexvy is presented as a vial with a mustard green flip-off cap containing the powder (antigen) and a vial with a brown flip-off cap containing the suspension (adjuvant). The powder and the suspension must be reconstituted prior to administration.



The powder and suspension should be inspected visually for any foreign particulate matter and/or variation of appearance. If either is observed, do not reconstitute the vaccine.

How to prepare Arexvy

Arexvy must be reconstituted prior to administration.

1. Withdraw the entire contents of the vial containing the suspension into the syringe.
2. Add the entire contents of the syringe into the vial containing the powder.
3. Gently swirl until the powder is completely dissolved.

The reconstituted vaccine is an opalescent, colourless to pale brownish liquid.

The reconstituted vaccine should be inspected visually for any foreign particulate matter and/or variation of appearance. If either is observed, do not administer the vaccine.

Chemical and physical in-use stability has been demonstrated for 4 hours at 2°C-8°C or at room temperature up to 25°C.
From a microbiological point of view, the product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and should not be longer than 4 hours.

Before administration

1. Withdraw 0.5 mL of the reconstituted vaccine into the syringe.
2. Change the needle so that you are using a new needle.

Administer the vaccine intramuscularly.
Any unused medicinal product or waste material should be disposed of in accordance with local requirements.