**PACKAGE LEAFLET: INFORMATION FOR THE USER**

**BioThrax Suspension for Injection**

Anthrax Vaccine Adsorbed (purified cell-free filtrate)

**Read this leaflet carefully and completely before your first injection of this medicine.**

- Keep this leaflet. You may need to read it again.
- If you have further questions, ask your doctor or healthcare provider.
- If any of the side effects gets serious, or if you notice any side effects not listed in **Section 4** of this leaflet, please tell your doctor or healthcare provider.

**In this leaflet:**



## 1 WHAT BIOTHRAX IS AND WHAT IT IS USED FOR

### What is BioThrax?

BioThrax is a vaccine used to prevent infection due to *Bacillus anthracis*.

### What is it used for?

It is used in adults to prevent anthrax disease.

Anthrax disease is a bacterial infection caused by exposure to *Bacillus anthracis* and your body's response to this infection. Vaccination with BioThrax prepares your body to fight off the infection by blocking the toxin that is produced by infection.

## 2 BEFORE YOU ARE INJECTED WITH BIOTHRAX

### Do NOT use BioThrax:

- If you are allergic to the active substance or any of the other ingredients in this vaccine (listed in **Section 6**).

### Take special care with BioThrax

Please inform your doctor if you:

- have an *impaired immune responsiveness* due to congenital or acquired immunodeficiency or
- are receiving *immunosuppressive* therapy;
- have had an *allergic reaction* following a previous dose of BioThrax or any of the vaccine components;

- have a *latex allergy* or hypersensitivity, because the vial stopper contains dry natural rubber blend which may contain trace amounts of latex proteins.

**Children**

The safety and effectiveness of BioThrax in children has not been established.

**Geriatrics**

The safety and effectiveness of BioThrax in subjects over 65 years of age has not been established.

**Taking Other medicines**

Please tell your doctor or healthcare provider if you are being treated with immunosuppresive therapy, or high-dose corticosteroid therapy, or cytotoxic medicine (e.g. chemotherapy).

**Using BioThrax with food and drink**

No special restrictions or precautions are indicated when receiving BioThrax vaccinations.

**Pregnancy and breast-feeding**

If you are pregnant, think you may be pregnant or are trying to get pregnant or breast-feeding, ask your doctor or healthcare provider to advise before receiving any vaccination or medication. As a precaution, pregnant women should not be routinely vaccinated with anthrax vaccine.

**Driving and using machines**

BioThrax has no or negligible influence on the ability to drive or use machinery. However, some of the side-effects listed under Section 4, may temporarily affect ability to drive or use machines.

## 3 HOW TO USE BIOTHRAX

This vaccine has been prescribed for you and will be administered by your doctor or healthcare provider. To administer, a small sterile needle and syringe will be used to withdraw a 0.5 mL dose of BioThrax from the multi-dose vial. The dose will be administered through an *intramuscular* (IM) injection in your upper arm.

**Recommended injection schedule**

For reliable protection, an initial vaccination regimen of 0.5 mL intramuscular (IM) at 0, 1 and 6 months, then booster doses every 3 years are recommended.

**If you miss an injection**

Notify your doctor or healthcare provider to determine the best course of action. In most instances, continuation of the schedule with adjustment to the times of injection is all that is needed to maintain your immunity.

**If you stop receiving the injections**

If you have any further questions on the use of this product, ask your doctor or healthcare provider.

## 4 POSSIBLE SIDE EFFECTS

Like all medicines, BioThrax may cause side effects, although not everybody gets them.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or healthcare provider. Provide them with information regarding your symptoms, time and date of side effect and when you received the vaccination. They can then use this information to treat you and report the incident as required by law.

***Very Common (more than 1 per 10)***

- Soreness, pain, redness, bruising, itching, swelling, or warmth at injection site
- Motion limitation in the injected arm
- A lump where the shot was given
- A burning sensation may occur immediately after the shot is given and can last about a minute
- Muscle aches, fatigue or headaches

***Common (less than 1 per 10, but equal or more than 1 per 100)***

- Discomfort in the armpit area (axillary lymph node).
- Chills, fever, dizziness, insomnia, nausea, or indigestion (dyspepsia).
- Cough, nasal/sinus ,or other respiratory tract infection
- Rash, itching.
- Joint, back or neck aches

***Uncommon (less than 1 per 100, but equal or more than 1 per 1000)***

- Injection site numbness/tingling
- Influenza-like illness, respiratory tract congestion, shortness of breath, sneezing, shingles (*herpes zoster*).
- Malaise
- Rapid heart rate
- Joint or muscle stiffness, extremity (arm) pain
- Eye allergy
- Skin redness (including skin flushing)
- Fainting
- Upper abdominal pain, vomiting, menstrual-like cramps (dysmenorrhea).

***Rare (more than 1 per 1000 but equal to or more than 1 per 10,000)***

- Serious allergic reaction. Signs of a serious allergic reaction include difficulty breathing, weakness, hoarseness or wheezing, a fast heartbeat, hives, dizziness, paleness or swelling of the throat, lips or face.
- Breast ductal carcinoma
- Increased pressure inside the skull (pseudotumor cerebri)

- Narrowing of duct leading to increased fluid in brain (aqueductal stenosis)
- Rotator cuff (shoulder tendon) tear
- Cold sweat

***Very rare (less than 1 per 10,000)***

- Severe, potentially life threatening allergic reaction (anaphylactic reactions)

**Side effects that have been reported during marketed use include:**

- Guillain-Barre syndrome (disorder in which immune system attacks nerves), seizure, brachial neuritis, somnolence
- Rhabdomyolysis (condition in which muscle cells break down)
- Swelling of deep layers of skin (angioedema), hair loss (alopecia), eczema, dry skin
- Slow heart rate, palpitations
- Difficulty in speaking (dysphonia)
- Diarrhoea, feeling of lump in throat (dysphagia)
- Enlarged axillary lymph node
- Hives at the injection site

If you experience any unusual condition, such as difficulty breathing, weakness, hoarseness or wheezing, a fast heartbeat, hives, dizziness, paleness or swelling of the throat, lips or face within a few minutes after the shot or within a few minutes to an hour after the shot, notify your doctor or healthcare provider immediately as this could be a sign of a severe reaction.

If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in Appendix 5

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

## 5 HOW TO STORE BIOTHRAX

- Keep out of the reach and sight of children.
- Do not use BioThrax after the expiry data which is stated on the label.
- Do not use more than 28 days after first opening.
- Store in refrigerator (2-8 °C).
- Do not freeze.
- Store in the original package in order to protect from light.

## 6 CONTENTS OF THE PACK AND OTHER INFORMATION

**What BioThrax contains**

One dose (0.5 mL) contains:

- Anthrax antigen filtrate: 50 micrograms

- Adsorbed on aluminium hydroxide (0.6 mg aluminium per dose)
- Benzethonium chloride
- Formaldehyde
- Sodium chloride
- Water for injections

The product is sterile and does **not** contain any living or dead bacteria.

The container of this medicinal product contains latex rubber. May cause severe allergic reactions.

**What BioThrax looks like and vial contents**

BioThrax is a milky-white suspension (when mixed) contained in a clear glass vial. The vial is closed with a stopper (chlorobutyl) and sealed with an aluminium cap. The product is supplied sterile and one vial contains enough vaccine for 10 injections of 0.5 mL.

**Marketing Authorisation Holder**

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For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder.

For product quality or safety concerns, please contact:

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This medicinal product is authorised in the Member States of the European Economic Area and in the United Kingdom (Northern Ireland) under the following names:

Germany, Netherlands, United Kingdom (Northern Ireland), Poland, Italy: BioThrax

France: BaciThrax

This leaflet was last revised in December 2022.