

## **Package leaflet: Information for the user**

### **IMVANEX suspension for injection**

Smallpox and monkeypox vaccine (Live Modified Vaccinia Virus Ankara)

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

**Read all of this leaflet carefully before you receive this vaccine 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 nurse.
- If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

#### **What is in this leaflet**

1. What IMVANEX is and what it is used for
2. What you need to know before you are given IMVANEX
3. How IMVANEX is given
4. Possible side effects
5. How to store IMVANEX
6. Contents of the pack and other information

#### **1. What IMVANEX is and what it is used for**

IMVANEX is a vaccine used to prevent smallpox, monkeypox and disease caused by vaccinia virus in adults.

When a person is given the vaccine, the immune system (the body's natural defence system) will produce its own protection in the form of antibodies against the smallpox, monkeypox and vaccinia viruses.

IMVANEX does not contain smallpox virus (Variola) or monkeypox virus or vaccinia viruses. It cannot spread or cause smallpox, monkeypox or vaccinia infection and disease.

#### **2. What you need to know before you are given IMVANEX**

##### **You must not receive IMVANEX:**

- if you are allergic or have previously had a sudden life-threatening allergic reaction to the active substance or any of the other ingredients of this medicine (listed in section 6) or chicken protein, benzonase, gentamicin or ciprofloxacin which may be present in the vaccine in very small amounts.

##### **Warnings and precautions**

Talk to your doctor or nurse before receiving IMVANEX:

- if you have atopic dermatitis (see section 4).
- if you have HIV infection or any other condition or treatment leading to a weakened immune system.
- if you are feeling nervous about the vaccination process or have ever fainted following any needle injection.

The protective efficacy of IMVANEX against smallpox, monkeypox and disease caused by vaccinia virus has not been studied in humans.

In case of illness with high temperature, your doctor will postpone the vaccination until you are feeling better. The presence of a minor infection, such as a cold, should not require postponement of the vaccination, but talk to your doctor or nurse first.

IMVANEX may not fully protect all people who are vaccinated.

Prior vaccination with IMVANEX may modify the cutaneous response ('take') to subsequently administered replication-competent smallpox vaccine resulting in a reduced or absent take.

### **Other medicines or vaccines and IMVANEX**

Tell your doctor or nurse if you are taking or have recently taken any other medicines or if you have recently received any other vaccine.

### **Pregnancy and breast-feeding**

If you are a pregnant or breast feeding, think you may be pregnant or are planning to have a baby, ask to your doctor for advice. The use of this vaccine during pregnancy and breast-feeding is not recommended. However, your doctor will assess whether the possible benefit in terms of preventing smallpox, monkeypox and disease caused by vaccinia virus would outweigh the potential risks to you and your foetus/baby.

### **Driving and using machines**

There is no information on the effect of IMVANEX on your ability to drive or use machines. However, it is possible that if you experience any of the side effects listed in section 4, then some of these may affect your ability to drive or use machines (e.g. dizziness).

### **IMVANEX contains sodium**

This medicine contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially 'sodium-free'.

## **3. How IMVANEX is given**

You can be given this vaccine whether or not you have received smallpox vaccination in the past.

The vaccine will be injected under the skin, preferably into the upper arm, by your doctor or a nurse. It must not be injected into a blood vessel.

### **If you have never been vaccinated against smallpox, monkeypox or vaccinia viruses:**

- You will receive two injections.
- The second injection will be given no less than 28 days after the first.
- Make sure you complete the vaccination course of two injections.

### **If you have previously been vaccinated against smallpox, monkeypox or vaccinia viruses:**

- You will receive one injection.
- If your immune system is weakened you will receive two injections with the second injection no less than 28 days after the first.

### **If you miss an appointment for your injection of IMVANEX**

If you miss a scheduled injection, tell your doctor or nurse and arrange another visit.

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

#### **4. Possible side effects**

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

##### **Serious side effects**

Contact a doctor immediately, or go immediately to the emergency department of your nearest hospital if you experience any of the following symptoms:

- difficulty in breathing
- dizziness
- swelling of the face and neck.

These symptoms may be a sign of a serious allergic reaction.

##### **Other side effects**

If you already have atopic dermatitis, you may experience more intense local skin reactions (such as redness, swelling and itching) and other general symptoms (such as headache, muscle pain, feeling sick or tired), as well as a flare-up or worsening of your skin condition.

The most common side effects reported were at the site of injection. Most of them were mild to moderate in nature and resolved without any treatment within seven days.

If you get any of the following side effects, tell your doctor.

**Very common** (may affect more than 1 in 10 people):

- headache,
- aching muscles,
- feeling sick,
- tiredness,
- pain, redness, swelling, hardness or itching at the injection site.

**Common** (may affect up to 1 in 10 people):

- chills,
- fever,
- joint pain, pain in extremities,
- loss of appetite,
- lump, discolouration, bruising or warmth at the injection site.

**Uncommon** (may affect up to 1 in 100 people):

- nose and throat infection, upper respiratory tract infection,
- swollen lymph nodes,
- abnormal sleep,
- dizziness, abnormal skin sensations,
- muscle stiffness,
- sore throat, runny nose, cough,
- diarrhea, vomiting,
- rash, itch, skin inflammation,
- bleeding, irritation,
- underarm swelling, feeling unwell, flushing, chest pain, pain in the armpit,
- increase of cardiac laboratory values (like Troponin I ), liver enzyme increased, white blood cell count decreased, mean platelet volume decreased.

**Rare** (may affect up to 1 in 1 000 people):

- sinus infection,
- influenza,
- redness and discomfort in the eye,
- hives (nettle rash),
- skin discolouration,
- sweating,
- skin bruising,
- night sweats,
- lump in skin,
- back pain,
- neck pain,
- muscle cramps,
- muscle pain,
- muscle weakness,
- swelling of the ankles, feet or fingers,
- faster heart beat,
- ear and throat ache,
- abdominal pain,
- dry mouth,
- spinning sensation (vertigo),
- migraine,
- nerve disorder causing weakness, tingling or numbness,
- drowsiness,
- scaling, inflammation, abnormal skin sensation, reaction at the injection site, rash, numbness, dryness, movement impairment, vesicles at the injection site,
- weakness,
- influenza like illness,
- swelling of the face, mouth and throat,
- white blood cell count increased,
- bruising.

**Unknown** (cannot be estimated from the available data):

- temporary one-sided facial drooping (Bell's palsy).

### **Reporting of side effects**

If you get any side effects, talk to your doctor or nurse. 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 V](#). By reporting side effects you can help provide more information on the safety of this medicine.

## **5. How to store IMVANEX**

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

Do not use this vaccine after the expiry date which is stated on the label after Exp. The expiry date refers to the last day of that month.

Store in a freezer (at  $-20^{\circ}\text{C} \pm 5^{\circ}\text{C}$  or  $-50^{\circ}\text{C} \pm 10^{\circ}\text{C}$  or  $-80^{\circ}\text{C} \pm 10^{\circ}\text{C}$ ). Expiry date depends on storage temperature. Do not refreeze the vaccine once thawed. After thawing, the vaccine can be stored at  $2^{\circ}\text{C} - 8^{\circ}\text{C}$  in the dark for up to 2 months within the approved shelf-life prior to use.

Store in the original package to protect from light.

## **6. Contents of the pack and other information**

### **What IMVANEX contains**

One dose (0.5 ml) contains:

- The active substance is Modified Vaccinia Ankara – Bavarian Nordic Live virus<sup>1</sup>, no less than  $5 \times 10^7$  Inf.U\*  
\*infectious units  
<sup>1</sup>Produced in chick-embryo cells
- The other ingredients are: trometamol, sodium chloride, and water for injections.

This vaccine contains trace residues of chicken protein, benzonase, gentamicin and ciprofloxacin.

### **What IMVANEX looks like and contents of the pack**

Once the frozen vaccine has been thawed, IMVANEX is a light yellow to pale white, milky suspension for injection.

IMVANEX is provided as a suspension for injection in a vial (0.5 ml).

IMVANEX is available in packs containing 1 single dose vial, 10 single dose vials or 20 single dose vials.

Not all pack sizes may be marketed.

### **Marketing Authorisation Holder and Manufacturer**

#### **Marketing Authorisation Holder**

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#### **Manufacturer**

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### **This leaflet was last revised in**

This medicine has been authorised under ‘exceptional circumstances’.

This means that because of the rarity of this disease it has been impossible to get complete information on this medicine.

The European Medicines Agency will review any new information on this medicine every year and this leaflet will be updated as necessary.

Detailed information on this medicine is available on the European Medicines Agency web site:  
<http://www.ema.europa.eu>

This leaflet is available in all EU/EEA languages on the European Medicines Agency website.

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