

PATIENT INFORMATION LEAFLET: INFORMATION FOR THE USER

IMVANEX suspension for injection

Smallpox and mpox vaccine (Live Modified Vaccinia Virus Ankara)

Read all of this leaflet carefully before you start using this medicine.¹

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your health care provider.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects becomes serious, or if you notice any side effects not listed in this leaflet, please tell your health care provider.

In this leaflet:

1. What IMVANEX is and what it is used for
2. Before you use IMVANEX
3. How to use IMVANEX
4. Possible side effects
5. How to store IMVANEX
6. Further information

1. WHAT IMVANEX IS AND WHAT IT IS USED FOR

IMVANEX is a vaccine used to prevent smallpox, mpox and disease caused by vaccinia virus in adults and adolescents aged 12 years and older.

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

WHO recommendation (WHO position paper – August 2024):

WHO recommends limiting the use of IMVANEX to outbreak response, except for laboratory personnel at high risk.

2. BEFORE YOU USE IMVANEX

Do not use 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.

Take special care with IMVANEX

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, mpox 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.

Using other medicines

Please tell your health care provider if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

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, mpox 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).

Important information about some of the ingredients of IMVANEX

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

3. HOW TO USE IMVANEX

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, mpox 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, mpox 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, IMVANEX 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).

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your health care provider.

5. HOW TO STORE IMVANEX

Keep out of the reach and sight of children.

Do not use IMVANEX 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°C – 8°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. FURTHER INFORMATION

What IMVANEX contains:

One dose (0.5 ml) contains:

- The active substance is Modified Vaccinia Ankara – Bavarian Nordic Live virus¹, no less than 5×10^7 Inf.U*
*infectious units
¹Produced 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.

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This leaflet was last approved on 10/2024.

Detailed information on this medicinal product is available on PQTm's website (see: <http://www.who.int/prequal>).