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

IMVANEX is a vaccine used to prevent smallpox, monkeypox 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, 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 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,
- throat pain, runny nose, cough,
- diarrhea, vomiting,
- rash, itch, skin inflammation,
- bleeding, irritation at the injection site,
- underarm swelling, feeling unwell, flushing, chest pain, ,

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

Unknown (frequency 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 HPRA Pharmacovigilance Website: www.hpra.ie. 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°C +/-5°C or -50°C +/-10°C or -80°C +/-10°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. 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[1], no less than 5×10^7 Inf.U*
  *infectious units
  [1]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
Bavarian Nordic A/S
Philip Heymans Alle 3
DK-2900 Hellerup
Denmark

Manufacturer
Bavarian Nordic A/S
Hejreskovvej 10A,
3490 Kvistgaard
Denmark

This leaflet was last revised in 02/2026.

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.

The following information is intended for healthcare professionals only:

Instructions for preparation and administration of the vaccine:

The vial should be allowed to reach a temperature between 8°C and 25°C before use. Swirl gently before use. IMVANEX is a light yellow to pale white colored, clear to milky suspension. It may contain light yellow to pale white floculates.
Visually inspect the suspension prior to administration. In case of any extraneous particles and/or abnormal appearance, the vaccine should be discarded.
Each vial is for single use.

A dose of 0.5 ml is withdrawn into a syringe for injection.

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.

Do not refreeze the vaccine once thawed.

In the absence of compatibility studies, this vaccine must not be mixed with other vaccines.