Appendix 4. Imvanex vaccination: patient information leaflet

IMVANEX suspension for injection

Smallpox vaccine (Live Modified Vaccinia Virus Ankara)

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

What IMVANEX is and what it is used for

MVA-BN (Imvanex) is a modified vaccinia Ankara vaccine, manufactured by Bavarian Nordic. It was initially developed to use for the prevention of smallpox. 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 virus. IMVANEX does not contain smallpox virus and cannot spread or cause smallpox.

As monkeypox is cause by a virus similar to the one that causes smallpox, vaccines designed for smallpox are considered effective in preventing or reducing the severity of the monkeypox. Whilst this vaccine is not currently licensed for specific use against monkeypox in Europe, in September 2019, the vaccine received approval for use in the prevention of monkeypox from the US Food and Drug Administration. As this medicine (Imvanex) has been authorised by the European Medicines Agency for use as pre- and post-exposure prophylaxis for smallpox, the vaccine has been manufactured to a high standard and has undergone independent batch testing before release. the UK Health Security Agency (UKHSA) and the Joint Committee on Vaccination and Immunisation (JCVI) recommends its use in response to cases of monkeypox.

UKHSA recommends that Imvanex is offered to:

1. Persons who already have had a significant contact with a patient with confirmed monkeypox (post exposure). Post exposure vaccination with a single dose of vaccine should be offered as soon as possible after a significant contact to maximise the benefit from the vaccine.
2. Healthcare workers who are currently caring for and who are due to start caring for a patient with confirmed monkeypox (pre exposure). A single dose of vaccine should be offered as soon as possible to provide some immediate benefit, and should offer some longer term protection if the patient remains in care. A second dose after 4 weeks will be offered if the healthcare worker is at continued risk.

Although there is good evidence that a full course of vaccine should protect against monkeypox, the level and duration of protection from a single dose given after or around the time of exposure to the infection is less clear. The vaccine is offered because it has a good safety profile and may help to modify or reduce the symptoms of disease if given within 2 weeks of exposure.

Can you use IMVANEX for post exposure in children

When deciding whether it is appropriate to use smallpox vaccination to reduce the risk of a child developing monkeypox after exposure, it is important to consider both the risk of catching the disease and the risk of a child getting severe monkeypox.

The risk of catching the disease will depend on the level of physical contact with the case, or (if not touching) the closeness and duration of time spent near the case or in the rooms where a case has been.

The severity of disease appears to depend on which part of Africa the monkeypox virus originates from. The overall risk of dying is more than one in 9 for those who were identified as having caught monkeypox in Central Africa, compared to around one in 25 for those in West Africa. The true risk of dying if you catch monkeypox is probably much lower than has been reported because many milder cases are not diagnosed.

In children there is less data available. However, a large study of over 100 adult and child cases in Nigeria found that those who died were mostly adults, and/or were those who were HIV-positive, had a secondary skin infection or were very young (under 1 year old). This suggest that the risk to older children is low. However, there is also some evidence from Central Africa that children of all ages are at higher risk of more severe disease and death than adults when infected with monkeypox. Therefore, we cannot be very certain about the risk to children and we must assume the risk of severe disease is at least as high as in adults.

The vaccine has been not been used widely in children but vaccine based on the same virus have been used in large studies in babies and seem to work very well and have an acceptable

safety record. The vaccine has been given safely to children, including at least one infant, in the UK after previous cases.

What you need to know before you receive IMVANEX

You must not receive IMVANEX:

If you have previously had a sudden life-threatening allergic reaction to any ingredient of Imvanex (these are listed in section 6) including those present in the vaccine in very small amounts (or chicken protein, benzonase or gentamicin).

Warnings and precautions

If you are ill with a high temperature you will need to be assessed by your doctor to determine if you may be displaying early signs of monkeypox. If it is assessed that your illness is not related to monkeypox, you may still be offered the vaccine. 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.

You can be given this vaccine whether or not you have received smallpox vaccination in the past. Tell your doctor or nurse before you receive 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

IMVANEX may not fully protect all people who are vaccinated.

Pregnancy and breast-feeding

If you are pregnant or breast feeding, think you may be pregnant or are planning to have a baby, talk to your doctor. The virus in the vaccine does not grow well in the human body and so cannot spread to an unborn child or through breast milk. Although the vaccine is not routinely recommended in pregnancy, your doctor will discuss with you about the benefits in terms of preventing monkeypox which is likely to outweigh the any theoretical risks of giving you this vaccine.

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.

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 (for example dizziness).

IMVANEX and sodium

This medicinal product contains less than 1mmol sodium (23 mg) per dose and is therefore essentially 'sodium-free'.

How IMVANEX is given

The vaccine will be injected under the skin, preferably into the upper arm, by your doctor or a nurse.

Side effects of IMVANEX

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

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

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

Common (may affect up to one in 10 people):

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

Uncommon (may affect up to one in 100 people):

- nose and throat infection, upper respiratory tract infection
- swollen lymph nodes
- abnormal sleep
- dizziness, abnormal skin sensations

- muscle stiffness, back pain, neck pain
- sore throat, runny nose, cough
- diarrhoea, vomiting, abdominal pain, dry mouth
- rash, itch, skin inflammation, skin discolouration
- warmth, bleeding, irritation, scaling, inflammation, abnormal skin sensation, reaction
- underarm swelling, flushing, chest pain, pain in the armpit
- bruising

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

- sinus infection
- pink eye
- hives (nettle rash)
- skin bruising
- sweating
- night sweats
- lump in skin
- muscle cramps
- muscle pain
- muscle weakness
- swelling of the ankles, feet or fingers
- swelling of the face, mouth and throat
- faster heart beat
- spinning sensation (vertigo)
- migraine
- nerve disorder causing weakness, tingling or numbness, drowsiness
- rash, numbness, dryness, movement impairment, blisters at injection site
- weakness
- feeling unwell
- influenza-like illness

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 7 days.

If you get any of the following side effects, tell your designated medical contact point.

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.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this vaccine.

What IMVANEX contains

One dose (0.5 ml) contains modified Vaccinia Ankara – Bavarian Nordic Live virus, in chick-embryo cells.

Other ingredients are: trometamol, sodium chloride, and water for injections. It also contains residues of gentamicin and benzonase.

This leaflet was revised by UKHSA on 8 May 2022. Detailed information on this medicine is available on the European Medicines Agency website.