**Patient information on Imvanex**

You are receiving this information because you will be vaccinated against monkeypox using the vaccine Imvanex®. This is a vaccine that has been registered for smallpox protection in Europe since 2013. Imvanex® has also been registered for monkeypox in Europe since 22 July 2022. As the smallpox virus is very similar to the monkeypox virus, it is expected that the vaccine will provide protection against monkeypox too. It has been tested on animals and proved to provide protection.

The monkeypox protection provided by Imvanex® has not been studied in humans. It is possible that Imvanex® will not provide full protection to all people receiving the vaccine. If you have not had a smallpox vaccine in the past, the immune response in the blood will not peak until 6 weeks after your jab. If you have had a smallpox vaccine in the past, it will peak 2 weeks after your jab. Which is why it continues to be important for you to get tested if you develop symptoms and for you to abide by the rules if you have been in contact with a confirmed case of monkeypox.

This information can also be read online in the official registration text for Imvanex®.

1. What is Imvanex® and for whom is this medicine used?
   Imvanex® is a vaccine used to prevent monkeypox infection. When someone is given the vaccine, the immune system (the body's natural 'army') starts to create its own protection against the disease in the form of antibodies against the smallpox virus. These antibodies also provide protection against monkeypox. Imvanex® does not contain any smallpox virus and cannot cause or spread smallpox.

2. When should you be extra cautious or not have this medicine?

   When should you not have this medicine?
   a. If you have previously had a sudden, serious allergic reaction to one of the ingredients in Imvanex®. Imvanex® contains the excipient trometamol. It could also contain the following substances in tiny quantities: chicken protein, benzonase, gentamicin and ciprofloxacin.
   b. If you are unwell and have a fever or raised body temperature. In such cases, your doctor will postpone your vaccination until you are feeling better. In that regard, it will be important to rule out the possibility of you having a monkeypox infection. If it turns out that you do have a monkeypox infection, you will no longer need to be vaccinated. In principle, the presence of a mild infection (e.g. a cold) is not a reason to postpone the vaccination, but do consult with your doctor or nurse first.

3. When should you be extra cautious with this medicine? Contact your doctor or nurse before having this medicine administered if:
   - You have atopic dermatitis

4. Are you taking any immunosuppressants? Are you scheduled to have any other vaccines administered or have you recently had any other vaccines?
   If so, please tell your doctor or nurse.

5. Pregnancy and breastfeeding. Are you pregnant, possibly pregnant, trying for a baby or breastfeeding? If so, please contact your doctor. This vaccine is not recommended for use during pregnancy or in the period during which you are breastfeeding. Nor will it therefore be offered prophylactically without exposure to monkeypox. This is because very little research has been done with the vaccine in pregnant women (maximum of 300 pregnant women). No pregnancy problems were identified in the women or in animal testing. Hence it is expected that this vaccine is just as safe for unborn babies as other vaccines given to pregnant women. Beyond this, it is not known whether Imvanex® is excreted in breast milk. However, if there has been considerable exposure to monkeypox, your doctor will assess with you whether the potential benefit in terms of preventing monkeypox outweighs the potential risks of administering the vaccine.

6. Children: the vaccine is registered for adults. Research has already been carried out on children aged 1 year and upwards, in which the same side effects were seen as in adults. So if a doctor deems it necessary for a child to get vaccinated (e.g. after considerable exposure to monkeypox), they may wish to discuss the need for vaccination and any risks thereof with you as a parent or carer.

7. Ability to drive and use machines. No information is available on the effect of Imvanex® on the ability to drive and use machines. Nonetheless, you might experience a side effect. Some of these side effects (e.g. dizziness) could affect your ability to drive and use machines.

8. Imvanex® contains sodium. This medicine contains less than 1 mmol of sodium (23 mg) per dose, which means it is essentially 'sodium-free'.

9. How will this vaccine be administered? The vaccine will be injected under the skin by a doctor or nurse, preferably in the upper arm. It cannot be injected into a blood vessel.

    a. If you have never been vaccinated against smallpox or monkeypox:
        - You will be given two injections.
    b. If you have previously been vaccinated against smallpox or monkeypox:
        - You will be given one injection.
    c. If you have a weakened immune system:
        - You will be given two injections

    If you need a second injection, this will not be given within 4 weeks of the first one. Please ensure that you complete the series of two injections.

10. What if you forget to have the vaccine administered? If you do not get a scheduled injection, please contact the Municipal Health Service (GGD) where you would have had your vaccination to make a new appointment. If you have any other questions on the use of this vaccine, feel free to get in touch with the GGD.

11. Possible side effects: As is the case with any vaccination, this vaccination could also have side effects, even if not everyone will experience them.

    Contact a doctor immediately or go straight to the emergency department at your nearest hospital if you get one of the following symptoms:

    a. breathing difficulties
    b. persistent dizziness
    c. swelling of the face and throat

    These symptoms could indicate a serious allergic reaction.

    Other side effects: If you have *atopic dermatitis*, you might experience more intense local skin reactions (e.g. redness, swelling and itching) and other symptoms (e.g. headache, muscle ache, nausea or fatigue). You might also experience a flare-up or worsening of your skin condition. The most commonly reported side effects occurred at the site of the injection. Most of these side effects were mild to moderate in nature and went away within seven days without treatment. If you experience one of the following side effects, please contact your doctor.

    Extremely common (occurs in more than 1 in 10 people):

    - headache
    - muscle ache
    - nausea
    - fatigue
    - pain, redness, swelling, thickening of the skin or itchiness at the site of the injection.

Common (occurs in no more than 1 in 10 people):

- chills
- fever
- joint pain, limb pain
- diminished appetite
- lump, discolouration, bruising or warm feeling at the site of the injection.

For less commonly occurring side effects, please see the patient information leaflet for a full overview.

12. Reporting side effects. Always discuss your symptoms with a doctor first. Serious or unexpected side effects/incidents, for example, can be reported to Lareb. By reporting side effects you will be helping us to amass more information on the safety of this medicine.