INFORMATION SHEET — Monkeypox vaccination with Jynneos®

This information sheet is provided in addition to your pre-vaccination consultation with the responsible healthcare professional at the vaccination centre. Please read this information sheet carefully before you have the monkeypox vaccination, and discuss any queries with the responsible healthcare professional.

Who is the vaccination recommended for?

The Jynneos® vaccine (modified vaccinia Ankara – Bavarian Nordic/MVA-BN) is recommended for adults aged 18 and older who are at high risk for monkeypox infection.

As primary preventive vaccination (pre-exposure prophylaxis) for the following persons (aged 18 or over, not previously infected with monkeypox):

- for men who have sex with men and for trans persons with changing male sexual partners.
- for specific groups who are exposed to monkeypox viruses in connection with their work, and who are at risk for monkeypox infection in spite of precautionary measures (e.g. healthcare personnel or specialist laboratory staff).

As post-exposure vaccination (post-exposure prophylaxis) for the following persons (aged 18 or over, not previously infected with monkeypox):

- for contacts, after a high-risk exposure to a confirmed or probable monkeypox case.
- for healthcare and laboratory personnel, after unprotected high-risk contact with a monkeypox case or infectious material.

General information on the vaccine

- The monkeypox virus is genetically similar to the smallpox virus. For this reason, existing smallpox vaccines can also be used effectively against monkeypox. These smallpox vaccines were administered in Switzerland until 1972 in order to eradicate smallpox. If you have already been vaccinated against smallpox, you should mention this during your pre-vaccination consultation.
- The current monkeypox vaccine (Jynneos®) is a live attenuated vaccine. It is manufactured by Bavarian Nordic in Denmark, using a modified vaccinia virus related to the smallpox virus. The new vaccines **do not cause any scarring**.
- The vaccine viruses have been weakened (attenuated) so that they can no longer replicate in human cells. For this reason, a person who has received the vaccine cannot contract smallpox or monkeypox as a result of the vaccination or transmit the vaccine virus to other people.
- The vaccine viruses are recognised as foreign by the immune system. As an immune response, antibodies and defence cells are formed to combat the virus, thus creating immune protection. On subsequent exposure to the virus, the body's defences are more rapidly activated. This means that the virus can be quickly neutralised and the risk of disease reduced.

Authorisation of the vaccine in Switzerland

- The vaccine Jynneos® is not authorised in Switzerland.
- In the EU, the vaccine was authorised under a different name in 2013 by the European Medicines Agency (EMA) for the prevention of smallpox (variola). In 2022, the EMA recommended that the vaccine should also be used for the prevention of monkeypox.
- In the USA, following a monkeypox outbreak in 2003, the efficacy and safety of Jynneos® was studied in relation to smallpox and monkeypox. In 2019, the vaccine was approved for the prevention of smallpox and monkeypox.
- In Switzerland, vaccination is performed in the absence of authorisation (so-called no-label use). No-label use means that the product is not authorised by Swissmedic, and vaccination with Jynneos® is carried out without country-specific prescribing/patient information.
- No-label use is permissible if the vaccination recommendations take the latest scientific findings into account and the person to be vaccinated consents to the vaccination.
- The usual liability rules are also applicable for Jynneos®: liability for any vaccine-related harm may fall to the vaccine manufacturer (product liability), the vaccination centre (agent's or state liability) or, on a subsidiary basis, the federal government under the Epidemics Act (contingent liability).
- The Federal Office of Public Health (FOPH) and the Federal Commission for Vaccination (FCV) recommend the vaccination with the aim of preventing severe disease, complications or deaths, and reducing monkeypox infections.

How does the vaccination work?

- Human studies showed that, in vaccinated individuals, the immune system forms protective antibodies against smallpox in response to the vaccination. It has not yet been determined with certainty how long the immunity lasts.
- Data from various animal studies has shown that the vaccine is also effective against monkeypox.
- There is evidence that adequate immunity is only attained after a second vaccination.
- Vaccination data is being continuously collected and analysed.

What adverse effects may occur after the vaccination?

The safety of the vaccine has been investigated in various clinical studies. Like every medicinal product, this vaccine may cause adverse effects. The adverse effects most frequently observed are local reactions at the injection site and systemic reactions (e.g. fever) typical of vaccinations. These adverse effects are mostly mild to moderate and generally resolve within 7 days after vaccination.

- Very common adverse effects (affects 1 in 10 or more of vaccinees): reactions at the injection site (pain, redness, swelling, hardening, itching) and headache, muscle pain, nausea and fatigue.
- Common adverse effects (affects 1 to 10 of 100 vaccinees) reactions at the injection site (nodule, haematoma, discoloration or warmth) and muscle stiffness, chills, fever, joint pain and appetite disorder.
- Uncommon adverse effects (affects 1 to 10 of 1'000 vaccinees): chest pain, musculoskeletal stiffness, paraesthesia, upper respiratory tract infection, nasopharyngitis, sore throat and cough; swollen lymph nodes, underarm swelling, sleep disorder, dizziness, vomiting, diarrhoea, rash, dermatitis, pruritus and flushing. After the vaccination, transient abnormalities may also be observed in certain laboratory investigations (e.g. hepatic enzymes or white blood cell count).
- Rare adverse effects (affects less than 1 in 1'000 vaccinees): reactions at the injection site (paraesthesia, rash, vesicles,

movement impairment), tachycardia, migraine and muscle spasms; musculoskeletal pain, abdominal pain, somnolence, sinusitis, conjunctivitis, sweating and dry mouth.
- Serious adverse effects may occur in rare cases: for example, allergic skin reactions such as urticaria have been observed. Also observed in rare cases are fluid accumulation and swelling (peripheral oedema, angioedema), especially in the arms and legs or also, for example, on the face (lips and cheeks). Signs of a severe allergic reaction are difficulty in breathing, dizziness and swelling of the face and neck. An allergic shock (anaphylaxis) or previously unknown reaction may occur in rare cases following vaccination. Also observed in rare cases are symptoms of peripheral sensory neuropathy (e.g. paraesthesia, numbness and pain).
- In persons with eczema (atopic dermatitis), more intense local skin reactions (such as redness, swelling and itching) and other general symptoms may be experienced after the vaccination. A flare-up or worsening of the skin condition may also occur.
- There are two methods of administration: injection under the skin (subcutaneous) or into the skin (intradermal). According to one study, local reactions (e.g. redness, swelling, mild discoloration at the injection site, possibly persisting for over 6 months) are seen more frequently with intradermal than with subcutaneous administration.
- At present, the risk of other rare serious or unexpected adverse effects cannot be completely ruled out. Based on experience with other vaccines, such events would be expected to occur within a number of months after vaccination. An effective reporting system of unexpected adverse reactions has been established by Swissmedic.
- Other – non-vaccine-related – health problems may continue to be observed, sometimes even immediately after a vaccination. This does not mean, however, that they are necessarily a result of the vaccination.
- If you notice any adverse effects, please contact a physician. This also applies to possible adverse effects not mentioned in this information sheet. In the event of severe symptoms or possible allergic reactions, a physician should be contacted without delay.

In the following cases, you should not have the vaccination:
- The vaccine must not be administered to anyone who has had a severe allergic reaction (allergic shock/ anaphylaxis) to a previous dose or to any ingredient of the vaccine. Jynneos® contains modified vaccinia Ankara – Bavarian Nordic (active substance), trometamol, sodium chloride and trace residues of benzonase, gentamicin and ciprofloxacin (antibiotics), chicken host-cell DNA and chicken protein. **If you have ever had an allergic reaction to any ingredient of the vaccine, you must inform the responsible healthcare professional at the vaccination centre.**
- It is not known whether individuals who have previously had a severe allergic reaction (allergic shock/anaphylaxis) to chicken eggs are at increased risk for a reaction to the vaccination. If this applies to you, please inform the responsible healthcare professional.
- Vaccination should be postponed in individuals suffering from an acute febrile illness (38.5°C or higher). It may, however, be performed in individuals with a cold or low-grade fever (below 38.5°C).
- Owing to the lack of adequate clinical safety data, the vaccination is not currently recommended for children and adolescents under 18 years of age or for pregnant women. In individual cases, vaccination may be performed after a careful risk/benefit assessment.
- The vaccination is not currently recommended for individuals who have recently contracted monkeypox. Due to the disease, the immune system has already come into contact with the virus and is now ready to recognise it.

N.B. To date, no studies have been performed that evaluate possible interaction with other vaccines or medicinal products. Therefore, Jynneos® should not be administered concomitantly with other vaccines or medicinal products. In addition, you should inform the responsible healthcare professional if any other (e.g. Covid) vaccinations are planned within the next 4 weeks.

When is the vaccine to be administered?

Primary preventive vaccination (pre-exposure prophylaxis): Vaccination is most effective before exposure to monkeypox. Preventive vaccination is performed as follows:
- For individuals not previously vaccinated against smallpox, basic immunisation requires two doses of vaccine given with an interval of at least 28 days.
- For individuals previously vaccinated against smallpox, one dose of vaccine is recommended.
- For immunocompromised patients (including those previously vaccinated against smallpox), two doses of vaccine are recommended, given with an interval of at least 28 days.
- For individuals who have already received two doses of Jynneos® more than 2 years earlier, a booster dose is recommended.

Post-exposure vaccination (post-exposure prophylaxis): Individuals may also receive the vaccination after exposure to monkeypox. The vaccine should be administered within 4 days after exposure, but it may be given up to the 14th day. Vaccination given within a few days may possibly prevent illness. Vaccination from 4 days after exposure may alleviate the symptoms but can probably no longer prevent illness. Post-exposure vaccination is performed as follows:
- For individuals not previously vaccinated against smallpox, one dose of vaccine is recommended.
- For individuals previously vaccinated against smallpox, one dose of vaccine is recommended.
- For immunocompromised patients (including those previously vaccinated against smallpox), two doses of vaccine are recommended, given with an interval of at least 28 days.
- For individuals who have already received two doses of Jynneos® more than 2 years earlier, a booster dose is recommended.

How is the vaccination administered?
- Normally, a 0.5 ml dose of vaccine is injected under the skin of the upper arm (subcutaneously).
- If supplies are scarce, a 0.1 ml dose of vaccine is injected into the skin of the lower arm (intradermally). The immune response is the same with both methods of administration.
- Individuals under 18, pregnant women (after a careful risk/benefit assessment), immunocompromised patients and individuals with keloid scarring always receive a 0.5 ml dose (even if supplies are scarce), injected subcutaneously.

Points to be noted before the vaccination:

The responsible healthcare professional at the vaccination centre should be informed about:
- allergies or previous allergic reactions
- (severe) allergic reactions or other reactions to an ingredient of the vaccine or to any other vaccination
- immunocompromised status (immune system severely weakened due to illness or treatment)
- eczema (atopic dermatitis) or keloid scarring
- a history of heart muscle inflammation (myocarditis) or inflammation of the membranes containing the heart muscle (pericarditis)

- fainting after previous vaccinations
- exposure to a case of monkeypox in the past 2 weeks
- previous vaccinations against smallpox or monkeypox
- other planned vaccinations
- any medication you take regularly

The above are not exclusion criteria for vaccination, but they require an individual assessment. You must therefore inform the responsible healthcare professional during the pre-vaccination consultation.

Points to be noted after the vaccination:

- Excessive physical exertion (e.g. intensive muscle or endurance training, extreme sports) should be avoided for a few days.
- If you experience pain or fever after the vaccination, you can take analgesic and antipyretic medication. You can contact your physician for advice.
- Immunity does not develop immediately after vaccination. As the response of the immune system to vaccination varies, the level of protection may also vary from one individual to another.
- Vaccination does not provide absolute protection against infection. It is also unclear how long immunity is maintained. You should therefore continue to protect yourself.
- Some individuals may contract monkeypox in spite of being vaccinated. If you notice any symptoms of monkeypox, you should consult a physician.

Where can I have the vaccination?

Your canton of residence can provide information on local vaccination facilities.

Who pays for the vaccination?

The vaccination costs will be covered by the federal government if reimbursement is not provided by your health insurer.

Do you have any other queries?

Any queries should be discussed with the responsible healthcare professional at the vaccination centre.

This information sheet is not a substitute for the pre-vaccination consultation with the responsible healthcare professional.

References

In Switzerland, as the vaccine is administered on a no-label use basis, no specifically adapted product information is available. For this reason, the manufacturer's product information from other countries have been consulted.

> World Health Organization (WHO): *Vaccines and Immunization for monkeypox: Interim Guidance; 24.08.2022*

> US Food and Drug Administration (FDA): *Fact Sheet for Healthcare Providers administering Jynneos® vaccine; 08.2022*

> European Medicines Agency (EMA): *Imvanex® EPAR: Assessment Report; 09.08.2022*

> European Medicines Agency (EMA): *Imvanex® EPAR: Product Information; 25.07.2022*

> UK Health Security Agency (UKHSA): *Recommendations for the use of pre and post exposure vaccination during a monkeypox incident; 26.08.2022*

> Robert Koch Institute (RKI): *Information Sheet for Vaccination against Monkeypox; 29.06.2022*

> Agence nationale de sécurité du médicament et des produits de santé (ANSM): *Avis de l'ANSM concernant la vaccination contre le virus Monkeypox; 20.06.2022*

> Eidgenössische Kommission für Impffragen (EKIF) & Bundesamt für Gesundheit (BAG): *Analyserahmen und Empfehlungen zur Impfung gegen Affenpocken (PDF, 01.09.2022)*

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