Package leaflet: Information for the user

SKYCovion™

Suspension and emulsion for emulsion for injection

COVID-19 vaccine (recombinant, adjuvanted)

▼This medicinal product 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, pharmacist or nurse.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What SKYCovion is and what it is used for

SKYCovion is a vaccine used for preventing COVID-19 caused by SARS-CoV-2 virus.

SKYCovion is given to adults aged 18 years and older.

The vaccine causes the immune system (the body's natural defences) to produce antibodies and specialised blood cells that work against the virus, so it may give protection against COVID-19.

None of the ingredients in this vaccine can give you COVID-19.

2. What you need to know before you receive SKYCovion

SKYCovion should not be given

- if you are allergic to the active substances or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor, pharmacist or nurse before you are given SKYCovion if:

- you have previously had a severe, life-threatening allergic reaction or breathing problem after any other vaccine injection or after you were given SKYCovion in the past.
- you have ever fainted following any needle injection.
- you have a weakened immune system, because of a disease such as HIV infection or a medicine such as corticosteroid that affects your immune system.
- you have a high fever (over 38°C) or severe infection; however, you can have your vaccination if you have a mild fever or upper airway infection like a cold.
- you have bleeding disorder such as haemophilia and thrombocytopenia or you use a medicine to prevent blood-clots.

If any of the above apply to you (or you are not sure), talk to your doctor, pharmacist, or nurse before you are given SKYCovion.

As with any vaccine, the 2-dose vaccination with SKYCovion may not fully protect all those who receive it. It is not known how long you will be protected for.

Children and adolescents

SKYCovion is not recommended for children aged below 18 years. There is no information available on the use of SKYCovion in children and adolescents younger than 18 years of age.

Other medicines and SKYCovion

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines or have recently received any other vaccines.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines

Some of the effects of vaccination mentioned in section 4 (Possible side effects) may temporarily affect your ability to drive or use machines. Wait until these effects have worn off before you drive or use machines.

SKYCovion contains sodium

This vaccine contains less than 1 mmol sodium (23 mg) per dose of 0.5 mL, that is to say essentially 'sodium-free'.

SKYCovion contains potassium

This vaccine contains less than 1 mmol potassium (39 mg) per dose of 0.5 mL, that is to say essentially 'potassium-free'.

3. How SKYCovion is given

Your doctor, pharmacist or nurse will inject the vaccine into the muscle (usually in the upper arm).

You will receive 2 injections. The second dose should be administered 4 weeks (28 days) after the first injection. You will be told when you need to return for your second injection.

When SKYCovion is given for the first injection, the second injection to complete the vaccination course should also be with this vaccine.

If you miss an appointment for your second injection of SKYCovion

If you forget to go back at the scheduled time, ask your doctor, pharmacist or nurse for advice.

It is important that you return for your second injection of this vaccine as you may not be protected against COVID-19 after the first injection. This is because the immune response in people who have never been infected by the SARS-CoV-2 virus is low after the first injection.

If you have any further questions on the use of SKYCovion, ask your doctor, pharmacist or nurse.

4. Possible side effects

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

In clinical studies, most side effects were mild to moderate in nature and resolved within a few days. If symptoms persist, conta,ct your doctor, pharmacist or nurse.
These can include:

Very common side effects: may affect more than 1 in 10 people
- pain where the injection is given
- feeling very tired (fatigue)
- fever, chills (more frequent after the second injection)
- muscle pain
- joint pain
- headache

Common side effects: may affect up to 1 in 10 people
- feeling sick (nausea) or getting sick (vomiting)
- diarrhoea
- redness, swelling where the injection is given

Uncommon side effects: may affect up to 1 in 100 people
- feeling dizzy
- tingling, prickling or numbness of the skin (paraesthesia)
- pain or discomfort in the arm, hand, leg and/or foot (pain in the extremity)
- chest pain
- rash
- feeling that your heart is pounding or racing (palpitations)
- feeling of warmth, itching where the injection is given

Rare side effects: may affect up to 1 in 1,000 people
- enlarged lymph nodes
- decreased skin sensation

- abdominal pain
- decreased appetite
- feeling of weakness (asthenia)
- drowsiness
- bruising where the injection is given
- itchy skin, hives (urticaria)
- excessive sweating (hyperhidrosis)

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.
If you are concerned about a side effect it can be reported directly via the Coronavirus Yellow Card reporting site https://coronavirus-yellowcard.mhra.gov.uk/ or search for MHRA Yellow Card in the Google Play or Apple App Store and include batch/Lot number if available. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store SKYCovion
Keep this medicine out of the sight and reach of children.

The following information about storage, expiry and use and handling is intended for healthcare professionals.

Do not use this medicine after the expiry date which is stated on the label and carton after "EXP". The expiry date refers to the last day of that month.

Store in a refrigerator (2°C - 8°C).

Do not freeze.

Store in the original package in order to protect from light.

After mixing, store the vaccine at 2 °C to 8 °C and use within 6 hours. Discard any unused vaccine.

Do not use this vaccine if you notice visible foreign particulate matter and/or abnormal physical appearance prior to administration.

6. Contents of the pack and other information
What SKYCovion contains:
- Active substance:
  1 dose (0.5 mL) contains 25 µg recombinant COVID-19 subunit nanoparticle.
- Adjuvant:
  The vaccine contains an 'adjuvant' AS03. This adjuvant contains squalene (10.69 milligrams), DL-α-tocopherol (11.86 milligrams) and polysorbate 80 (4.86 milligrams).
- Other ingredients:
  The other ingredients are: sodium chloride, tromethamine, arginine, sucrose, water for injections, disodium hydrogen phosphate, potassium dihydrogen phosphate, potassium chloride.

What SKYCovion looks like and contents of the pack
- The antigen suspension is clear or slightly opalescent liquid provided in a multidose vial (Type I glass) with a stopper (chlorobutyl) and an aluminium overseal and a plastic flip-off cap.
- The adjuvant emulsion is whitish to yellowish homogeneous milky liquid provided in a separate multidose vial (Type I glass) with a stopper (chlorobutyl) and an aluminum seal with a plastic flip-off cap.
- Prior to administration, the antigen and adjuvant components should be mixed. The mixed vaccine is a whitish to yellowish homogeneous milky liquid.
- One pack containing 10 vials of 2.5 mL antigen suspension.
- One pack containing 10 vials of 2.5 mL adjuvant emulsion.

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The following information is intended for healthcare professionals only:
Administer SKYCovion intramuscularly after mixing with accompanied adjuvant vial as a course of 2 doses (0.5 mL each) with 4-week (28 days) interval.

Traceability
In order to improve the traceability of biological medicinal products, the name and the batch number of the administered product should be clearly recorded.

Handling instructions and administration
This vaccine should be handled by a healthcare professional using aseptic technique to ensure the sterility of each dose.

Preparation for use
Before mixing the two components, the suspension (antigen) and emulsion (adjuvant) should be allowed to reach room temperature for a minimum of 15 minutes.

Prior to administration, the two components, adjuvant and antigen, must be mixed.

The vaccine is mixed by withdrawing the entire contents of the vial containing the adjuvant by means of a 5 ml syringe and by adding it to the vial containing the antigen. It is recommended to equip the syringe with a 23-G needle (or narrower).

Record the date and time of mixing on the antigen vial label. Use within 6 hours after mixing.

Inspect the vial
Gently mix the multidose vial by inverting the vial 10 times before and in between each dose withdrawal so that the antigen and the adjuvant are completely mixed.

After mixing, each multidose vial contains a whitish to yellowish homogeneous milky liquid emulsion.

Visually inspect the contents of the vial for any visible foreign particulate matter and/or abnormal physical appearance prior to administration. Do not administer the vaccine if either are present.

Administer the vaccine
After mixing, the vial contains 5.0 mL corresponding to 10 doses of 0.5 mL.

Each 0.5 mL dose is withdrawn into a 1 mL syringe for injection and administered intramuscularly, preferable in the deltoid muscle of the upper arm. It is recommended to equip the syringe with a 23-G needle or narrower.

The vaccine should be administered in accordance with the recommended posology (see section 4.2).

The vaccine taken by the syringe should be used immediately.

Storage after mixing
After mixing, store the vaccine between 2°C to 8 °C for up to 6 hours

Discard
Discard this vaccine if not used within 6 hours after mixing

Disposal
Any unused medicinal product or waste material should be disposed of in accordance with local requirements.