PATIENT INFORMATION LEAFLET

▼This vaccine is subject to additional monitoring. This triangle will enable the rapid identification of a new safety information. You can help by reporting any side effects that occur. See the end of Section 4 for how to report side effects.

TURKOVAC 3 mcg/0,5 mL suspension for IM injection
For intramuscular administration.
Sterile

- ***Active Substance:*** One dose of vaccine (0.5 mL): contains 3 mcg/0.5 mL of antigen from the SARS-CoV-2 virus[1] (inactive).
  It is produced in [1](VERO CCL-81) cell culture.
- ***Excipient(s):*** Contains aluminum hydroxide, sodium chloride, potassium chloride, potassium dihydrogen phosphate, disodium hydrogen phosphate heptahydrate and water for injection.

Read this PATIENT INFORMATION LEAFLET carefully before administering this vaccine, as it contains important information for you.

- *Keep this patient information leaflet. You may need to read it again.*
- *If you have any further questions, ask your doctor or pharmacist.*
- *This vaccine has been prescribed for you. Do not give it to others.*
- *When you go to the doctor or hospital after the administration of this vaccine, tell your doctor that this vaccine had been administered.*
- *Follow these instructions exactly as written. Do not use **higher or lower** dose other than your recommended dose for the vaccine.*

What is in this leaflet:

Headings are included.

1. What TURKOVAC is and what is it used for?

TURKOVAC is a vaccine administered for active immunization and reminder dose against the SARS-CoV-2 virus for the prevention of diseases caused by the SARS-CoV-2 virus.
It is administered to individuals over 18 years of age.
It is presented in packages with flip-off cap, bromo buthyl stopper, containing 10 vials (type I transparent) with 5 doses in 1 package.

2. What you need to know before using TURKOVAC

DO NOT USE TURKOVAC in below cases;

If;

- you have hypersensitivity to any of the components of this vaccine, a history of life-threatening allergies/anaphylaxis,
- anaphylaxis has developed after the previous dose administration.

USE TURKOVAC CAREFULLY in the following cases;

- In patients with low platelet counts or bleeding disorders, intramuscular (IM) injections may cause bleeding.
- In patients who are on immunosuppressive drug therapy or who are immunodeficient, there is not enough data on this vaccine. The immune response to the vaccine may not be sufficient. Possible benefits and possible risks in those currently receiving immunosuppressive therapy should be evaluated and the options of administering the vaccine or postponing the vaccination until the end of treatment should be evaluated on a patient-by-patient basis. For patients with congenital and acquired immune deficiencies, the vaccine response may vary depending on the underlying disease.
- Intravenous (IV) / subcutaneous (SC) immunoglobulin, plasma and other blood product administrations do not prevent the administration of inactivated vaccines, but simultaneous administration is not preferred.
- Uncontrolled and/or unresponsive epilepsy, the presence of progressive neurological diseases and neurological diseases such as Guillain-Barre Syndrome (a disease of the nervous system), transverse myelitis (neurological disorder caused by inflammation of the spinal cord) should be evaluated on a patient basis.
- As with other vaccines, complete protection may not be achieved in all individuals vaccinated with TURKOVAC. Therefore, even if vaccination is achieved, the implementation of personal protective measures should be continued.
- If you have encountered the above situations that require careful administration of this vaccine, even in the past, please consult your doctor.
- It is not preferable to administer it if you are in the period of acute exacerbation of fever, acute illness and chronic (prolonged) diseases.
- As a psychogenic response to injection with a needle, syncope (fainting) can be observed after vaccination or even before vaccination. This may be accompanied by many neurological symptoms such as temporary visual impairment, paresthesia (numbness) and tonic-clonic movements during recovery. It is important to have the necessary procedures ready to prevent injuries that may occur due to syncope.
- In order to better track biotechnological medicinal products, the brand name and batch number of the administered product should be clearly recorded (or indicated) in the patient file.

Use of TURKOVAC with food and drink
There is no interaction with food and drinks in terms of administration method.

Pregnancy
Consult your doctor or your pharmacist before using the drug.

In clinical trials, there is no data on the administration of TURKOVAC since women during pregnancy are excluded from the scope of the study.
There is not enough data on the administration of the inactivated pandemic COVID-19 vaccine (TURKOVAC) during pregnancy. It is recommended by the World Health Organization that pandemic SARS-CoV-2 vaccines can be administered to pregnant women who are at high risk of severe transmission of COVID-19 disease, if they wish.

If you notice you are pregnant during treatment, consult your doctor or pharmacist immediately.

Lactation
Consult your doctor or your pharmacist before using the drug.

There are no data on the administration of TURKOVAC in clinical studies, as breastfeeding women were excluded from the study.
There are insufficient data on the administration of inactivated pandemic COVID-19 vaccine (TURKOVAC) during breastfeeding. It is recommended by the World Health Organization that pandemic SARS-CoV-2 vaccines can be administered to pregnant women who are at high risk of severe transmission of COVID-19 disease, if they wish.

Driving and using machines
The effects of TURKOVAC on the ability to drive and use machines have not been evaluated.

Important information about some excipients in the content of TURKOVAC
TURKOVAC contains less than 1 mmol (23 mg) sodium in a 0.5 mL single dose; that is, the sodium content is negligible.
TURKOVAC contains less than 1 mmol (39 mg) potassium in a 0.5 mL single dose; that is, the potassium content is negligible.

Use with other medicines
- There are no scientific data on its administration together with other vaccines, before or after.
- There are no data on the completion of the primary series in COVID-19 vaccination by interchangeably administering TURKOVAC with other COVID-19 vaccines.
- Immunosuppressive (immune suppressing) drugs: Immune inhibitor monoclonal antibodies, chemotherapy drugs, corticosteroids, etc. may affect the body's immune response to this vaccine.

If you are currently using or have recently used any prescription or non-prescription medicine, or if you have recently had any vaccinations other than this one, please inform your doctor about them.

3. How to use TURKOVAC?

Instructions for appropriate use and dose/administration frequency:

The vaccine is administered in two doses, four weeks apart, in individuals over 18 years of age to develop immunity to the SARS-CoV-2 virus. The booster dose is administered as a single dose.

The vaccine administration dose is 3 mcg / 0.5 mL.

The vaccine should be administered while the person is sitting.

In terms of possible allergic reactions after vaccination, they should not leave the health facility for 15 minutes. People with a history of allergies should not leave the health facility for 30 minutes.

Route and Method of administration:

The vaccine must be injected intramuscularly (IM). The preferred injection site is the deltoid region. The vaccine should be administered while the person is sitting.

It is not injected into a vein.

The vaccine should not be administered by subcutaneous (SC) or intradermal (ID).

Various age groups:

Use in children:

There is insufficient data in people aged 18 years and younger.

Use in elderly:

There are insufficient data in people aged 65 and over.

Special cases for use:

Based on current information, it is not recommended to be administered to patients with active COVID-19, those who have had COVID-19 disease within 180 days (confirmed by PCR testing) and have been in contact with a confirmed case of COVID-19 within 10 days prior to administration of the vaccine.

Kidney/ Liver failure:

No clinical studies and data are available.

If you have the impression that the effect of TURKOVAC is too strong or too weak, talk to your doctor.

If you have any acute, chronic or allergic disease, inform your doctor about it.

If you have used more TURKOVAC than you should:

If you have used TURKOVAC more than you should, talk to a doctor or pharmacist.

Please do not forget to take the packaging or the patient information leaflet of the vaccine with you.

If you forget to use TURKOVAC
If the timely administration of the determined dose is forgotten or delayed for any reason, consult your doctor about how to administer the following doses.
Do not take a double dose to make up for forgotten doses.

Effects which may occur when treatment with TURKOVAC is terminated
There aren't any.

4. What are the possible side effects?
Like all medicines, there may be side effects in people who are sensitive to the substances contained in TURKOVAC.

If any of the following develops, IMMEDIATELY inform your doctor and go to the nearest hospital emergency department:
- Allergic reactions (hypersensitivity reactions), whose symptoms include shortness of breath, wheezing, skin rash and itching or swelling of the face and lips.
These are all very serious side effects.
If you have one of these, it means you have a serious allergy to TURKOVAC. You may need emergency medical attention or hospitalization.

Side effects are listed as shown in the following categories:
Very Common: Can be seen in at least 1 of 10 patients.
Common : Can be seen in less than 1 in 10 patients, but in more than 1 in 100 patients.
Uncommon : Can be seen in less than 1 in 100 patients, but in more than 1 in 1000 patients.
Rare : Can be seen in less than 1 in 1000 patients, but in more than 1 in 10.000 patients.
Very rare : Can be seen in at least 1 of 10.000 patients.
Unknown : Cannot be estimated from the available data

Very Common
- Pain at the injection site

Common
- Hardening or swelling at the injection site
- Headache
- Throat ache
- Runny nose
- Diarrhea
- Muscle pain
- Tiredness
- Cough
- Nasal congestion

Uncommon

- Arm pain at the injection site
- Redness at the injection site
- Sensitivity at the injection site
- Eye pain
- Blurred vision
- Chest pain
- Sneeze
- Hypotension
- Tachycardia
- Vomiting
- Nausea
- Constipation
- Abdominal pain
- Difficulty swallowing
- Itching on the body
- Low back pain
- Fever
- Chill
- Sweating
- Dizziness
- Loss of odor
- Itching in the throat
- Joint pain

If you experience any side effect not mentioned in this patient information leaflet, inform your doctor or your pharmacist.

Reporting of suspected adverse reactions

If you get any side effects not listed in this leaflet, talk to your doctor or pharmacist. You can also report side effects directly to your doctor or pharmacist. You can also report side effects directly to your country's related health authority. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store *TURKOVAC*?

Keep TURKOVAC out of the reach and sight of children and within its packaging.

Store in the refrigerator between 2 - 8 °C. Care should be taken not to freeze the vaccine. Frozen products should not be thawed and administered. Protect from light.

Use in compliance with the expiry date.

Do not use TURKOVAC after the expiry date on the package/carton/vial / use before the expiry date.

It can be stored on any shelf of the vaccine cabinet.
In no-frost refrigerators that do not have a vaccine cabinet (if there is no vaccine cabinet, only no-frost refrigerators should be used), it should be stored preferably on the second shelf from the top and on the side of the shelf close to the door, so that it does not touch the inner wall of the cabinet and is not in front of the blowing channels.
There should preferably be a freezing indicator in the cabinet.

Cold chain should be provided in accordance with the Extended Immunization Program Circular.

If defects are noticed in the product and/or its packaging, TURKOVAC is not administered.

Planning should be done so that the vial will be used within 8 hours at the latest. The opening time should be recorded on the vial. If there is any vaccine left in the vial after 8 hours, it should not be used and the remaining vaccine should be disposed of properly.

Do not throw away expired or unused vaccines! Give it to the collection system determined by the Ministry of Environment, Urbanization and Climate Change.

Marketing Authorisation Holder
SBT Sağlık Bilim ve Teknolojileri A.Ş.
Üniversiteler Mah. Şehit Mehmet Bayraktar Cad. No:3
Çankaya/ANKARA

Manufacturing Site:
DOLLVET Biyoteknoloji A.Ş.
Şanlıurfa OSB 1. Kısım
Koçören OSB Mah. 106. Cad. No:6
Eyyübiye/ŞANLIURFA

This patient leaflet was approved on 10/05/2023.

THE FOLLOWING INFORMATION IS FOR MEDICAL PERSONNEL WHO WILL ADMINISTER THIS MEDICATION

TURKOVAC is in the form of an opalescent suspension. Layered precipitates can be removed by agitation, after agitation there should be no residue or agglomeration. It should be shaken well before use.

Care should be taken not to freeze the vaccine. Frozen products should not be thawed and administered. Protect from light.

It must not administered when a foreign particle is detected in the vaccine, when a crack or disorder is detected in the vaccine packaging.

In accordance with the rules of asepsis, the s**topper of the vial should be wiped with an antiseptic** and administered without waiting by withdrawing 0.5 mL to the vaccine injector distributed by the Ministry of Health in accordance with this vaccine. No other injector should be used.

1 dose is 0.5 mL.

It is administered intramuscularly (IM) to people over 18 years of age at an angle of 90º as 0.5 mL.

If there is any vaccine left in the vial after using 5 doses of vaccine, the remaining amount in the vial should not be used as a new vaccine dose and should be disposed of appropriately.

The vaccine must be injected intramuscularly (IM). The preferred injection site is the deltoid region. The vaccine should be administered while the person is sitting.

It must not be injected intravenously. The vaccine should not be administered subcutaneously (SC) or intradermally (ID).