



COVID-19 VACCINE

MC Pharma

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS 4

PROPRIETARY NAME: COVID-19 VACCINE MC PHARMA INTRAMUSCULAR INJECTION

Read all this leaflet carefully before you are given COVID-19 VACCINE MC PHARMA

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

Read all of this leaflet carefully because it contains important information for you

COVID-19 VACCINE MC PHARMA is available upon recommendation by your doctor/pharmacist for you to prevent COVID-19 caused by the SARS-CoV-2 virus

What is in this leaflet

1. What COVID-19 VACCINE MC PHARMA is and what it is used for
2. What you need to know before you are given COVID-19 VACCINE MC PHARMA
3. How is COVID-19 VACCINE MC PHARMA given
4. Possible side effects
5. How to store COVID-19 VACCINE MC PHARMA
6. Contents of the pack and other information

1. What COVID-19 VACCINE MC PHARMA is and what it is used for

COVID-19 VACCINE MC PHARMA is a vaccine used for preventing COVID-19 caused by the SARS-CoV-2 virus.

COVID-19 VACCINE MC PHARMA is given to adults aged 18 years and older.

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

None of the ingredients in this vaccine can cause COVID-19

2. What you need to know before you are given COVID-19 VACCINE MC PHARMA

Do not have the vaccine if

- You are allergic to the active substance or any of the other ingredients of this vaccine (listed in section 6).
- You have a previous diagnosis of blood disorders.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before you are given COVID-19 VACCINE MC PHARMA if:

- you have ever had a severe allergic reaction after injection of any other vaccine,
- you have ever fainted following any needle injection,
- you have a severe infection with a high temperature (over 38°C),
- you have a problem with bleeding or bruising, or if you are taking an anticoagulant medicine (to prevent blood clots),
- your immune system does not work properly (immunodeficiency) or you are taking medicines that weaken the immune system (such as high-dose corticosteroids, immunosuppressants or cancer medicines)
- You have uncontrolled epilepsy and other progressive neurological disorders.
- Drugs and equipment such as epinephrine should be available for emergency treatment in the event of an occasional severe allergic reaction. The vaccine should be watched for at least 30 minutes after vaccination.

As with any vaccine, vaccination with COVID-19 VACCINE MC PHARMA may not fully protect all those who receive it. It is not known how long you will be protected.

Special Patient Group

Elderly or geriatric patients

- Immunocompromised
- Pregnant and lactating mothers

3. How COVID-19 VACCINE MC PHARMA is given

A registered doctor, pharmacist or nurse will inject the vaccine into the muscle in the upper arm.

How much vaccine will you receive

Each vial contains 0.5 ml of product for each administration by intramuscular injection, each dose contains 6.5U/0.5 ml of inactivated SARS-CoV-2 antigen.

Immunization Program

This vaccine will be administered by a healthcare professional of national health authorities and CDC in accordance with the national immunization program and strategies.

COVID-19 VACCINE MC PHARMA is injected into a muscle, usually the upper part of the arm. Two 0.5ml successive dose 2-4 weeks apart.

After the injection your doctor, pharmacist or nurse will watch over you for around 30 minutes to monitor for signs of an allergic reaction.

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

4. Possible side effects

COVID-19 VACCINE MC PHARMA may cause side effects, although not everybody will experience them. These side effects are likely to occur within the first few (2) days of being vaccinated.

Get urgent medical attention if you get symptoms of a severe allergic reaction. Such reactions may include a combination of any of the following symptoms:

- feeling faint or light-headed
- changes in your heartbeat
- shortness of breath
- wheezing
- swelling of your lips, face, or throat
- hives or rash

- nausea or vomiting

- stomach pain.

The following side effects can happen with this vaccine.

Very common: may affect more than 1 in 10 people

- headache
- nausea

- muscle aches

- pain where the injection is given

- feeling very tired

Common: may affect up to 1 in 10 people

- redness where the injection is given

- swelling where the injection is given

- chills

- joint pain

- cough

- fever

Uncommon: may affect up to 1 in 100 people

- rash

- muscle weakness

- arm or leg pain

- feeling weak

- feeling generally unwell

- sneezing

- sore throat

- back pain

- tremor

- excessive sweating

- unusual feeling in the skin, such as tingling or a crawling feeling (paresthesia)

Rare: may affect up to 1 in 1000 people

- allergic reaction

- hives

- swollen lymph nodes (lymphadenopathy)

- decreased feeling or sensitivity, especially in the skin (hypo aesthesia)

- persistent ringing in the ears (tinnitus)

- vomiting

Very Rare: may affect up to 1 in 10000 people

- blood clots often in unusual locations (e.g., brain, liver, bowel, spleen) in combination with low level of blood platelets

- serious nerve inflammation, which may cause paralysis and difficulty breathing (Guillain-Barré syndrome (GBS))

Unknown (cannot be estimated from the available data)

- severe allergic reaction

- capillary leak syndrome (a condition causing fluid leakage from small blood vessels).

Tell your doctor, pharmacist or nurse if you have any side effects that bother you or do not go away.

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 national reporting system COVID-19 Hotline 08000

029 999 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 COVID-19 VACCINE MC PHARMA

Store and transport in a refrigerated (2°C-8°C) condition, protect from light. Do not freeze.

6. Contents of the pack and other information

What COVID-19 VACCINE MC PHARMA contains

The COVID-19 VACCINE MC PHARMA Vaccine (Vero Cell), inactivated is formulated with a SARS-CoV-2 strain.

COVID-19 VACCINE MC PHARMA contains SARS-CoV-2 vaccine (Vero Cell), inactivated

The active substance is Adenovirus type 26 encoding the SARS-CoV-2 s.

What COVID-19 VACCINE MC PHARMA looks like and contents of the pack

The product is a semi-transparent turbid suspension with slight white color, which could be layered due to precipitation, and the precipitation can be easily dispersed by shaking.

Pack Size Description 1 Vial (0.5 ml)

1 Vial / box.

1 doses / vial per box

EXP: 12 months (Tentatively)

Holder of Certificate of Registration

MC Pharma (PTY) LTD

62 Constantia Avenue

Mirand, Pretoria, 0157

Gauteng, Republic of South Africa

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31 January 2022

Access to the corresponding Professional Information

www.covid19vaccinemcpharma.co.za

TUB



COVID-19 VACCINE

MC Pharma

PASIENTINLICHTINGSBLAADJIE

SKEDULE STATUS 4

EIENDOMSNAAM: COVID-19 VACCINE MC PHARMA INTRAMASCULAR INJECTION

Lees die hele pamflet noukeurig deur voordat COVID-19 VACCINE MC PHARMA aan u toegedien word

- Bewaar hierdie pamflet voorhand in weer hierna moet verwys of dit lees.
- Indien enige verdere vrae, raadpleeg asseblief jou dokter, apteker, verpleegster of ander gesondheidsorgverskaffer.
- Indien jy enige nuwe-effekte kry, raadpleeg jou dokter, apteker of verpleegster. Dit sluit enige moontlike nuwe-effekte in wat nie in hierdie pamflet gelyk word nie

LEES DIE HELE PAMFLET NOUKEURIG DEUR WANT DIT BEVAT BELANGRIKE INLICHTING.

COVID-19 VACCINE MC PHARMA is beskikbaar op aanbeveling van jou dokter/apteker vir die voorkoming van COVID-19 wat deur die SARS-CoV-2-virus veroorsaak word.

Wat in hierdie pamflet ingesluit word

- Wat COVID-19 VACCINE MC PHARMA is en waarvoor dit gebruik word
- Wat jy moet weet voordat COVID-19 VACCINE MC PHARMA aan jou toegedien word
- Hoe COVID-19 VACCINE MC PHARMA toegedien word
- Moontlike nuwe-effekte
- Hoe om COVID-19 VACCINE MC PHARMA te berei
- Inhoud van die pakkie en enige verdere inligting

1. Wat COVID-19 VACCINE MC PHARMA is en waarvoor dit gebruik word

COVID-19 VACCINE MC PHARMA is 'n entstof wat gebruik word vir die voorkoming van COVID-19 wat deur die SARS-CoV-2-virus veroorsaak word.

COVID-19 VACCINE MC PHARMA kan slegs gegee word vir volwassenes, 18 jaar en ouer. Die entstof ondersteun die menslike immuunstelsel (die liggaam se natuurlike verdedigingsmeganisme) teen COVID-19. Dit verken hulp met die produksie van teenliggaampies en gespesialiseerde witbloedselle om die virus teen te werk. Daardeur word beskerming gebied teen COVID-19.

2. Wat jy moet weet voordat COVID-19 VACCINE MC PHARMA toegedien word

Moet nie die entstof gebruik as

- Jy allergies is vir enige van die aktiewe- of ander bestanddele wat hierdie entstof bevat nie (soos gelys in afdeling 6).
- Jy enige vorige simptome getoon het of gedignoseer was met bloedaftwykings.

Waarskuwings en voorsorgmaatreëls

Raadpleeg jou dokter, apteker of verpleegster voordat COVID-19 VACCINE MC PHARMA aan jou toegedien word indien:

- Jy enige ernstige allergiese reaksies getoon het na die inspuiting van enige ander entstof,
- Jy 'n oot of/ou geword het na enige naaldinspuiting,
- Jy 'n ernstige infeksie het met 'n hoë temperatuur (meer as 38°C)
- Jy probleme ondervind met bloeding of kneusing, of as jy 'n antikoagulant medisyne gebruik (om bloedklonte te voorkom),
- Jou immuunstelsel nie behoorlik werk nie (immuunbrek) of jy neem medisyne wat die immuunstelsel verswak (soos hoë dosis kortikosteroïde, immuunonderdrukkers of kankermedisyne)
- Jy lei aan onbeheerde epilepsie of ander progressiewe neurologiese afwykings.
- Medisyne en toerusting soos spinerlino moet beskikbaar wees vir noodbehandeling in die geval van 'n ernstige allergiese reaksie. Die entstof moet vir ten minste 30-minute na inenting dopgehou word. Die allergiese reaksies vind nie algemeen plaas nie.

Soos met enige entstof, sal inenting met COVID-19 VACCINE MC PHARMA moontlik nie almal wat dit ontvang ten volle beskerm nie. Dit is nie bekend hoe lank jy beskerm sal word nie.

Spesiale Pasientgroep

Begrade of getraiteerde pasiënte
Immuunonderdruk
Swanger en vrouens wat borsvoed

3. Hoe COVID-19 VACCINE MC PHARMA toegedien word

Die entstof moet deur 'n geregistreerde dokter, apteker of verpleegster toegedien word deur dit in te spuit in die bo-arm spier.

Hoeveelheid entstof wat jy sal ontvang

Elke flesse bevat 0.5 ml produk vir elke toediening deur binnespiers inspuiting. Elke dosis bevat 0.5 ml geïnaktiveerde SARS-CoV-2 antigeen.

Immunisasie Program Die inspuiting sal toegedien word deur 'n gesondheidsorgwerker, nasionale gesondheidsorganisasies en CDC, na aanleiding van nasionale immuniserings programme en strategieë.

COVID-19 VACCINE MC PHARMA word gewoonlik in 'n spier in die bo-arm toegedien. Twee opeenvolgende dosisse van 0.5ml sal 2 – 4 uitmekaar toegedien word.

Na die inspuiting sal die dokter, verpleegster of apteker jou vir 30 minute monitor om tekens van 'n allergiese reaksie waar te neem.

Indien u enige verdere vrae het kan dit aan die dokter, verpleegster of gesondheidswerker gerig word.

4. Moontlike nuwe-effekte

COVID-19 VACCINE MC PHARMA mag nuwe-effekte he. Die nuwe-effekte sal nie noodwendig deur almal ervaar word nie. Die nuwe-effekte sal moontlik binne die eerste 2 dae na die toediening van die entstof voorkom .

Mediese behandeling is nodig indien enige van die allergiese reaksie simptome ondervind word. Dit kan ook 'n kombinasie van die volgende simptome wees:

- Lighoofdigheid of duiseligheid
- Hartklop veranderinge
- Kortasem
- Hyg na asem
- Geswolle lippe, gesig of keel
- Veluitslag
- Naarheid of vomering
- Maagyn

Die volgende nuwe-effekte kan ook voorkom met die toediening van die entstof:

Baie algemeen: Kan meer as 1 uit 10 mense affekteer:

- Hoofpyn
- Naarheid
- Spierpyn
- Lokale pyn waar die inspuiting toegedien is
- Algemene moegheid

Algemeen: kan 1 – 10 mense affekteer

- Rooihoid waar die inspuiting toegedien is
- Swelling waar die inspuiting toegedien is
- Koue lillings
- Hoos
- Koors
- Pyn in gewrigte

Nie algemeen nie: kan 1 uit 100 mense affekteer:

- Uitslag
- Spier swakheid
- Arm of been pyn
- Algemene gevoel van swakheid/Dies
- Seer keel
- Rugpyn
- Uitermatige sweetpatrone
- Vreemde sensoriese gevoel op vel,
- Diaree

Raar: kan 1 uit 1000 mense affekteer:

- Allergiese reaksie
- Kroppe op die vel
- Geswolle limfkliere
- Velsensitiwiteit wat mag versleg
- Tinnitus of aanhoudende gesuis in die ore
- Braking

Uiters raar: kan 1 uit 10 000 mense affekteer:

- Bloedklonte, baie keer op verskeie plekke (brein, lever, miel) dit kan gepaardgaan met lae vlakke van bloedplaatjies
- Ernstige inflammasie in die senues wat tot verlamming en moeilike asemaling kan lei (Guillain-Barre syndrome) Onbekende resultate
- Ernstige allergiese reaksies
- Kapillêre lek sindroom

Lig u dokter of verpleegster in indien u simptome ondervind wat nie weg wil gaan nie.

Aanmelding van nuwe effekte

Indien enige nuwe-effekte ondervind word stel u dokter of verpleegster in kennis. Dit sluit enige van die nuwe effekte in wat in die pamflet voorhand is en wat nie in die nasionale COVID-19 Hotline gerig word, 08000 029 999. Sluit as die verpakingsnommer ook in indien dit beskikbaar is. Deur die rapportering van nuwe effekte kan u help om die gebruik van die medisyne veiliger te maak. Hoe meer inligting beskikbaar is hoe beter.

5. Berging van COVID-19 VACCINE MC PHARMA

Berg of vervoer teen 2°C tot 8°C. Moet nie vries nie. Beskerm teen lig.

6. Inhoudelike van die pakkie en ander algemene inligting

COVID-19 VACCINE MC PHARMA bevat die volgende

Die COVID-19 VACCINE MC PHARMA Vaccine (Vero Cell), ongaatveer is saamgestel deur 'n SARS-CoV-2 variant. COVID-19 VACCINE MC PHARMA bevat SARS-CoV-2 Vaccine (Vero Cell), Ongaatveer. Die aktiewe bestanddeel is Adenovirus tipe 26 getrekodeer as SARS-CoV-2 s.

COVID-19 VACCINE MC PHARMA se voorkoms en inhoud van die pak

Die produk is 'n semi-deursynende, effense wit kleurige suspensie. Die suspensie kan in lae voorkom as gevolg van die skaking tussen die verskillende inhoudelike bestanddele en/of samestelling van die produk. Deur dit goed te skud, sal die entstof se inhoudelike weer meng om terug te keer na die normale voorkoms daarvan.

Pak Grootte - 1 Bus (0.5 ml)
1 Bus/Boks of pakkie
1 dosisse of bedienings / bus per pak
EXP: 12 maande (Tentatiewelik)

**Houer van Registrasie Sertifikaat
MC Pharma (PTY) LTD**
62 Constantia Avenue
Mrandi, Pretoria, 0157
Gauteng, Republic of South Africa

Hierdie inligtingstelsel is laas hersien in
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56/30.5/0795

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Toegang tot Professionele inligting
www.covid19vaccinemcpharma.co.za