

Applicant: Strides Pharm (SA) (Pty) Ltd.
Product Name: Morlipar 200 mg
Dosage form and strength: Capsule, Molnupiravir 200 mg

Date of approval (registration):
04 July 2023

Module 1.0 Administration Information

Approved Patient Information Leaflet

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS **S4**

MORLIPAR 200 mg capsules

Molnupiravir

Sugar-free

Read all of this leaflet carefully before you start taking MORLIPAR 200 mg

- 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.
- MORLIPAR 200 mg has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What is MORLIPAR 200 mg and what it is used for
2. What you need to know before you take MORLIPAR 200 mg
3. How to take MORLIPAR 200 mg
4. Possible side effects
5. How to store MORLIPAR 200 mg
6. Contents of the pack and other information

1. WHAT IS MORLIPAR 200 mg AND WHAT IT IS USED FOR

MORLIPAR contains the active ingredient molnupiravir. Molnupiravir is an antiviral medicine used to treat mild to moderate COVID-19 (caused by SARS-CoV-2) in adults who do not currently need oxygen due to COVID-19 and who are at risk for developing severe illness.

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MORLIPAR may help people with COVID-19 stay out of the hospital and feel better.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE MORLIPAR 200 mg

Do not take MORLIPAR 200 mg:

- if you are hypersensitive (allergic) to molnupiravir or any of the other ingredients of MORLIPAR (listed in section 6).

Warnings and precautions

Talk to your doctor or pharmacist before taking MORLIPAR.

Children

Do not give this medicine to children and adolescents aged less than 18 years. The use of MORLIPAR in persons aged less than 18 years has not yet been studied.

Other medicines and MORLIPAR 200 mg

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

Pregnancy and breastfeeding

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking MORLIPAR.

Pregnancy

MORLIPAR is not recommended in pregnancy. MORLIPAR has not been studied in pregnancy and it is not known if MORLIPAR will harm your baby while you are pregnant.

Fertility

If you can become pregnant, you should use effective birth control while you are taking MORLIPAR and for 4 days after the last dose of MORLIPAR.

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Breastfeeding

Breastfeeding is not recommended during treatment and for 4 days after the last dose of MORLIPAR. This is because it is not known if MORLIPAR gets into breast milk and will be passed to the baby.

Driving and using machines

Molnupiravir has no or negligible influence on the ability to drive and use machines.

3. HOW TO TAKE MORLIPAR 200 mg

Do not share medicines prescribed for you with any other person.

Always take MORLIPAR exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

You should start MORLIPAR within 5 days of the onset of COVID-19 symptoms.

How much to take

The recommended dose of MORLIPAR is four 200 mg capsules, every 12 hours for 5 days.

How to take

Swallow the capsule whole with plenty of fluid (for instance a glass of water), Do not open, break, or crush the capsules. This medicine can be taken with or without food.

If you take more MORLIPAR than you should

If you take too many tablets, contact a doctor or pharmacist for advice. If possible, show them the pack, or this leaflet.

If you forget to take MORLIPAR

It is important that you do not miss or skip doses of this medicine. If you forget to take a dose within 10 hours of the time it is usually taken, you should take it as soon as possible and take the next one at the usual time. If you forget to take a dose by more than 10 hours, you should not take the missed dose and instead take the next one at the usual time. Do not take a double dose to make up for a missed dose. If you

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are not sure what to do, call your doctor or pharmacist.

If you stop taking MORLIPAR

Do not stop taking MORLIPAR without talking to your doctor first. This will give the medicine the best chance to keep you from becoming severely ill from COVID-19.

4. POSSIBLE SIDE EFFECTS

MORLIPAR can have side effects. Not all side effects reported for MORLIPAR are included in this leaflet.

Should your general health worsen or if you experience any untoward effects while taking MORLIPAR, please consult your health care provider for advice.

If any of the following happens, stop taking MORLIPAR and tell your doctor immediately or go to the casualty department at your nearest hospital:

allergic reaction (hypersensitivity) – the signs may include swelling, difficulty breathing, rashes or itchiness or fainting. These are all very serious side effects. If you have them, you may have had a serious reaction to MORLIPAR. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Frequent side effects:

- diarrhoea
- nausea
- feeling dizzy
- headache

Less frequent side effects:

- vomiting
- rash
- hives
- reddening of skin

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If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist, or nurse. You can also report side effects to SAHPRA via the "6.04 Adverse Drug Reaction Reporting Form", found online under SAHPRA's publications:

https://www.sahpra.org.za/wp-content/uploads/2021/11/6.04_ARF1_v6.0_28Oct2021.docx.pdf, or via the

SAHPRA portal: <https://primaryreporting.who-umc.org/ZA> or via the Med Safety App:

<https://medsafety.sahpra.org.za/>. By reporting side effects, you can help provide more information on the safety of MORLIPAR.

5. HOW TO STORE MORLIPAR

Store all medicines out of reach of children.

Store at or below 30°C.

Store in the original package / container.

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

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What MORLIPAR contains:

The active substance is molnupiravir.

The other ingredients are as follows:

Capsule content: microcrystalline cellulose, povidone, crospovidone, colloidal silicone dioxide, magnesium stearate.

Hard gelatin capsules shell: titanium dioxide, gelatin, sodium lauryl sulphate.

Printing ink: shellac E904, dehydrated alcohol E1510, isopropyl alcohol, butyl alcohol, propylene glycol E1520, strong ammonia solution E527, yellow iron oxide E172.

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What MORLIPAR 200 mg looks like and contents of the pack

MORLIPAR 200 mg is a white to off white powder filled in size '2' Hard gelatin capsule with white opaque cap, imprinted with 'S464' in white colour ink inside the gold band and white opaque body imprinted with '200' in white colour ink inside the gold band on body.

40 capsules are packed as 10 X 4 blisters in a carton.

Holder of Certificate of Registration

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