

PROPOSED PATIENT INFORMATION LEAFLET	Module 1.5.5.4
LAGEVRIO™ Capsules	Application no.: 561225
Applicant: MSD (Pty) Ltd	Version: Clean
Date of submission to SAHPRA: 04 November 2022	New application for registration
Response to HA Clinical Query 4 received 21 September 2022	

1. **SCHEDULING STATUS**

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4. **LAGEVRIO™ Capsules**

5. Molnupiravir

6.

7. **Read all of this leaflet carefully, before you start taking LAGEVRIO™.**

- Keep this leaflet. You may need to read it again.
- LAGEVRIO™ has been prescribed for you personally. Do not share LAGEVRIO™ with any other person.
- Ask your health care provider or pharmacist if you need more information or advice.

8.

9. **What is in this leaflet**

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

16.

17. **1. What LAGEVRIO™ is and what it is used for**

18. LAGEVRIO™ is an antiviral medicine that works against the virus that causes coronavirus disease 2019 (COVID-19).

19. LAGEVRIO™ is a medicine used to treat mild to moderate COVID-19 in adults who do not currently need oxygen due to COVID-19 and are at risk for progressing to severe illness.

20. Your healthcare provider has recommended or given you LAGEVRIO™ (**molnupiravir**) for the treatment of COVID-19. LAGEVRIO™ may help people with COVID-19 stay out of the hospital and feel better.

21.

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22.

What is COVID-19?

- COVID-19 is caused by a virus called SARS CoV-2.
- You can get COVID-19 through contact with another person who has the virus.

COVID-19 illnesses have ranged from very mild (including some with no reported symptoms) to severe, including illness resulting in death. While information so far suggests that most COVID-19 illness is mild, serious illness, including breathing problems, can happen and may cause some of your other medical conditions to become worse. Older people and people of all ages with severe, long lasting (chronic) medical conditions like heart disease, lung disease and diabetes, for example seem to be at higher risk of being hospitalized for COVID-19.

What are the Symptoms of COVID-19?

The symptoms of COVID-19 may include fever, cough, and shortness of breath.

23.

2. What you need to know before you take LAGEVRIO™

24.

Do not take LAGEVRIO™ if:

- you are allergic to molnupiravir or any of the other ingredients of LAGEVRIO™ (listed in section 6).

25.

2.1 What should I tell my doctor before and while taking LAGEVRIO™?

26.

Tell your healthcare provider about all of your medical conditions, including if you:

- are pregnant or plan to become pregnant.
- are breastfeeding or plan to breastfeed.
- have any allergies.
- have any serious illnesses.
- are taking any medicines (prescription, over-the-counter, vitamins, or herbal products)

27.

Other medicines and LAGEVRIO™

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

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31. **2.2 Pregnancy**

- 32.
- Your doctor will advise you regarding the safety of LAGEVRIO™ during pregnancy.
 - LAGEVRIO™ has not been studied in pregnancy and it is not known if LAGEVRIO™ will harm your baby while you are pregnant.
 - LAGEVRIO™ is not recommended in pregnancy.
 - If you are pregnant, think you may be pregnant, or are planning to have a baby, ask your doctor for advice.
 - If you can become pregnant, you should use effective birth control while you are taking LAGEVRIO™ and for 4 days after stopping.

33. **2.3 Breastfeeding**

34.

- Do not breastfeed your child if you are taking LAGEVRIO™ and for 4 days after the last dose of LAGEVRIO™.
- It is not known if LAGEVRIO™ gets into breast milk and will be passed to the baby.
- If you are breastfeeding or are planning to breastfeed, tell your doctor before taking LAGEVRIO™.

35.

36. **Driving and using machines**

37. Some patients have reported dizziness during treatment with LAGEVRIO™. If you experience this effect, do not drive or use machines until the effect wears off (see Section 4, possible side effects).

38.

39. **3. How to take LAGEVRIO™**

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

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

42. Take 4 capsules of LAGEVRIO™ every 12 hours (for example, at 8 am and at 8 pm).

43. Take LAGEVRIO™ for 5 days.

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44. Take LAGEVRIO™ with or without food.
45. Do not open, break, or crush the capsules. If you cannot swallow capsules whole, tell your healthcare provider.
46. **3.1 If you take more LAGEVRIO™ than you should**
47. In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.
48. **3.2 If you forget to take LAGEVRIO™**
49.
 - It is important that you do not miss or skip doses of this medicine.
 - What to do if you miss a dose:
 - If it has been **less than 10 hours** since the missed dose, take it as soon as you remember
 - If it has been **more than 10 hours** since the missed dose, skip the missed dose and take your dose at the next scheduled time.
 - Do not double the dose of LAGEVRIO™ to make up for a missed dose.
 - If you are not sure what to do, call your doctor or pharmacist.
- 50.
51. **4. Possible side effects**
52. LAGEVRIO™ can cause side effects.
53. Not all side effects reported for LAGEVRIO are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking LAGEVRIO please consult your doctor, pharmacist or other healthcare professional for advice.
- 54.
55. If any of the following happens, stop taking LAGEVRIO™ and tell your doctor immediately or go to the casualty department at your nearest hospital:
 - allergic reaction (hypersensitivity) – the signs may include wheezing, difficulty breathing, rashes or hives, itchiness, swelling. These are all very serious side effects. If you have them, you may have had a serious reaction to LAGEVRIO™. You may need urgent medical attention or hospitalisation.
- 56.
57. **The most common side effects of LAGEVRIO™ in adults are:**

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58. • diarrhoea
59. • dizziness
60. • nausea
61. • headache
- 62.
63. Tell your healthcare provider about these side effects or any other unusual symptoms that develop after you receive LAGEVRIO™.
64. There may be side effects that are not listed here. Ask your healthcare provider for more information.
65. If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.
- 66.
67. **Reporting of side effects**
68. If you get side effects, talk to your doctor or 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/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of LAGEVRIO™.
- 69.
70. **How to store LAGEVRIO™**
71. Store LAGEVRIO™ in the original bottle.
72. Store at or below 25 °C.
73. Store all medicines out of the reach of children.
74. Do not use after the expiry date stated on the label.
- 75.
76. **6. Contents of the pack and other information**
77. 40 capsules packaged in a plastic bottle with a closure.
78. LAGEVRIO™ contains the following inactive ingredients: croscarmellose sodium, hydroxypropyl cellulose, magnesium stearate and microcrystalline cellulose.
79. The capsule shell contains the following inactive ingredients: hypromellose, red iron oxide, and titanium dioxide.



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80. The white ink on the capsule contains the following inactive ingredients: butyl alcohol, dehydrated alcohol, isopropyl alcohol, potassium hydroxide, propylene glycol, purified water, shellac and titanium dioxide.

81.

82. **What LAGEVRIO™ looks like and the contents of the pack**

83. LAGEVRIO™ is available as a Swedish Orange opaque capsule with corporate logo and “82” printed with white ink

84. 40 capsules packaged in a HDPE bottle.

85.

86. **Holder of Certificate of Registration**

87. MSD (Pty) Ltd

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1685

South Africa

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89. **This leaflet was last revised in**

90.

91. **Registration number**

92. To be inserted upon registration approval

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