

Appendix A – Vial and carton global labels for casirivimab and imdevimab with English-only labelling

Global Inner Label – Casirivimab (300 mg/2.5 mL)	
<p>The image shows a rectangular label for Casirivimab. On the left side, there are two vertical labels: 'Lot' at the top and 'EXP' at the bottom. The main text on the label reads: 'Casirivimab 120 mg/mL concentrate for solution for infusion'. Below this, there is a blue box containing '300 mg/2.5 mL' and 'IV after dilution'. To the right of this box is the Roche logo. Further right, it says 'Must administer with imdevimab'. At the bottom right corner, there is a small number '10238448 IE (EG)'.</p>	
Global Inner Label – Casirivimab (300 mg/2.5 mL) – English Text from Label	
<p>Casirivimab 120 mg/mL concentrate for solution for infusion</p> <p>300 mg/2.5 mL IV after dilution</p> <p>Must administer with imdevimab</p> <p>EXP LOT</p>	


Global Inner Label – Imdevimab (300 mg/2.5 mL)	
<p>The image shows a rectangular label for Imdevimab. On the left side, there are two vertical labels: 'Lot' at the top and 'EXP' at the bottom. The main text on the label reads: 'Imdevimab 120 mg/mL concentrate for solution for infusion'. Below this, there is a green box containing '300 mg/2.5 mL' and 'IV after dilution'. To the right of this box is the Roche logo. Further right, it says 'Must administer with casirivimab'. At the bottom right corner, there is a small number '10238451 IE (EG)'.</p>	
Global Inner Label – Imdevimab (300 mg/2.5 mL) – English Text from Label	
<p>Imdevimab 120 mg/mL concentrate for solution for infusion</p> <p>300 mg/2.5 mL IV after dilution</p> <p>Must administer with casirivimab</p> <p>EXP LOT</p>	


Global Outer Label – Casirivimab and Imdevimab 300 mg/2.5 mL (120 mg/mL)

Casirivimab and Imdevimab 120 mg/mL
concentrate for solution for infusion


120 mg/mL

For intravenous use after dilution

 2 vials of 6 mL



Roche Pharma AG
Emil-Barell-Strasse 1
79639 Grenzach-Wyhlen
Germany



www.cas-imd.ca


Roche

Casirivimab and Imdevimab 120 mg/mL
concentrate for solution for infusion

120 mg/mL

For intravenous use after dilution

 2 vials of 6 mL



1570
BE (EU)
09494201

One vial contains 300 mg/2.5 mL of casirivimab (120 mg/mL).
The other vial contains 300 mg/2.5 mL of imdevimab (120 mg/mL).
Excipients: L-histidine, L-histidine monohydrochloride monohydrate, polysorbate 80, sucrose, Water for injection.


7 613326 044608


Read the package leaflet before use
Casirivimab and Imdevimab must be administered together as a single intravenous infusion
For single use only
Keep out of the sight and reach of children
For pandemic use
Store in a refrigerator at 2°C to 8°C. Do not freeze. Do not shake the vials. Keep the vials in the outer carton to protect from light
Medical product subject to medical prescription
NO SIMON 0713326044608
SN (G1)
EXP
Batch (10)


Casirivimab and Imdevimab 120 mg/mL
concentrate for solution for infusion

120 mg/mL

For intravenous use after dilution

 2 vials of 6 mL





**Global Outer Label – Casirivimab and Imdevimab 300 mg/2.5 mL (120 mg/mL)
– English Text from Label**

Casirivimab and Imdevimab 120 mg/mL
concentrate for solution for infusion

120 mg/mL

For intravenous use after dilution

2 vials of 6 mL

One vial contains 300 mg/2.5 mL of casirivimab (120 mg/mL).

One vial contains 300 mg/2.5 mL of imdevimab (120 mg/mL).

L-histidine, L-histidine monohydrochloride monohydrate, polysorbate 80, sucrose, Water
for injection.

Sticker

QR code

www.cas-imd.ca

Read the package leaflet before use

Casirivimab and Imdevimab must be administered together as a single intravenous
infusion

For single use only

Keep out of the sight and reach of children

For pandemic use

Store in a refrigerator at 2°C to 8°C. Do not freeze. Do not shake the vials. Keep the vials
in the outer carton to protect from light

Medicinal product subject to medical prescription

Roche Pharma AG

Emil-Barell-Strasse 1

79639 Grenzach-Wyhlen

Germany

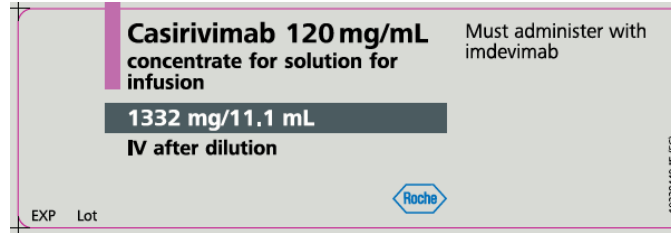
PC (GTIN 01)

SN

EXP

BATCH

Global Inner Label – Casirivimab (1332 mg/11.1 mL)



Global Inner Label – Casirivimab (1332 mg/11.1 mL)– English Text from Label

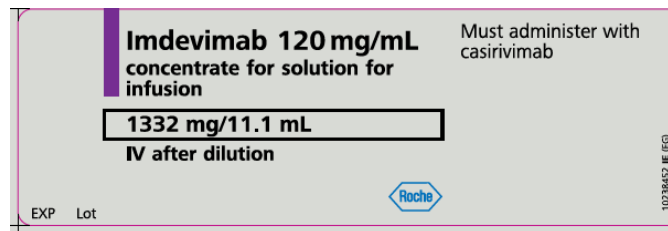
Casirivimab 120 mg/mL
concentrate for solution for infusion

1332 mg/11.1 mL
IV after dilution

Must administer with imdevimab

EXP LOT

Global Inner Label – Imdevimab (1332 mg/11.1 mL)



Global Inner Label – Imdevimab (1332 mg/11.1 mL) – English Text from Label

Imdevimab 120 mg/mL
concentrate for solution for infusion

1332 mg/11.1 mL
IV after dilution

Must administer with casirivimab

EXP LOT

Global Outer Label – Casirivimab and Imdevimab 1332 mg/11.1 mL (120 mg/mL)

Casirivimab and Imdevimab 120 mg/mL
concentrate for solution for infusion

120 mg/mL

For intravenous use after dilution

2 vials of 20 mL

10238447
M (G)
1572

Casirivimab and Imdevimab
120 mg/mL
concentrate for solution for infusion

For intravenous use after dilution

120 mg/mL

2 vials of 20 mL

QR code: www.casirivimab.com

One vial contains 1332 mg/11.1 mL of casirivimab (120 mg/mL).
One vial contains 1332 mg/11.1 mL of imdevimab (120 mg/mL).
L-histidine, L-histidine monohydrochloride monohydrate, polysorbate 80, sucrose, Water for injection.

Read the package leaflet before use
Casirivimab and Imdevimab must be administered together as a single intravenous infusion
For single use only
Keep out of the sight and reach of children

For pandemic use
Store in a refrigerator at 2°C to 8°C. Do not freeze. Do not shake the vials. Keep the vials in the outer carton to protect from light
Medicinal product subject to medical prescription

7 613326 044585

Casirivimab and Imdevimab 120 mg/mL
concentrate for solution for infusion

120 mg/mL

For intravenous use after dilution

2 vials of 20 mL

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79639 Grenzach-Wyhlen
Germany

**Global Outer Label – Casirivimab and Imdevimab 1332 mg/11.1 mL (120 mg/mL)
– English Text from Label**

Casirivimab and Imdevimab 120 mg/mL
concentrate for solution for infusion

120 mg/mL

For intravenous use after dilution

2 vials of 20 mL

One vial contains 1332 mg/11.1 mL of casirivimab (120 mg/mL).

One vial contains 1332 mg/11.1 mL of imdevimab (120 mg/mL).

L-histidine, L-histidine monohydrochloride monohydrate, polysorbate 80, sucrose, Water for injection.

Read the package leaflet before use

Casirivimab and Imdevimab must be administered together as a single intravenous infusion

For single use only

Keep out of the sight and reach of children

For pandemic use

Store in a refrigerator at 2°C to 8°C. Do not freeze. Do not shake the vials. Keep the vials in the outer carton to protect from light

Medicinal product subject to medical prescription

Roche Pharma AG

Emil-Barell-Strasse 1

79639 Grenzach-Wyhlen

Germany

Sticker

QR code

www.cas-imd.ca

PC (GTIN 01)

SN (21)

EXP

BATCH (10)