

<b>General Info:</b>	<b>Final Booklet Index Page</b> <b>Study: 2 g granules baloxavir marboxil (40 mg/20 ml)</b>
<b>Master Label Document:</b>	<b>RPT-0328950_v1.0</b>
<b>Label Info:</b>	<b>Vial 2 g granules baloxavir marboxil (40 mg/20 ml)</b> <b>Final Label Size: 36x85 mm, 30x45 mm</b>
<b>Material ID:</b>	39030770
<b>Created by:</b>	<b>Global Clinical Artwork Management</b> E-mail: global_clinical_artwork_mgmt.gips-gcam@roche.com
<b>Creation Date:</b>	October 1, 2024

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	<b>2 g granules baloxavir marboxil (40 mg/20 ml)</b> For oral use after reconstitution. <b>Use as directed in the protocol.</b> (1) Batch no. (2) Expiry date (3) For expiry date updates see outer container. (4) Pat.no. (5) Administration date <b>Do not store above 30°C.</b> Keep bottle in outer carton. For clinical trial use only. University Medical Centre Utrecht, Heidelberglaan 100, 3584 CX Utrecht, NL	
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	<p><b>2 g granula baloksavirmarboxila (40 mg/20 ml)</b>          Za primjenu kroz usta nakon rekonstitucije.  <b>Primijeniti sukladno planu ispitivanja.</b>          (1) Broj serije          (2) Rok valjanosti          (3) Za ažurirani rok valjanosti vidjeti vanjski spremnik.          (4) Br.bolesnika          (5) Datum primjene  <b>Ne čuvati na temperaturi iznad 30°C.</b>          Čuvati bočicu u vanjskom pakiranju.          Samo za primjenu u kliničkom ispitivanju.          University Medical Centre Utrecht, Heidelberglaan          100, 3584 CX Utrecht, NL</p>	
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	<p><b>2 g granuli baloxavir marboxil (40 mg/20 ml)</b>          Pro perorální podání po rekonstituci.  <b>Užívejte dle protokolu.</b>          (1) Č.sarže          (2) Datum expirace          (3) Informace o době použitelnosti je na vnějším obalu.          (4) Pac. č.          (5) Datum podání  <b>Uchovávejte při teplotě do 30°C.</b>          Lahvičku uchovávejte ve vnějším obalu.          Pouze pro použití v klinickém hodnocení.          University Medical Centre Utrecht, Heidelberglaan 100,          3584 CX Utrecht, NL</p>	
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	<p>2 g granulaat baloxavir marboxil (40 mg/20 ml)          Voor oraal gebruik na reconstitutie.  <b>Gebruik volgens instructie in het protocol.</b>          (1) Chargenr.          (2) Vervaldatum          (3) Voor vervaldatum updates zie buitenverpakking.          (4) Pat.nr.          (5) Toedieningsdatum  <b>Bewaren beneden 30°C.</b>          Houd de fles in de buitenverpakking.          Uitsluitend voor gebruik in klinische studie.          University Medical Centre Utrecht, Heidelberglaan          100, 3584 CX Utrecht, NL</p>	
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	<p><b>2 g baloksaviirmarboxiili graanuleid (40 mg/20 ml)</b>          Suukaudne pärast manustamiskõlblikuks muutmist.  <b>Kasutage vastavalt protokollile.</b>          (1) Partii number          (2) Kõlblikkusaeg          (3) Kõlblikkusaaja uuendamise kohta vaata välispakendilt.          (4) Pt. nr.          (5) Manustamise kuupäev  <b>Hoida temperatuuril kuni 30°C.</b>          Hoida pudel välispaendis.          Ainult kliinilises uuringus kasutamiseks.          University Medical Centre Utrecht, Heidelberglaan 100,          3584 CX Utrecht, NL</p>	
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	<p><b>Baloksaviirimarboxiili rakeet 2 g (40 mg/20 ml)</b>          Suun kautta käyttövalmiiksi saattamisen jälkeen.  <b>Käytä tutkimussuunnitelman mukaisesti.</b>          (1) Eränro          (2) Käyt.viim./Utg.dat.          (3) Päivitetty kesto aika, katso ulkopakkaus.          (4) Pot.nro          (5) Käyttöpäivä  <b>Säilytä alle 30°C.</b>          Pidä pullo ulkopakkauksessa.          Kliiniseen tutkimukseen. För klinisk prövning.          University Medical Centre Utrecht, Heidelberglaan          100, 3584 CX Utrecht, NL</p>	
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	<p><b>Baloxavir marboxil 2 g granulés (40 mg/20 ml)</b>          Voie orale après reconstitution.  <b>A utiliser comme indiqué dans le protocole.</b>          (1) Lot no.          (2) Date de péremption          (3) Pour les mises à jour de la date de péremption, voir l'emballage extérieur.          (4) Pat.no.          (5) Date d'administration  <b>Conserver à une température ne dépassant pas 30°C.</b>          Conserver le flacon dans l'emballage extérieur.          Pour recherche biomédicale uniquement.          University Medical Centre Utrecht, Heidelberglaan 100,          3584 CX Utrecht, NL</p>	
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	<p>1 Flasche mit 2 g Granulat Baloxavir marboxil (40 mg/20 ml) Zum Einnehmen nach Zubereitung. <b>Gemäß Protokoll anwenden.</b> (1) Ch.-B. (2) Verwendbar bis (3) Aktualisierungen bezüglich des Verfallsdatums siehe Umkarton. (4) Pat.-Nr. (5) Verabreichungsdatum <b>Nicht über 30°C lagern.</b> Die Flasche im Umkarton aufbewahren. Zur klinischen Prüfung bestimmt. University Medical Centre Utrecht, Heidelberglaan 100, 3584 CX Utrecht, NL</p>	
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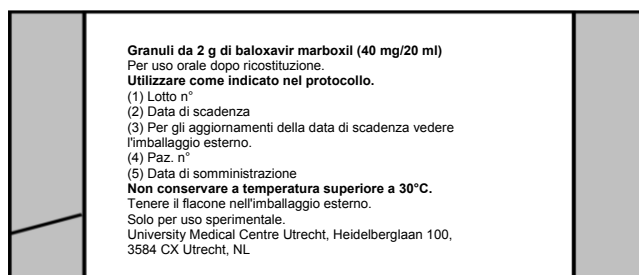
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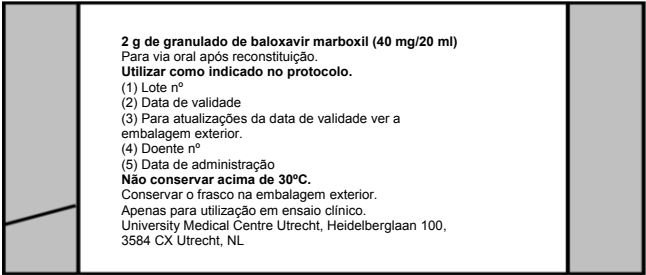
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	<p><b>2 g baloxavir marboxil granule (40 mg/20 ml)</b>  Pentru administrare orală după reconstituire.  <b>A se utiliza conform indicațiilor din protocol.</b>  (1) Lot Nr.  (2) Data expirării  (3) Pentru actualizări privind data de expirare, consultați ambalajul exterior.  (4) Pac.nr.  (5) Data administrării  <b>A nu se pastra la temperaturi peste 30°C.</b>  Păstrați flaconul în cutia de carton.  Numai pentru folosire în studiu clinic.  University Medical Centre Utrecht, Heidelberglaan 100,  3584 CX Utrecht, NL</p>	
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	<p><b>2 g granula baloksavir marboksila (40 mg/20 ml)</b>          Za oralnu upotrebu nakon rastvaranja.  <b>Upotrebiti prema uputstvu iz protokola.</b>          (1) Broj serije          (2) Važi do          (3) Za ažurirane podatke o roku upotrebe videti spoljni kontejner          (4) Pacijent br.          (5) Datum primene  <b>Ne čuvati na temperaturi iznad 30°C.</b>          Čuvati bocu u spoljnjem pakovanju.          Samo za primenu u kliničkoj studiji.          University Medical Centre Utrecht, Heidelberglaan 100,          3584 CX Utrecht, NL</p>	
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	<p><b>2 g granule marboksilbaloksavirat (40 mg/20 ml)</b>          Za peroralno uporabo po rekonstituciji.  <b>Uporabljajte v skladu s protokolom.</b>          (1) Serija          (2) Rok uporabnosti          (3) Za posodobitve roka uporabe glejte zunanjo ovojnino.          (4) Št. bolnika          (5) Datum aplikacije  <b>Shranjujte pri temperaturi do 30°C.</b>          Stekleničko shranjujte v zunanji obojnini.          Zdravilo je namenjeno kliničnemu preskušanju.          University Medical Centre Utrecht, Heidelberglaan 100,          3584 CX Utrecht, NL</p>	
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	<p><b>2 g gránulos baloxavir marboxil (40 mg/20 ml)</b>          Para uso oral tras reconstitución  <b>Usar según lo indicado en el protocolo.</b>          (1) N°. lote          (2) CAD          (3) Ver las actualizaciones de fecha de caducidad en el          embalaje exterior          (4) N° pac          (5) Fecha de administración  <b>No conservar a temperatura superior a 30°C.</b>          Conservar frasco en el embalaje exterior.          Muestra para investigación clínica.          University Medical Centre Utrecht, Heidelberglaan 100,          3584 CX Utrecht, NL</p>	
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 Print Name

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 Date

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 Signature



<b>General Info:</b>	<b>Final Country Booklet Label Approval</b>
	Molecule name: 2 g granules baloxavir marboxil (40 mg/20 ml)
<b>Masterlabel Dokument:</b>	RPT-0328950_v1.0
<b>Country Info:</b>	Country Specific Booklet Page for: English (AU, IN, MY, PK, ZA) Monash
<b>Label Info:</b>	Vial 2 g granules baloxavir marboxil (40 mg/20 ml) Final Label Size: 36x85 mm, 30x45 mm
<b>Created by:</b>	Clinical Label Management, F. Hoffmann-La Roche Ltd. global_clinical_artwork_mgmt.gips-gcam@roche.com
<b>Creation Date:</b>	October 1, 2024

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	<b>2 g granules baloxavir marboxil (40 mg/20 ml)</b> For oral use after reconstitution. <b>Use as directed in the protocol.</b> (1) Batch no. (2) Expiry date (3) For expiry date updates see outer container. (4) Pat.no. (5) Administration date <b>Do not store above 30°C.</b> Keep bottle in outer carton. For clinical trial use only. Monash University, Wellington Road, Clayton, Victoria 3800	
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<b>General Info:</b>	<b>Final Country Booklet Label Approval</b>
	Molecule name: 2 g granules baloxavir marboxil (40 mg/20 ml)
<b>Masterlabel Dokument:</b>	RPT-0328950_v1.0
<b>Country Info:</b>	Country Specific Booklet Page for: English (NP) Monash
<b>Label Info:</b>	Vial 2 g granules baloxavir marboxil (40 mg/20 ml) Final Label Size: 36x85 mm, 30x45 mm
<b>Created by:</b>	Clinical Label Management, F. Hoffmann-La Roche Ltd. global_clinical_artwork_mgmt.gips-gcam@roche.com
<b>Creation Date:</b>	October 1, 2024

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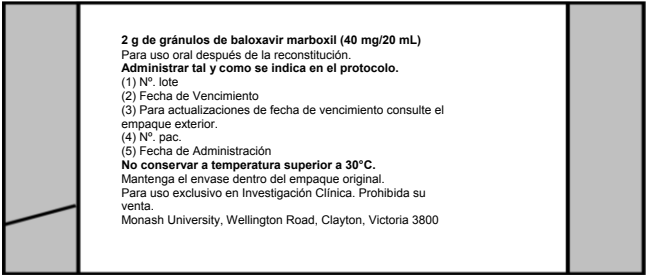
Date

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Signature

General Info:	Final Country Booklet Label Approval
	Molecule name: 2 g granules baloxavir marboxil (40 mg/20 ml)
Masterlabel Dokument:	RPT-0328950_v1.0
Country Info:	Country Specific Booklet Page for: Spanish LATAM (CO) Monash
Label Info:	Vial 2 g granules baloxavir marboxil (40 mg/20 ml) Final Label Size: 36x85 mm, 30x45 mm
Created by:	Clinical Label Management, F. Hoffmann-La Roche Ltd. global_clinical_artwork_mgmt.gips-gcam@roche.com
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	Molecule name: 2 g granules baloxavir marboxil (40 mg/20 ml)
<b>Masterlabel Dokument:</b>	RPT-0328950_v1.0
<b>Country Info:</b>	Country Specific Booklet Page for: English (NZ) Wellington Hospital
<b>Label Info:</b>	Vial 2 g granules baloxavir marboxil (40 mg/20 ml) Final Label Size: 36x85 mm, 30x45 mm
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<b>Creation Date:</b>	October 1, 2024

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<input type="checkbox"/> To be corrected <input type="checkbox"/> Approved	<div style="border-bottom: 1px solid black; width: 100%;"></div> Print Name
<div style="border-bottom: 1px solid black; width: 100%;"></div> Date	<div style="border-bottom: 1px solid black; width: 100%;"></div> Signature

<b>General Info:</b>	<b>Final Country Booklet Label Approval</b>
	Molecule name: 2 g granules baloxavir marboxil (40 mg/20 ml)
<b>Masterlabel Dokument:</b>	RPT-0328950_v1.0
<b>Country Info:</b>	Country Specific Booklet Page for: English (CA) Unity Health Toronto
<b>Label Info:</b>	Vial 2 g granules baloxavir marboxil (40 mg/20 ml) Final Label Size: 36x85 mm, 30x45 mm
<b>Created by:</b>	Clinical Label Management, F. Hoffmann-La Roche Ltd. global_clinical_artwork_mgmt.gips-gcam@roche.com
<b>Creation Date:</b>	October 1, 2024

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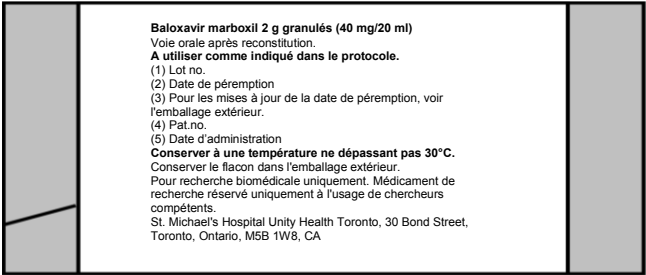
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General Info:	Final Country Booklet Label Approval
	Molecule name: 2 g granules baloxavir marboxil (40 mg/20 ml)
Masterlabel Dokument:	RPT-0328950_v1.0
Country Info:	Country Specific Booklet Page for: French (CA) Unity Health Toronto
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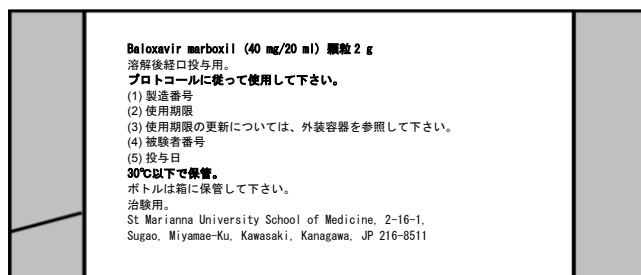
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<b>General Info:</b>	<b>Final Country Booklet Label Approval</b>
	Molecule name: 2 g granules baloxavir marboxil (40 mg/20 ml)
<b>Masterlabel Dokument:</b>	RPT-0328950_v1. 0
<b>Country Info:</b>	Country Specific Booklet Page for: Japanese (JP) St Marianna University
<b>Label Info:</b>	Vial 2 g granules baloxavir marboxil (40 mg/20 ml) Final Label Size: 36x85 mm, 30x45 mm
<b>Created by:</b>	Clinical Label Management, F. Hoffmann-La Roche Ltd. global_clinical_artwork_mgmt.gips-gcam@roche.com
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	Molecule name: 2 g granules baloxavir marboxil (40 mg/20 ml)
<b>Masterlabel Dokument:</b>	RPT-0328950_v1.0
<b>Country Info:</b>	Country Specific Booklet Page for: English (SG) National University Hospital
<b>Label Info:</b>	Vial 2 g granules baloxavir marboxil (40 mg/20 ml) Final Label Size: 36x85 mm, 30x45 mm
<b>Created by:</b>	Clinical Label Management, F. Hoffmann-La Roche Ltd. global_clinical_artwork_mgmt.gips-gcam@roche.com
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