

General Info:	Final Booklet Index Page
	Study: 2 g granules baloxavir marboxil (40 mg/20 ml)
Master Label Document:	RPT-0328950_v1.0
Label Info:	Box: 1 bottle of 2 g granules baloxavir marboxil (40 mg/20 ml)
	Final Label Size: 45x75 mm / Text Area: 39x42 mm
Material ID:	39030769
Created by:	Global Clinical Artwork Management
	E-mail: global_clinical_artwork_mgmt.gips-gcam@roche.com
Creation Date:	October 1, 2024

Following section is relevant for approval

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Masterlabel Dokument:	RPT-0328950_v1.0
Country Info:	Country Specific Booklet Page for: English (GB, IE, IL) University Medical Centre Utrecht
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Created by:	Clinical Label Management, F. Hoffmann-La Roche Ltd. email: kaiseraugst.gips-labelmgmt@roche.com
Creation Date:	October 1, 2024

Following section is relevant for approval

	<p>1 bottle of 2 g granules baloxavir marboxil (40 mg/20 ml) For oral use after reconstitution. Use as directed in the protocol. (1) Batch no. (2) Expiry date (3) Pat.no. (4) Investigator (5) Administration date (6) Reconstitution date / time Do not store above 30°C. After reconstitution with 20 ml water store below 25°C for up to 2 hours. Gently swirl the bottle for approximately 1 minute. Do not shake the bottle, as doing so would create foam. Keep the bottle tightly closed in order to protect from moisture. Keep bottle in outer carton. For clinical trial use only. University Medical Centre Utrecht, Heidelberglaan 100, 3584 CX Utrecht, NL</p>	
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Country Info:	Country Specific Booklet Page for: Croatian (HR) University Medical Centre Utrecht
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Created by:	Clinical Label Management, F. Hoffmann-La Roche Ltd. email: kaiseraugst.gips-labelmgmt@roche.com
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	<p>1 bočica s 2 g granula baloksavimarboxila (40 mg/20 ml) Za primjenu kroz usta nakon rekonstitucije. Primijeniti sukladno planu ispitivanja. (1) Broj serije (2) Rok valjanosti (3) Br.bolesnika (4) Ispitivač (5) Datum primjene (6) Datum / vrijeme rekonstitucije Ne čuvati na temperaturi iznad 30°C. Nakon rekonstitucije s 20 ml vode čuvati na temperaturi ispod 25°C najdulje 2 sata. Nježno vrtite bočicu otprilike 1 minutu. Nemojte tresti bočicu jer bi se time stvorila pjena. Bočicu čuvajte čvrsto zatvorenom radi zaštite od vlage. 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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Created by:	Clinical Label Management, F. Hoffmann-La Roche Ltd. email: kaiseraugst.gips-labelmgmt@roche.com
Creation Date:	October 1, 2024

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	<p>1 lahvička se 2 g granulí baloxavir marboxil (40 mg/20 ml) Pro perorální podání po rekonstituci. Užívejte dle protokolu. (1) Č.sarže (2) Datum expirace (3) Pac. č. (4) Zkoušející lékař (5) Datum podání (6) Datum / čas rekonstituce Uchovávejte při teplotě do 30°C. Po rekonstituci s 20 ml vody uchovávejte do 25°C po dobu maximálně 2 hodin. Jemně kružíte lahvičkou přibližně 1 minutu. Lahvičkou netřepíte, aby se nevytvořila pěna. Uchovávejte lahvičku těsně uzavřenou, aby byl přípravek chráněn před vlhkostí. 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>1 fles met 2 g granulaat baloxavir marboxil (40 mg/20 ml)</p> <p>Voor oraal gebruik na reconstitutie.</p> <p>Gebruik volgens instructie in het protocol.</p> <p>(1) Chargenr. (2) Vervaldatum</p> <p>(3) Pat.nr. (4) Onderzoeker</p> <p>(5) Toedieningsdatum</p> <p>(6) Datum / tijd reconstitutie</p> <p>Bewaren beneden 30°C.</p> <p>Na reconstitutie met 20 ml water tot 2 uren te bewaren beneden 25°C. Draai de fles zachtjes gedurende ongeveer 1 minuut. Schud de fles niet, omdat dit schuim creëert. Houd de fles goed gesloten ter bescherming tegen vocht. Houd de fles in de buitenverpakking.</p> <p>Uitsluitend voor gebruik in klinische studie.</p> <p>University Medical Centre Utrecht, Heidelberglaan 100, 3584 CX Utrecht, NL</p>	
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	<p>1 pudel, mis sisaldab 2 g baloksaviirmarboxiili graanuleid (40 mg/20 ml) Suukaudne pärast manustamiskõlblikuks muutmist. Kasutage vastavalt protokollile. (1) Partii number (2) Kõlblikkusaeg (3) Pt. nr. (4) Uurija (5) Manustamise kuupäev (6) Lahustamise kuupäev / aeg Hoida temperatuuril kuni 30°C. Pärast lahustamist 20 ml veega säilitage temperatuuril alla 25 °C kuni 2 tundi. Keerutage pudelit õrnalt ligikaudu 1 minuti jooksul. Ärge raputage pudelit, sest raputamisel tekib vaht. Hoida pudel tihedalt suletuna, niiskuse eest kaitstult. Hoida pudel välispaendis. Ainult kliinilises uuringus kasutamiseks. University Medical Centre Utrecht, Heidelberglaan 100, 3584 CX Utrecht, NL</p>	
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Label Info:	Box with 1 bottle of 2 g granules baloxavir marboxil (40 mg/20 ml) Final Label Size: 45x75 mm, 39x42 mm
Created by:	Clinical Label Management, F. Hoffmann-La Roche Ltd. email: kaiseraugst.gips-labelmgmt@roche.com
Creation Date:	October 1, 2024

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	<p>1 pullo jossa baloksaviirimarboxiili rakeet 2 g (40 mg/20 ml) Suun kautta käyttövalmiiksi saattamisen jälkeen. Käytä tutkimussuunnitelman mukaisesti. (1) Eränro (2) Käyt.viim./Utg.dat. (3) Pot.nro (4) Tutkija (5) Käyttöpäivä (6) Käyttövalmistuspäivä /-aika Säilytä alle 30°C. Veden lisäyksen (20 ml) jälkeen säilytä alle 25°C enintään 2 tunnin ajan. Kääntele pulloa varovasti pyöritellen noin 1 minuutin ajan. Älä ravista pulloa koska siihen voi muodostua vaahtoa. Pidä pullo tiiviisti suljettuna. Herkkä kosteudelle. Pidä pullo ulkopakkauksessa. Kliniseen tutkimukseen. För klinisk prövning. University Medical Centre Utrecht, Heidelberglaan 100, 3584 CX Utrecht, NL</p>	
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Label Info:	Box with 1 bottle of 2 g granules baloxavir marboxil (40 mg/20 ml) Final Label Size: 45x75 mm, 39x42 mm
Created by:	Clinical Label Management, F. Hoffmann-La Roche Ltd. email: kaiseraugst.gips-labelmgmt@roche.com
Creation Date:	October 1, 2024

Following section is relevant for approval

	<p>1 flacon de baloxavir marboxil 2 g granulés (40 mg/20 ml) Voie orale après reconstitution. A utiliser comme indiqué dans le protocole. (1) Lot no. (2) Date de péremption (3) Pat.no. (4) Investigateur (5) Date d'administration (6) Date / Heure de reconstitution Conserver à une température ne dépassant pas 30°C. Après reconstitution avec 20 ml d'eau, conserver à une température ne dépassant pas 25°C pendant 2 heures maximum. Remuer doucement le flacon pendant environ 1 minute. Ne pas secouer le flacon, car cela entraînerait la formation de mousse. Conserver le flacon bien fermé à l'abri de l'humidité. 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. Gemäß Protokoll anwenden. (1) Ch.-B. (2) Verwendbar bis (3) Pat.-Nr. (4) Prüfarzt (5) Verabreichungsdatum (6) Datum / Zeit der Rekonstitution Nicht über 30°C lagern. Nach der Rekonstitution mit 20 ml Wasser bis zu 2 Stunden unter 25°C lagern. Die Flasche für ungefähr 1 Minute behutsam hin- und herbewegen. Die Flasche nicht schütteln, um Schaumbildung zu vermeiden. Die Flasche fest verschlossen halten, um den Inhalt vor Feuchtigkeit zu schützen. Die Flasche im Umkarton aufbewahren. Zur klinischen Prüfung bestimmt. University Medical Centre Utrecht, Heidelberglaan 100, 3584 CX Utrecht, NL</p>	
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	<p>1 flacone di granuli da 2 g di baloxavir marboxil (40 mg/20 ml) Per uso orale dopo ricostituzione. Utilizzare come indicato nel protocollo. (1) Lotto n° (2) Data di scadenza (3) Paz. n° (4) Sperimentatore (5) Data di somministrazione (6) Data / ora di ricostituzione Non conservare a temperatura superiore a 30°C. Dopo la ricostituzione con 20 ml di acqua conservare sotto i 25°C fino a 2 ore. Agitare delicatamente la bottiglia per circa 1 minuto. Non agitare la bottiglia, in quanto questo potrebbe creare schiuma. Tenere la bottiglia ben chiusa per proteggere dall'umidità. Tenere il flacone nell'imballaggio esterno. Solo per uso sperimentale. University Medical Centre Utrecht, Heidelberglaan 100, 3584 CX Utrecht, NL</p>	
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Created by:	Clinical Label Management, F. Hoffmann-La Roche Ltd. email: kaiseraugst.gips-labelmgmt@roche.com
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	<p>1 frasco de 2 g de granulado de baloxavir marboxil (40 mg/20 ml) Para via oral após reconstituição. Utilizar como indicado no protocolo. (1) Lote nº (2) Data de validade (3) Doente nº (4) Investigador (5) Data de administração (6) Data / hora da reconstituição Não conservar acima de 30°C. Após reconstituição, com 20 ml de água, conservar abaixo dos 25°C até 2 horas. Rode o frasco suavemente em círculo durante aproximadamente 1 minuto. Não agite o frasco, pois poderá criar espuma. Mantenha o frasco bem fechado para proteger da humidade. Conservar o frasco na embalagem exterior. Apenas para utilização em ensaio clínico. University Medical Centre Utrecht, Heidelberglaan 100, 3584 CX Utrecht, NL</p>	
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	<p>1 flacon cu 2 g baloxavir marboxil granule (40 mg/20 ml) Pentru administrare orală după reconstituire. A se utiliza conform indicațiilor din protocol. (1) Lot.Nr. (2) Data expirării (3) Pac.nr. (4) Investigator (5) Data administrării (6) Data / Ora reconstituirii A nu se păstra la temperaturi peste 30°C. După reconstituirea cu 20 ml apă, a se păstra la temperaturi sub 25°C timp de până la 2 ore. Rotiți ușor flaconul timp de aproximativ 1 minut. Nu agitați flaconul, deoarece acest lucru va crea spumă. A se păstra flaconul bine închis pentru a fi protejat de umiditate. 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>1 bočica sa 2 g granula baloksavir marboksila (40 mg/20 ml) Za oralnu upotrebu nakon rastvaranja. Upotrebiti prema uputstvu iz protokola. (1) Broj serije (2) Važi do (3) Pacijent br. (4) Istraživač (5) Datum primene (6) Datum / vreme rekonstitucije Ne čuvati na temperaturi iznad 30°C. Nakon rekonstitucije sa 20 ml vode čuvati na temperaturi ispod 25°C do 2 sati. Lagano okrećite bočicu oko 1 minut. Nemojte mućkati jer može doći do stvaranja pene. Čuvati bočicu čvrsto zatvorenu radi zaštite od vlage. Čuvati bocu u spoljnjem pakovanju. Samo za primenu u kliničkoj studiji. University Medical Centre Utrecht, Heidelberglaan 100, 3584 CX Utrecht, NL Proizvođač: Shionogi Pharma CO., LTD., Settsu, Osaka 566-0022, Japan</p>	
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	<p>1 steklenička 2 g granule marboksilbaloksavirat (40 mg/20 ml) Za peroralno uporabo po rekonstituciji. Uporabljajte v skladu s protokolom.</p> <table border="0"> <tr> <td>(1) Serija</td> <td>(2) Rok uporabnosti</td> </tr> <tr> <td>(3) Št. bolnika</td> <td>(4) Raziskovalec</td> </tr> <tr> <td colspan="2">(5) Datum aplikacije</td> </tr> <tr> <td colspan="2">(6) Datum / ura rekonstitucije</td> </tr> </table> <p>Shranjujte pri temperaturi do 30°C. Po rekonstituciji z 20 ml vode hranite do 25°C največ 2 uri. Previdno vrtite stekleničko približno 1 minuto. Stekleničke ne stresajte, saj bi to povzročilo peno. Stekleničko shranjujte tesno zaprto za zagotovitev zaščite pred vlago. Stekleničko shranjujte v zunanji ovojnini.</p> <p>Zdravilo je namenjeno kliničnemu preskušanju. University Medical Centre Utrecht, Heidelberglaan 100, 3584 CX Utrecht, NL</p>	(1) Serija	(2) Rok uporabnosti	(3) Št. bolnika	(4) Raziskovalec	(5) Datum aplikacije		(6) Datum / ura rekonstitucije		
(1) Serija	(2) Rok uporabnosti									
(3) Št. bolnika	(4) Raziskovalec									
(5) Datum aplikacije										
(6) Datum / ura rekonstitucije										

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- ☐ To be corrected
☐ Approved

Print Name

Date

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 (ES) University Medical Centre Utrecht
Label Info:	Box with 1 bottle of 2 g granules baloxavir marboxil (40 mg/20 ml) Final Label Size: 45x75 mm, 39x42 mm
Created by:	Clinical Label Management, F. Hoffmann-La Roche Ltd. email: kaiseraugst.gips-labelmgmt@roche.com
Creation Date:	October 1, 2024

Following section is relevant for approval

	<p>1 bote de 2 g gránulos baloxavir marboxil (40 mg/20 ml) Para uso oral tras reconstitución Usar según lo indicado en el protocolo. (1) N°. lote (2) CAD (3) N° pac (4) Investigador (5) Fecha de administración (6) Fecha / Hora reconstitución No conservar a temperatura superior a 30°C. Una vez reconstituido con 20 ml de agua, almacenar por debajo de 25°C hasta un tiempo máximo de 2 horas. Invertir y agitar suavemente el bote durante 1 minuto aproximadamente. No agitar fuertemente el bote, ya que esto crearía espuma. Mantener el bote bien cerrado para protegerlo de la humedad. 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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General Info:	Final Country Booklet Label Approval
Masterlabel Document:	Molecule name: 2 g granules baloxavir marboxil (40 mg/20 ml) RPT-0328950_v1.0
Country Info:	Country Specific Booklet Page for: English (AU, IN, MY, PK, ZA) Monash
Label Info:	Box with 1 bottle of 2 g granules baloxavir marboxil (40 mg/20 ml) Final Label Size: 45x75 mm, 39x42 mm
Created by:	Clinical Label Management, F. Hoffmann-La Roche Ltd. email: kaiseraugst.gips-labelmgmt@roche.com
Creation Date:	October 1, 2024

Following section is relevant for approval

	1 bottle of 2 g granules baloxavir marboxil (40 mg/20 ml) For oral use after reconstitution. Use as directed in the protocol. (1) Batch no. (2) Expiry date (3) Pat.no. (4) Investigator (5) Administration date (6) Reconstitution date / time Do not store above 30°C. After reconstitution with 20 ml water store below 25°C for up to 8 hours. Gently swirl the bottle for approximately 1 minute. Do not shake the bottle, as doing so would create foam. Keep bottle in outer carton. For clinical trial use only. Monash University, Wellington Road, Clayton, Victoria 3800	
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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: English (NP) Monash
Label Info:	Box with 1 bottle of 2 g granules baloxavir marboxil (40 mg/20 ml) Final Label Size: 45x75 mm, 39x42 mm
Created by:	Clinical Label Management, F. Hoffmann-La Roche Ltd. global_clinical_artwork_mgmt.gips-gcam@roche.com
Creation Date:	October 1, 2024

Following section is relevant for approval

	1 bottle of 2 g granules baloxavir marboxil (40 mg/20 ml) For oral use after reconstitution. Use as directed in the protocol. (1) Batch no. (2) Expiry date (3) Pat.no. (4) Investigator (5) Administration date (6) Reconstitution date / time Do not store above 30°C. After reconstitution with 20 ml water store below 25°C for up to 2 hours. Gently swirl the bottle for approximately 1 minute. Do not shake the bottle, as doing so would create foam. Keep the bottle tightly closed in order to protect from moisture. Keep bottle in outer carton. For clinical trial use only. Monash University, Wellington Road, Clayton, Victoria 3800 Manufacturer: Shionogi Pharma CO., LTD., Settsu, Osaka 566-0022, Japan	
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Date

Signature

General Info:	Final Country Booklet Label Approval
Masterlabel Document:	Molecule name: 2 g granules baloxavir marboxil (40 mg/20 ml) RPT-0328950_v1.0
Country Info:	Country Specific Booklet Page for: Spanish LATAM (CO) Monash
Label Info:	Box with 1 bottle of 2 g granules baloxavir marboxil (40 mg/20 ml) Final Label Size: 45x75 mm, 39x42 mm
Created by:	Clinical Label Management, F. Hoffmann-La Roche Ltd. email: kaiseraugst.gips-labelmgmt@roche.com
Creation Date:	October 1, 2024

Following section is relevant for approval

<p>1 envase de 2 g de gránulos de baloxavir marboxil (40 mg/20 mL) Para uso oral después de la reconstitución. Administrar tal y como se indica en el protocolo. (1) N°. lote (2) Fecha de Vencimiento (3) N°. pac. (4) Investigador (5) Fecha de Administración (6) Fecha / hora de reconstitución No conservar a temperatura superior a 30°C. Después de la reconstitución con 20 ml de agua, conservar por debajo de 25 °C durante un máximo de 8 horas. Mezcle suavemente por aproximadamente 1 minuto. No agite el envase, ya que esto genera espuma. Mantenga el envase dentro del empaque original. Mantener fuera del alcance de los niños. Para uso exclusivo en Investigación Clínica. Prohibida su venta. Monash University, Wellington Road, Clayton, Victoria 3800</p>

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 Date

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General Info:	Final Country Booklet Label Approval
Masterlabel Document:	Molecule name: 2 g granules baloxavir marboxil (40 mg/20 ml) RPT-0328950_v1.0
Country Info:	Country Specific Booklet Page for: English (NZ) Wellington Hospital
Label Info:	Box with 1 bottle of 2 g granules baloxavir marboxil (40 mg/20 ml) Final Label Size: 45x75 mm, 39x42 mm
Created by:	Clinical Label Management, F. Hoffmann-La Roche Ltd. email: kaiseraugst.gips-labelmgmt@roche.com
Creation Date:	October 1, 2024

Following section is relevant for approval

	<p>1 bottle of 2 g granules baloxavir marboxil (40 mg/20 ml) For oral use after reconstitution. Use as directed in the protocol. (1) Batch no. (2) Expiry date (3) Pat.no. (4) Investigator (5) Administration date (6) Reconstitution date / time Do not store above 30°C. After reconstitution with 20 ml water store below 25°C for up to 8 hours. Gently swirl the bottle for approximately 1 minute. Do not shake the bottle, as doing so would create foam. Keep bottle in outer carton. For clinical trial use only. Investigational drug to be used by qualified investigators only. Medical Research Institute of New Zealand, Wellington Hospital, Riddiford St, Newtown, Wellington 6021, NZ</p>	
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☐ Approved

 Print Name

 Date

 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: English (CA) Unity Health Toronto
Label Info:	Box with 1 bottle of 2 g granules baloxavir marboxil (40 mg/20 ml) Final Label Size: 45x75 mm, 39x42 mm
Created by:	Clinical Label Management, F. Hoffmann-La Roche Ltd. email: kaiseraugst.gips-labelmgmt@roche.com
Creation Date:	October 1, 2024

Following section is relevant for approval

	<p>1 bottle of 2 g granules baloxavir marboxil (40 mg/20 ml) For oral use after reconstitution. Use as directed in the protocol. (1) Batch no. (2) Expiry date (3) Pat.no. (4) Investigator (5) Administration date (6) Reconstitution date / time Do not store above 30°C. After reconstitution with 20 ml water store below 25°C/77°F for up to 2 hours. Gently swirl the bottle for approximately 1 minute. Do not shake the bottle, as doing so would create foam. Keep the bottle tightly closed in order to protect from moisture. Keep bottle in outer carton. For clinical trial use only. Investigational drug to be used by qualified investigators only. St. Michael's Hospital Unity Health Toronto, 30 Bond Street, Toronto, Ontario, M5B 1W8, CA</p>	
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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
Label Info:	Box with 1 bottle of 2 g granules baloxavir marboxil (40 mg/20 ml) Final Label Size: 45x75 mm, 39x42 mm
Created by:	Clinical Label Management, F. Hoffmann-La Roche Ltd. email: kaiseraugst.gips-labelmgmt@roche.com
Creation Date:	October 1, 2024

Following section is relevant for approval

	<p>1 flacon de baloxavir marboxil 2 g granulés (40 mg/20 ml) Voie orale après reconstitution. A utiliser comme indiqué dans le protocole. (1) Lot no. (2) Date de péremption (3) Pat.no. (4) Investigateur (5) Date d'administration (6) Date / Heure de reconstitution Conserver à une température ne dépassant pas 30°C. Après reconstitution avec 20 ml d'eau, conserver à une température ne dépassant pas 25°C pendant 2 heures maximum. Remuer doucement le flacon pendant environ 1 minute. Ne pas secouer le flacon, car cela entraînerait la formation de mousse. Conserver le flacon bien fermé à l'abri de l'humidité. Conserver le flacon dans l'emballage extérieur. Pour recherche biomédicale uniquement. Médicament de recherche réservé uniquement à l'usage de chercheurs compétents. St. Michael's Hospital Unity Health Toronto, 30 Bond Street, Toronto, Ontario, M5B 1W8, CA</p>	
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Print Name

Date

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: Japanese (JP) St Marianna University
Label Info:	Box with 1 bottle of 2 g granules baloxavir marboxil (40 mg/20 ml) Final Label Size: 45x75 mm, 39x42 mm
Created by:	Clinical Label Management, F. Hoffmann-La Roche Ltd. global_clinical_artwork_mgmt.gips-gcam@roche.com
Creation Date:	October 1, 2024

Following section is relevant for approval

	Baloxavir marboxil (40 mg/20 ml) 顆粒 2 g 入り 1 ボトル 溶解後経口投与用。 プロトコルに従って使用して下さい。 (1) 製造番号 (2) 使用期限 (3) 被験者番号 (4) 治験責任・分担医師 (5) 投与日 (6) 溶解日 / 溶解時刻 30℃以下で保管。 20ml の水で溶解後、25℃以下で保管(最大2時間)。 ボトルを約1分間静かに回転させて下さい。泡が 発生するため、ボトルを振らないで下さい。湿気を防 ぐため、ボトルをしっかり閉めて保管して下さい。 ボトルは箱に保管して下さい。治験用。 St Marianna University School of Medicine, 2- 16-1, Sugao, Miyamae-Ku, Kawasaki, Kanagawa, JP 216-8511	
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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: English (SG) National University Hospital
Label Info:	Box with 1 bottle of 2 g granules baloxavir marboxil (40 mg/20 ml) Final Label Size: 45x75 mm, 39x42 mm
Created by:	Clinical Label Management, F. Hoffmann-La Roche Ltd. global_clinical_artwork_mgmt.gips-gcam@roche.com
Creation Date:	October 1, 2024

Following section is relevant for approval

	<p>1 bottle of 2 g granules baloxavir marboxil (40 mg/20 ml) For oral use after reconstitution. Use as directed in the protocol.</p> <p>(1) Batch no. (2) Expiry date (3) Pat.no. (4) Investigator (5) Administration date (6) Reconstitution date / time</p> <p>Do not store above 30°C. After reconstitution with 20 ml water store below 25°C for up to 2 hours. Gently swirl the bottle for approximately 1 minute. Do not shake the bottle, as doing so would create foam. Keep the bottle tightly closed in order to protect from moisture. Keep bottle in outer carton. For clinical trial use only. National University Hospital (SG) Pte Ltd, 1E Kent Ridge Road, #13-00, SG 119228</p>	
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