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Status: Approved

Roche

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Title: MV43976\_TOCI\_200MG\_10ML\_BX\_39029772

Final Booklet Index Page

General Info:

Study: Tocilizumab 200 mg/10 ml

Master Label Document:

TEC-0220137\_v1.0

Label Info:

Box: 1 vial tocilizumab 200 mg/10 ml

Final Label Size: 45x75 mm / Text Area: 39x42 mm

Material ID:

39029772

Created by:

Global Clinical Artwork Management

E-mail: global\_clinical\_artwork\_mgmt.gips-gcam@roche.com

Creation Date:

March 8, 2024

Following section is relevant for approval

Country	Page
University Medical Centre Utrecht	
English (GB, IE, IL)	4
Croatian (HR)	5
Czech (CZ)	6
Dutch (BE, NL)	7
Estonian (EE)	8
Finnish (FI)	9
French (BE, CH, FR)	10
German (BE, CH, DE)	11
Italian (CH, IT)	12
Portuguese (PT)	13
Romanian (RO)	14
Serbian (RS)	15
Slovenian (SI)	16
Spanish (ES)	17

Final Booklet Index Page

General Info:	Study: Tocilizumab 200 mg/10 ml
Master Label Document:	TEC-0220137_v1.0
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	Final Label Size: 45x75 mm / Text Area: 39x42 mm
Material ID:	39029772
Created by:	Global Clinical Artwork Management E-mail: global_clinical_artwork_mgmt.gips-gcam@roche.com
Creation Date:	March 8, 2024

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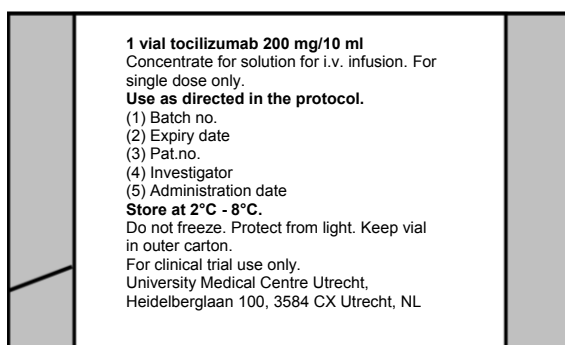
Country	Page
Monash University	
English (AU, IN, MY, PK, SA, ZA)	18
English (NP)	19
Arabic (SA)	20
Spanish LATAM (CO)	21
Medical Research Institute of New Zealand	
English (NZ)	22
Unity Health Toronto	
English (CA)	23
French (CA)	24
St Marianna University School of Medicine	
Japanese (JP)	25
National University Hospital (SG) Pte Ltd	
English (SG)	26

General Info:

Final Country Booklet Label Approval

Molecule name: Tocilizumab 200 mg/10 ml	
Masterlabel Document:	TEC-0220137_v1.0
Country Info:	Country Specific Booklet Page for: English (GB, IE, IL) University Medical Centre Utrecht
Label Info:	Box with 1 vial tocilizumab 200 mg/10 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:	March 8, 2024

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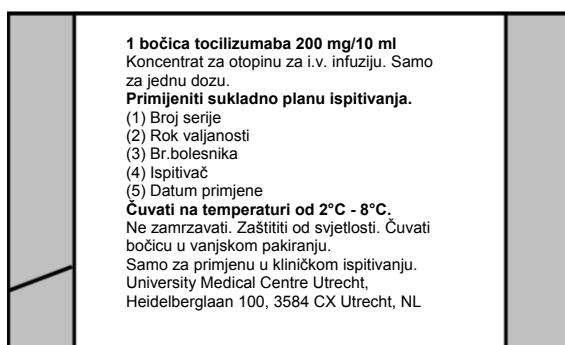
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General Info:

Final Country Booklet Label Approval

Molecule name: Tocilizumab 200 mg/10 ml	
Masterlabel Document:	TEC-0220137_v1.0
Country Info:	Country Specific Booklet Page for: Croatian (HR) University Medical Centre Utrecht
Label Info:	Box with 1 vial tocilizumab 200 mg/10 ml Final Label Size: 45x75 mm, 39x42 mm
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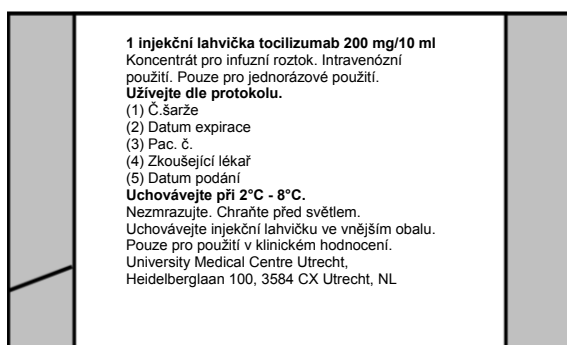
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General Info:

Final Country Booklet Label Approval

Molecule name: Tocilizumab 200 mg/10 ml	
Masterlabel Document:	TEC-0220137_v1.0
Country Info:	Country Specific Booklet Page for: Czech (CZ) University Medical Centre Utrecht
Label Info:	Box with 1 vial tocilizumab 200 mg/10 ml Final Label Size: 45x75 mm, 39x42 mm
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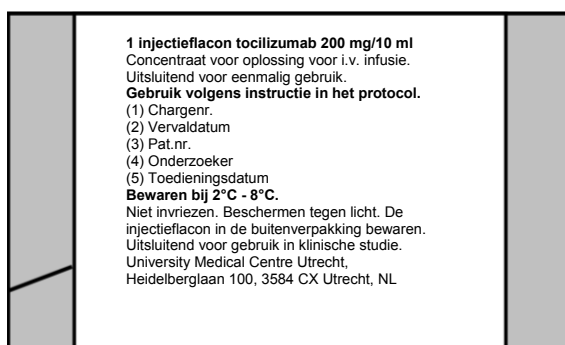
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Final Country Booklet Label Approval

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Masterlabel Document:	TEC-0220137_v1.0
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Label Info:	Box with 1 vial tocilizumab 200 mg/10 ml Final Label Size: 45x75 mm, 39x42 mm
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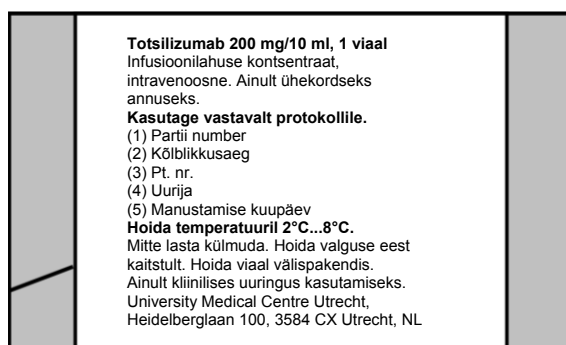
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## General Info:

## Final Country Booklet Label Approval

Molecule name: Tocilizumab 200 mg/10 ml	
Masterlabel Document:	TEC-0220137_v1.0
Country Info:	Country Specific Booklet Page for: Estonian (EE) University Medical Centre Utrecht
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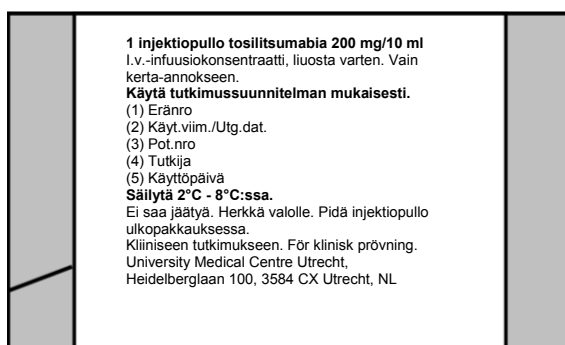
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General Info:

Final Country Booklet Label Approval

Molecule name: Tocilizumab 200 mg/10 ml	
Masterlabel Document:	TEC-0220137_v1.0
Country Info:	Country Specific Booklet Page for: Finnish (FI) University Medical Centre Utrecht
Label Info:	Box with 1 vial tocilizumab 200 mg/10 ml Final Label Size: 45x75 mm, 39x42 mm
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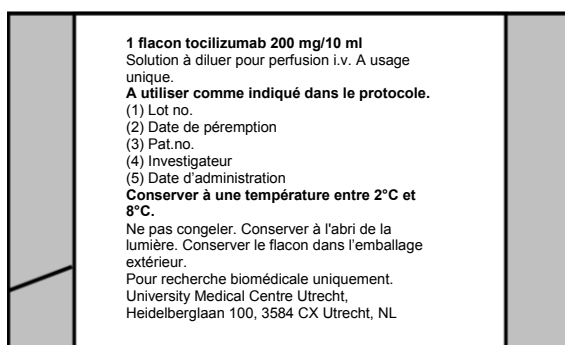


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Final Country Booklet Label Approval

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Country Info:	Country Specific Booklet Page for: French (BE, CH, FR) University Medical Centre Utrecht
Label Info:	Box with 1 vial tocilizumab 200 mg/10 ml Final Label Size: 45x75 mm, 39x42 mm
Created by:	Clinical Label Management, F. Hoffmann-La Roche Ltd. email: kaiseraugst.gips-labelmgmt@roche.com
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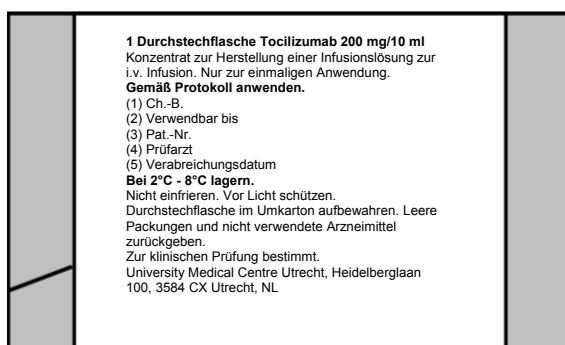
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Final Country Booklet Label Approval

Molecule name: Tocilizumab 200 mg/10 ml	
Masterlabel Document:	TEC-0220137_v1.0
Country Info:	Country Specific Booklet Page for: German (BE, CH, DE) University Medical Centre Utrecht
Label Info:	Box with 1 vial tocilizumab 200 mg/10 ml Final Label Size: 45x75 mm, 39x42 mm
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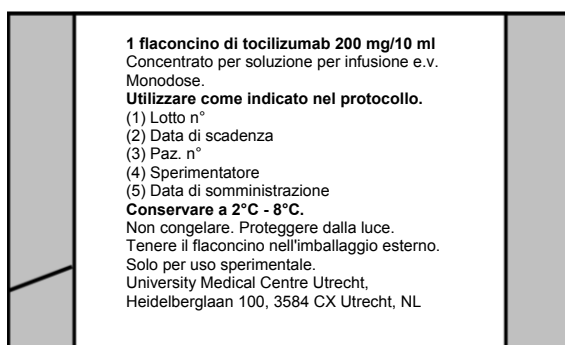
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**General Info:**

**Final Country Booklet Label Approval**

<b>Molecule name: Tocilizumab 200 mg/10 ml</b>	
<b>Masterlabel Document:</b>	<b>TEC-0220137_v1.0</b>
<b>Country Info:</b>	<b>Country Specific Booklet Page for: Italian (CH, IT) University Medical Centre Utrecht</b>
<b>Label Info:</b>	<b>Box with 1 vial tocilizumab 200 mg/10 ml</b> Final Label Size: 45x75 mm, 39x42 mm
<b>Created by:</b>	<b>Clinical Label Management, F. Hoffmann-La Roche Ltd.</b> email: kaiseraugst.gips-labelmgmt@roche.com
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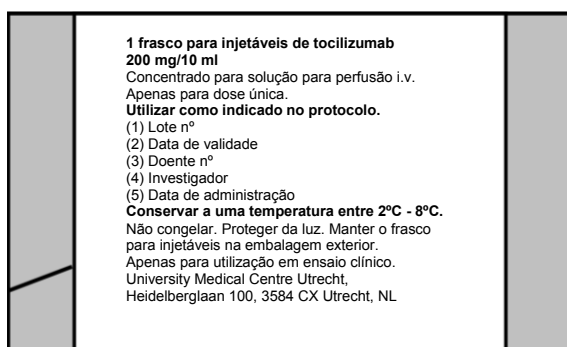
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General Info:

Final Country Booklet Label Approval

Molecule name: Tocilizumab 200 mg/10 ml	
Masterlabel Document:	TEC-0220137_v1.0
Country Info:	Country Specific Booklet Page for: Portuguese (PT) University Medical Centre Utrecht
Label Info:	Box with 1 vial tocilizumab 200 mg/10 ml Final Label Size: 45x75 mm, 39x42 mm
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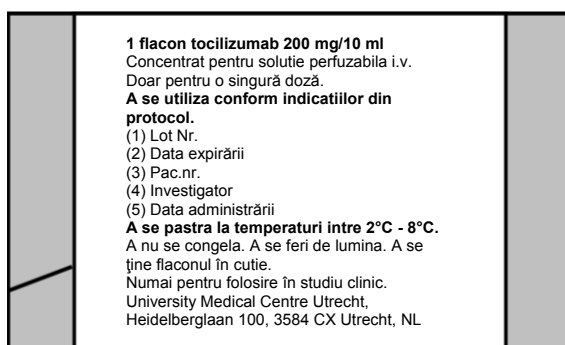
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**General Info:**

**Final Country Booklet Label Approval**

<b>Molecule name:</b> Tocilizumab 200 mg/10 ml	
<b>Masterlabel Document:</b>	<b>TEC-0220137_v1.0</b>
<b>Country Info:</b>	<b>Country Specific Booklet Page for: Romanian (RO) University Medical Centre Utrecht</b>
<b>Label Info:</b>	<b>Box with 1 vial tocilizumab 200 mg/10 ml</b> Final Label Size: 45x75 mm, 39x42 mm
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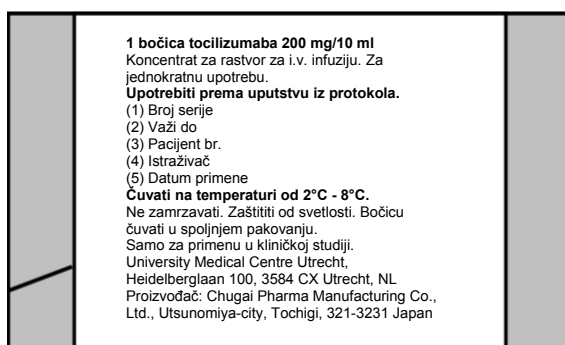
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Final Country Booklet Label Approval

Molecule name: Tocilizumab 200 mg/10 ml	
Masterlabel Document:	TEC-0220137_v1.0
Country Info:	Country Specific Booklet Page for: Serbian (RS) University Medical Centre Utrecht
Label Info:	Box with 1 vial tocilizumab 200 mg/10 ml Final Label Size: 45x75 mm, 39x42 mm
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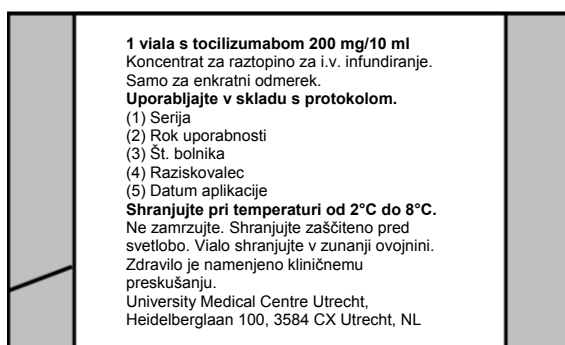
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<b>Molecule name: Tocilizumab 200 mg/10 ml</b>	
<b>Masterlabel Document:</b>	<b>TEC-0220137_v1.0</b>
<b>Country Info:</b>	<b>Country Specific Booklet Page for: Slovenian (SI) University Medical Centre Utrecht</b>
<b>Label Info:</b>	<b>Box with 1 vial tocilizumab 200 mg/10 ml</b> Final Label Size: 45x75 mm, 39x42 mm
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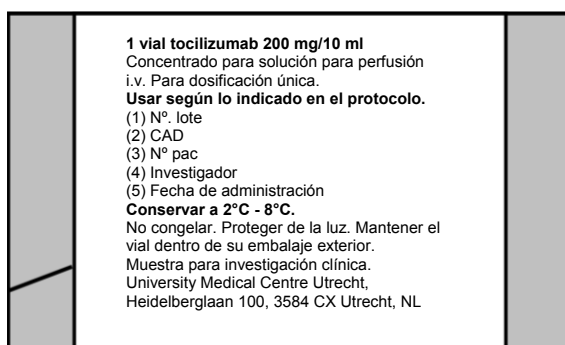
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General Info:

Final Country Booklet Label Approval

Molecule name: Tocilizumab 200 mg/10 ml	
Masterlabel Document:	TEC-0220137_v1.0
Country Info:	Country Specific Booklet Page for: Spanish (ES) University Medical Centre Utrecht
Label Info:	Box with 1 vial tocilizumab 200 mg/10 ml Final Label Size: 45x75 mm, 39x42 mm
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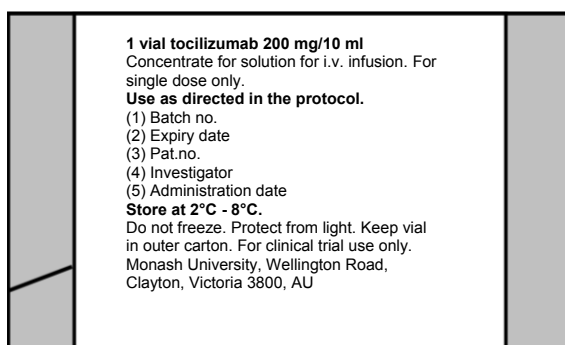


General Info:

Final Country Booklet Label Approval

Molecule name: Tocilizumab 200 mg/10 ml	
Masterlabel Document:	TEC-0220137_v1.0
Country Info:	Country Specific Booklet Page for: English (AU, IN, MY, PK, SA, ZA) Monash
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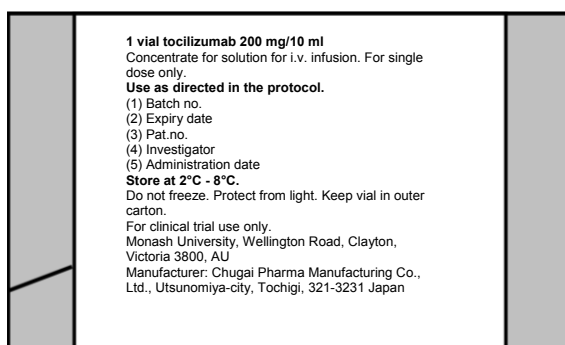
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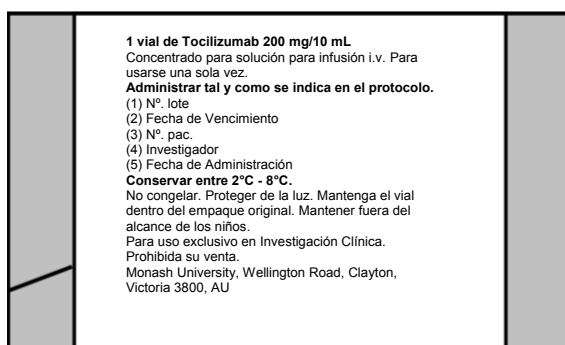
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Molecule name: Tocilizumab 200 mg/10 ml	
Masterlabel Document:	TEC-0220137_v1.0
Country Info:	Country Specific Booklet Page for: Spanish LATAM (CO) Monash
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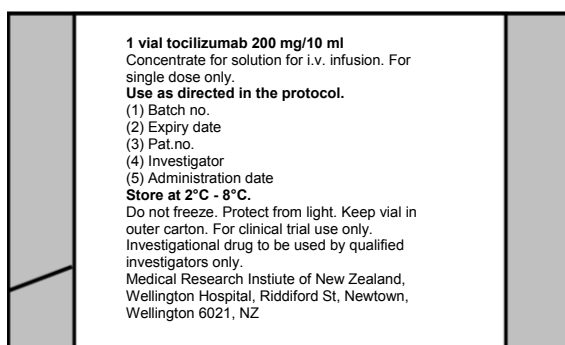
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<b>Masterlabel Document:</b>	<b>TEC-0220137_v1.0</b>
<b>Country Info:</b>	<b>Country Specific Booklet Page for: English (NZ) Wellington Hospital</b>
<b>Label Info:</b>	<b>Box with 1 vial tocilizumab 200 mg/10 ml</b> Final Label Size: 45x75 mm, 39x42 mm
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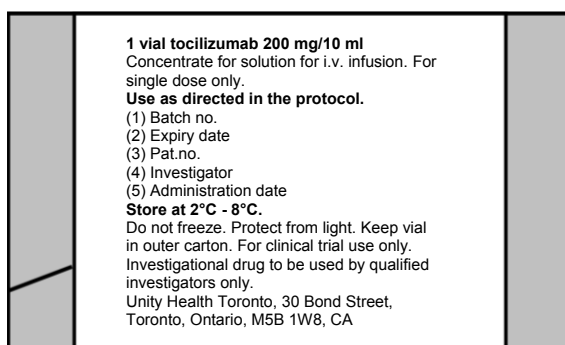
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Masterlabel Document:	TEC-0220137_v1.0
Country Info:	Country Specific Booklet Page for: English (CA) Unity Health Toronto
Label Info:	Box with 1 vial tocilizumab 200 mg/10 ml Final Label Size: 45x75 mm, 39x42 mm
Created by:	Clinical Label Management, F. Hoffmann-La Roche Ltd. email: kaiseraugst.gips-labelmgmt@roche.com
Creation Date:	March 8, 2024

Following section is relevant for approval



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To approve the labels, please print them out, sign each page, scan all and send them back as attachment to your Roche contact person by e mail.

- ☐ To be corrected  
☐ Approved

\_\_\_\_\_  
Print Name

\_\_\_\_\_  
Date

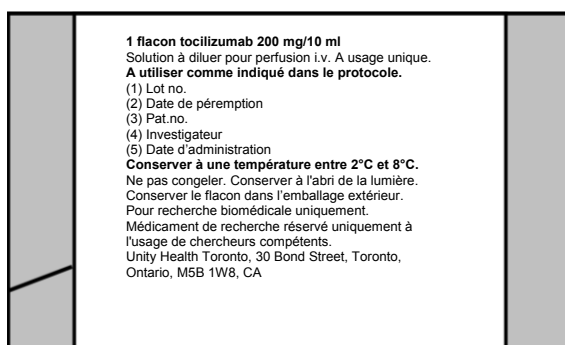
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Signature

## General Info:

## Final Country Booklet Label Approval

Molecule name: Tocilizumab 200 mg/10 ml	
Masterlabel Document:	TEC-0220137_v1.0
Country Info:	Country Specific Booklet Page for: French (CA) Unity Health Toronto
Label Info:	Box with 1 vial tocilizumab 200 mg/10 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:	March 8, 2024

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\_\_\_\_\_  
Print Name

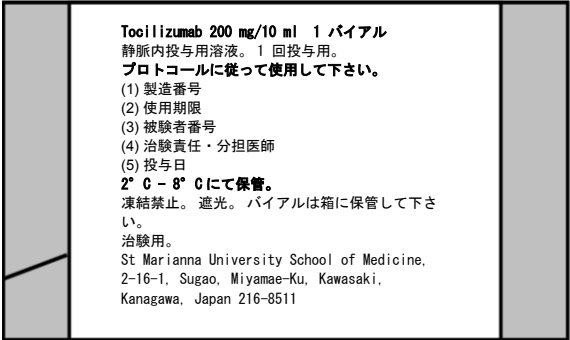
\_\_\_\_\_  
Date

\_\_\_\_\_  
Signature

General Info: Final Country Booklet Label Approval

Masterlabel Document:	Molecule name: Tocilizumab 200 mg/10 ml TEC-0220137_v1.0
Country Info:	Country Specific Booklet Page for: Japanese (JP) St Marianna University
Label Info:	Box with 1 vial tocilizumab 200 mg/10 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:	March 8, 2024

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- ☐ Approved

\_\_\_\_\_

Print Name

\_\_\_\_\_

Date

\_\_\_\_\_

Signature

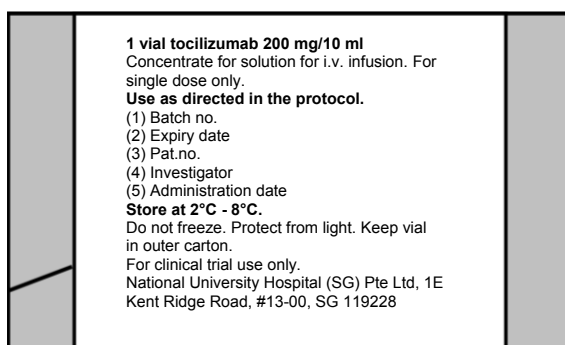


General Info:

Final Country Booklet Label Approval

Molecule name: Tocilizumab 200 mg/10 ml	
Masterlabel Document:	TEC-0220137_v1.0
Country Info:	Country Specific Booklet Page for: English (SG) National University Hospital
Label Info:	Box with 1 vial tocilizumab 200 mg/10 ml Final Label Size: 45x75 mm, 39x42 mm
Created by:	Clinical Label Management, F. Hoffmann-La Roche Ltd. email: kaiseraugst.gips-labelmgmt@roche.com
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