

Emergency: +47 91502770 / mail: solidact@ous-hf.no

Study medicine LOGISTICS:

- filmcoated 2mg tablets containing **baricitinib**
- filmcoated 2 mg tablets that are **placebo**

IMPERATIVE upon receipt:

- send **Acknowledgement of Receipt** to solidact@theradispharma.com **IMMEDIATELY** and within max. 24 hours
- send **temperature** readings to solidact@theradispharma.com as soon as possible and within max. 24 h
- **report** temperature excursions, damaged products, lost products to solidact@theradispharma.com and solidact@ous-hf.no as soon as possible and within max. 24 h
- in case of **emergency**: need for recall of product etc. call no. +47 91502770 **IMMEDIATELY** and ask for one of the persons in the sponsor team

Supply:

- ordering and resupply are automatic
- Theradis Pharma ships from Monday to Thursday
- Shipment takes 24 – 48 hours

SHIPMENT OF INVESTIGATIONAL MEDICINAL PRODUCTS (IMPs)

THERADIS PHARMA		Sponsor: OSLO UNIVERSITY HOSPITAL	TP Request ID: OSH001-09
		Study ID: EU-SolidAct	IRT ID: NA
		Int. Ref.: OSH001	Site ID: 001


Expeditor - Central Pharmacy		Recipient	
THERADIS PHARMA 41 chemin des Presses, 68890 Capoen-sur-Mer, FRANCE Tel: +33 (0)4 97 02 09 39		Investigator: Olav Dalgard	
Date of request: 09/Jun/2021		Shipping address: Hospital pharmacy Åkerhus Universitetssykehus Sykehospitalet Ahus, Nordbyggen Sykehovveien 25 1474 Larssenbyen Norway	
Date of shipment: 10/Jun/2021			
Transport conditions: Non strict ambient temperature			
TP Coordinator: Cristiane Duboc		Attention of: Pharmacist Larsen Erikand / Saffiric Nafesa	
TP Project Leader: Tu-Van PHAM		Tel: +47 403 07 879	

QTY	PRESENT DO	PRODUCT DESCRIPTION	BATCH NUMBER	EXPIRY DATE
10	X	Bottles of 36 tablets of Baricitinib 2mg or Placebo KW Numbers: 1081; 1082; 1083; 1084; 1085; 1086; 1087; 1088; 1089; 1090	P21031	31/Jun/2024
1	X	Batch certificate (VGB1)	P21031	NA
1	X	Instruction for checking the transport temperature + logger (tempmate)	Site IMP reception_tempmate_S1_VGB2	
Nb of parcels: Comments: Bottles are packed in 1 Cristal Zip Bag				

ACKNOWLEDGEMENT OF RECEIPT
To be completed by the QP at time of reception and sent by Email or by Fax to Theradis Pharma
Email: solidact@theradispharma.com - Fax N°: +33 (0)4 97 10 08 78

WARNING: Upon reception, immediately check the temperature logger and print the PDF report (temperature curve) and then send it to Theradis Pharma.

Date of reception: 11/6 JUN 2021 Nb of parcels received: 1/1
IMPs have been received in **GOOD** condition and the temperature has remained between +10°C/+30°C during the transport
→ IMPs are **ACCEPTABLE**
If not please tick the box: NOT ACCEPTABLE
Then put the IMPs immediately in quarantine, contact Theradis Pharma and comment below:
Comments:

 **Data Report** tempmate.®

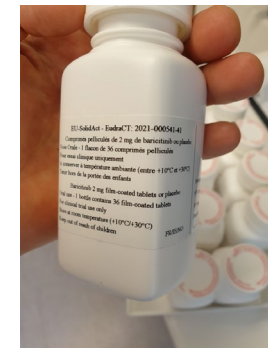
File Created Date: 14-Jun-21 07:10:55
Note: All times shown are based on UTC +02:00 and 24-Hour clock [DD-MMM-YY HH:MM:SS]

Device Information		Log Interval: 52M 10M 60S		Temperature Type: °C
Serial Number: 5121011468-33	Log Interval: 52M 10M 60S	Start Mode: Start by Button		
Model Number: S1C16A01000	Start Delay: 00D 00H 00M 00S			
Version: V2.2				

Trip Information	
Serial ID: 0003001	Description: Temperature recording.

Logging Summary	
Highest Temperature: 28.4°C	Record Mode: Stop when full
Lowest Temperature: 22.5°C	Stop Mode: Stop by Button
Average Temperature: 25.5°C	Data Points: 554
MBT: 22.0°C	Alarm At: N/A

Marked Events
NA



Storage:
10 to 30 °C



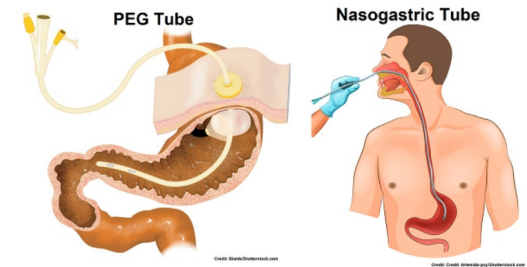
Study medicine CLINICAL:

- filmcoated **2mg tablets** containing **baricitinib**
- filmcoated **2 mg tablets** that are **placebo**

Daily dose = 4 mg orally with or without food

Administration	Dispersion	Rinse
Oral dispersion	10 mL	10 mL
Gastrostomy tube (G/PEG tube)	15 mL	15 mL
Nasogastric tube (NG tube)	30 mL	15 mL

- tablets may be crushed
- dispersed tablets are stable in water for up to 4 hours



Oral dispersion: disperse in 10 mL with gentle swirling and administer immediately, rinse container with additional 10 mL of room temperature water and administer.

G/PEG tube: disperse in 15 mL with gentle swirling, withdraw entire contents into syringe and administer immediately. Rinse container with additional 15 mL of room temperature water and administer.

NG tube: disperse in 30 mL with gentle swirling, withdraw entire contents into syringe and administer immediately. To avoid clogging of small diameter tubes (<12 Fr), the syringe can be held horizontally and shaken during administration. Rinse container with additional 15 mL of room temperature water and administer.