A) PRIMARY PACKAGING (FOIL/ SACHET)

***Remark 1**: For foil sachet that comes in secondary packaging (inner/outer box)/ loose packaging / procedure pack*
***Remark 2**: Due to space constraint of foil sachet packaging, all other information on warning and/or precaution shall be captured on the secondary packaging (outer/inner box) / IFU leaflet (for loose packaging/ procedure pack)*
***Remark 3**: Labelling shall be made available in the official languages accepted by the Member States in which the device is intended to be marketed. Refer QA-34, Appendix IV: MDR – Language Requirements for manufacturers.*

Front Foil/Sachet

Brand Name [logo] / Sub-brand Name
Water-based Lubricant
[Volume/ weight of lubricant *(in S.I Unit)***]**

Back Foil/Sachet

[*Brand*]® Lubricant is used as additional lubricant during intercourse for alleviation of vaginal dryness.

Do not re-use	OR	
Read the ingredients listed on the packaging carefully and consult instruction for use	OR	
Lubricant is a medical device	OR	MD

Ingredients: *Ingredient list shall be written according to lubricant variant formulation – refer to ingredient master list **IFU-02-IML***

"LOT" and/or LOT : *(LOT number format as per defined in T-WI-QA-02)*

"EXP" and/or : YYYY-MM or YYYY/MM

CE mark *(minimum height of 5mm with notified body's number)*

Any additional marking required by local regulations

B) PRIMARY PACKAGING (TUBE/ BOTTLE) / SECONDARY PACKAGING (INNER/OUTER BOX)

***Remark 1**: Instruction for use shall be made available in the official languages accepted by the Member States in which the device is intended to be marketed. Refer QA-34, Appendix IV: MDR – Language Requirements for manufacturers.*

Brand Name [logo] / Sub-brand Name
Water-based Lubricant
[Volume/ weight of lubricant (*in S.I Unit*)**]**

DOES NOT CONTAIN SPERMICIDE. NOT A CONTRACEPTIVE.

[*Brand*]® Lubricant is non-sterile, non-irritating, greaseless and water-soluble medical device to be used by lay persons – adult male or female. It is used as additional lubricant during intercourse for alleviation of vaginal dryness. It helps to reduce friction associated with thin and/or dry genital tissue, during sexual intercourse.

• Avoid contact with eyes and ears. • High glycol content may affect sperm motility. Avoid using this product if you are planning to conceive • This product is not a contraceptive and does not protect against pregnancy. • This product does not contain microbicides and does not protect against sexual transmitted infection and HIV. • Compatible with natural rubber latex and polyisoprene condoms. • Not compatible with polyurethane condoms.		
• Lubricant is a medical device	OR	
• Store in a cool, dry place away from direct sunlight.	OR	
• Do not use if package is torn or broken.	OR	
• Use within 6 months after opening *(for water-based lubricants in tube or bottle packaging only)*	OR	
• Do not re-use *(for lubricant in sachet packaging only)*	OR	
• Dispose empty packaging hygienically in a closed rubbish bin.	OR	

Direction/ Instruction for use: Squeeze/pump required amount of lubricant, typically about 2 to 5g per application, onto your clean fingers and/or apply directly onto vagina, penis or condom surface.

Ingredients: *Ingredient list shall be written according to lubricant variant formulation – refer to ingredient master list **IFU-02-IML***

Innolatex (Thailand) Limited
E1-6, Export Processing Zone,
Southern Industrial Estate,
Village 4, Chalung Sub-district,
Hatyai District,
Songkhla, 90110,
Thailand

CE mark
(minimum height of 5mm with notified body's number)

EU REP
Advena Limited
Tower Business Centre, 2nd Flr.,
Tower Street, Swatar, BKR 4013 Malta

 : **XXX company & address**

UDI
UDI or other format [Barcode]
(When AIDC carriers other than the UDI carrier are part of the product labelling, the UDI carrier shall be readily identifiable and UDI symbol may be used as appropriate. Otherwise, the use of UDI symbol shall not be obligatory)

REF
Manufacturer's catalogue number / product reference number
(*Refers to Annex II: Brand Listing of the Declaration of Conformity*)

"LOT" and/or LOT : *(LOT number format as per defined in T-WI-QA-02)*

"EXP" and/or  : YYYY-MM or YYYY/MM

C) IFU LEAFLET/ INTERIOR PART OF SECONDARY PACKAGING (*if applicable*)

***Remark 1**: Instruction for use shall be made available in the official languages accepted by the Member States in which the device is intended to be marketed. Refer QA-34, Appendix IV: MDR – Language Requirements for manufacturers.*

Brand Name [logo] / Sub-brand Name
Water-based Lubricant

DOES NOT CONTAIN SPERMICIDE. NOT A CONTRACEPTIVE.

[*Brand*]® Lubricant is non-sterile, non-irritating, greaseless and water-soluble medical device to be used by lay persons – adult male or female. It is used as additional lubricant during intercourse for alleviation of vaginal dryness. It helps to reduce friction associated with thin and/or dry genital tissue, during sexual intercourse.

Direction/ instruction for use: Squeeze/pump required amount of lubricant, typically about 2 to 5g per application, onto your clean fingers and/or apply directly onto vagina, penis or condom surface.

Ingredients: *Ingredient list shall be written according to lubricant variant formulation – refer to ingredient master list **IFU-02-IML***

Warnings
• Avoid contact with eyes and ears. • High glycol content may affect sperm motility. Avoid using this product if you are planning to conceive • This product is not for ingestion. Keep out of reach of children. In the event of accidental ingestion, seek medical assistance immediately. • Do not use during childbirth unless under medical supervision • Do not use on infected, broken, breached, or injured vaginal or vulvar tissue. Consult your doctor before using this product. • Do not use this product with other topical or systemic gynaecological medication. Product interactions are unknown, consult your healthcare provider before use.
Precautions
• This product is not a contraceptive and does not protect against pregnancy. • This product does not contain microbicides and does not protect against sexual transmitted infection and HIV. • Compatible with natural rubber latex and polyisoprene condoms. • Not compatible with polyurethane condoms. • Apply a small amount of lubricant on your inner thigh or forearm 24 hours before use. Check the area for any signs of irritation. • Use with caution during menstruation and menopause, discontinue if irritation and discomfort occurs. • If symptoms persist, immediately consult your doctor • Effects of lubricant on pregnant and/or nursing woman are unknown. Consult your doctor before use. • Use within 6 months after opening *(for lubricants in tube or bottle packaging only)* • Do not re-use *(for lubricants in sachet packaging only)* • User may reapply as needed to maintain lubrication during intercourse. • Excessive use of lubricant may cause discharge and discomfort. • Store in ambient temperature, dry place, away from direct sunlight • Dispose empty packaging hygienically in a closed rubbish bin • Report any serious incident that occurred from using the device to the manufacturer and the relevant national competent authority
Contraindications
• There is no known effect of this lubricant on pregnant and/or nursing woman, woman with vaginal trauma/surgery and/or vaginal infection. Consult doctor before using this product. • Not recommended for use in case of known allergies to any of the ingredients
Definition of Symbols *(All symbols used on product label conform to the harmonized standards, except below with their description)*

	Indicates that the product shall be used within 6 months after opening
	Indicates instruction to dispose empty packaging into rubbish bin

Innolatex (Thailand) Limited
E1-6, Export Processing Zone,
Southern Industrial Estate,
Village 4, Chalung Sub-district,
Hatyai District,
Songkhla, 90110,
Thailand

CE mark
(minimum height of 5mm with notified body's number)

Date of Issue : *The date of issue may align with the issuance date of the actual IFU in any acceptable format (i.e. May 2025). If the actual IFU has been revised, revision identifier may be added next to the new issuance date (i.e. May 2025 (v2)).*

Any additional information required by local regulations

Document History

Version No	Author	Date	Description of Change
00	Syazwani Shaari	14.12.2021	Initial release
01	Syazwani Shaari	03.03.2021	a) Remove additional caution statement for warming lubricant
02	Syazwani Shaari	09.05.2022	a) Update period after opening from 3 months to 6 months b) Add statement that “Lubricant is a single use device (for foil sachet packaging)
03	Syazwani Shaari	22.06.2022	a) Add “volume or weight” b) Add “body massage” claim c) Add statement “helps to reduce friction associated with thin and/or dry genital tissue, during sexual intercourse.” d) Separate direction for use for tube/bottle packaging vs foil sachet packaging f) Update ingredient list INCI name for Nipaguard EHP and Velsan Flex
04	Wandee Rattanajamnong	20.01.2023	a) Rearrange format b) Add dimension of CE mark c) Add symbol for distributor d) Add symbols that could be use e) Remove definition for medical device and single use symbols f) Add draft labelling information for silicone oil-base lubricant g) Include additional caution for warming lubricant
05	Wandee Rattanajamnong	20.01.2023	a) Font formatting
06	Wandee Rattanajamnong	09.03.2023	a) Remove the caution statement for warming lubricant b) Remove labelling information for silicone oil-based lubricant
07	Syazwani Shaari	22.06.2023	a) Include percentage of Hydroxyethyl cellulose, 1.5% b) Add definition symbol for “Medical Device” c) Add definition symbol for “Single Use” for foil packaging
08	Apinya Jiwraprapat	24.08.2023	a) Update period after opening from 3 to 6 months
09	Aimi Amirah	29.02.2024	a) Revise Intended use "alleviation of vaginal dryness" b) Add sentence for compatibility of lubricant with condoms c) Additional claim "suitable and may be used for body massage" d) Remove ingredient list
10	Aimi Amirah	06.05.2024	a) Remove statement on "high glycol content"
11	Aimi Amirah	14.05.2024	a) Include statement “This product is not compatible with polyurethane condom
12	Aimi Amirah	05.06.2025	a) Rearrange format draft label b) Provide separate labelling information by type of packaging d) Include ingredient master list no. IFU-02-IML e) Update “EC REP” symbol to “EU REP” symbol f) Update direction for use instruction
13	Aimi Amirah	12.01.2026	a) Rephrase intended use statement b) Include “Medical Device” statement and symbol for sachet packaging c) Update information to be included in the IFU leaflet d) Included QA-34 procedure as reference for MDR – Language requirements

			e) Include symbol for Reference/ Catalogue number for tube/bottle and secondary packaging (inner/ outer box) f) Specify that the volume/ weight of lubricant shall be in S.I unit g) Remove the specific brand (i.e. myONE brand) and revise it only “[Brand]” h) Rephrase direction/ instruction for use to specify “clean fingers” i) update warning & precaution