





**PRIMARY PACKAGING/ INDIVIDUALLY SEALED CONTAINER**

Brand Name or Identity of Manufacturer/Importer

“LOT” and/or  : *(LOT number format as per defined in K-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



**SECONDARY PACKAGING/ CONSUMER BOX**

*Remark: Equivalent statement may be used to convey the information in this secondary packaging; however, it shall carry the same meaning*

**FRONT PANEL**

**Brand Name [logo]  
[Sub-brand/ Types]  
No. of condoms contain in the package**

**BACK/LEFT SIDE/RIGHT SIDE PANELS**

Brand Name® logo  
[Types]

[With reservoir tip]  
[Nominal width]  
[Smooth, Parallel sided]  
[Lubricated]  
[Clear]  
[Odourless]  
[Drawing of a condom] (*Optional to convey all above information*)

Brand Name® [Types/ Texture] condoms are designed for pleasure and reliability.

- Conform to ISO 23409:2011

When used correctly every time you have sex, condom intended for contraception and prevention of sexually transmitted infections.

**SUITABLE FOR LATEX SENSITIVE USERS**

Synthetic nitrile male condoms do not contain natural rubber latex and are suitable choice for people who have known or suspected allergy to natural rubber latex.

OR



Condom is medical device.

OR



Use each condom only once.

OR



For maximum benefit, carefully follow the condom instructions inside this package.

OR



Store in a cool, dry place away from direct sunlight.

OR







\* Only use silicone oil-based lubricants.  
**DO NOT USE WATER BASED LUBRICANTS.**


100% ELECTRONICALLY TESTED


QUALITY  
ASSURANCE  
[logo]



<p>“Manufacturer” OR </p>	<p><b>Karex Industries Sdn. Bhd.</b> PTD 7906 &amp; 7907, Taman Pontian Jaya, Batu 34, Jalan Johor, 82000 Pontian, Johor Darul Takzim, Malaysia.</p>	<p><b>CE mark</b> (minimum height of 5mm with notified body’s number)</p>
<p>“EU Authorized Representative” OR </p>	<p><b>Advena Limited</b> Tower Business Centre, 2nd Flr., Tower Street, Swatar, BKR 4013 Malta.</p>	
<p>“Importer” OR </p>	<p><b>XXX company &amp; address</b></p>	
<p></p>	<p>UDI or other format [Barcode] <i>(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)</i></p>	

**BOTTOM PANEL**

“LOT” and/or  : (LOT number format as per defined in K-WI-QA-02)

“EXP” and/or  : YYYY-MM or YYYY/MM



**INSTRUCTION FOR USE (IFU)**

*Remark: Equivalent statement may be used to convey the information in this IFU; however, it shall carry the same meaning.*

INTENDED USE	Intended for contraception and prevention of sexually transmitted infections.
INTENDED USER	Intended to be used by lay persons, adult male or female.
INDICATION	Condom is a medical device used for prevention unwanted pregnancy and sexually transmitted infections.
CLINICAL BENEFITS	Prevent unwanted pregnancy. Prevent and reduce the risk of spreading sexually transmitted infections, including human immunodeficiency virus (HIV).
* WARNINGS/ SAFETY PRECAUTION	<ul style="list-style-type: none"> <li>• For maximum benefit, carefully follow the condom instructions inside this package.</li> <li>• If extra lubricant is needed, only use silicone oil-based lubricants. <b>DO NOT USE WATER BASED LUBRICANTS</b>, as these may damage the condom.</li> <li>• Consult a doctor or pharmacist about the compatibility of topical medicines that are applied to the penis or vagina and might come in contact with the condom, as these may also damage the condom.</li> <li>• Do not use the condom if the materials are sticky or brittle. If the individual container is obviously damaged, discard that condom and use a new one from an undamaged package.</li> <li>• Seek medical assistance as soon as possible, at least within 72 hours should a condom leak or burst during use.</li> <li>• Condoms are for single use only; reused condom could increase the risk of breakage and infection.</li> <li>• When used correctly every time you have sex, condom helps prevent pregnancy, reduce the risk of transmitting HIV/AIDS and other sexually transmitted infectious.</li> <li>• No method of contraception can provide 100% protection against pregnancy or transmission of HIV and STIs. If you suspect that you or your partner may have become pregnant or infected, consult your doctor immediately.</li> <li>• Synthetic nitrile male condoms do not contain natural rubber latex and are suitable choice for people who have known or suspected allergy to natural rubber latex.</li> <li>• Some highly sensitive individuals may however experience allergic reactions to ingredients in these condoms. If you or your partner experience itching, irritation, discharge, rash, pain, swelling and/or burning sensation, to some extent causing infection of the vagina or penis, discontinue use and seek medical advice.</li> <li>• Store in a cool dry place away from direct sunlight.</li> <li>• Keep away from children.</li> <li>• There is a risk of choking using a condom orally.</li> <li>• Report any serious incident occurred on the condom to the manufacturer and the relevant national competent authority.</li> </ul>

 **Karex Industries Sdn. Bhd.**  
 PTD 7906 & 7907, Taman Pontian Jaya,  
 Batu 34, Jalan Johor, 82000 Pontian,  
 Johor Darul Takzim, Malaysia.

**CE mark**  
 Revision Date: xxxxxxxx 2024  
 Master reference information: K-IFU-14 (v.8)  
 ISO 23409:2011

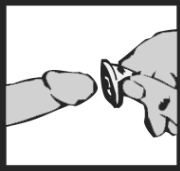


**BACK**

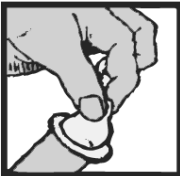
**Instruction For Use**



1. Carefully tear off foil pack, making sure not to damage the condom.



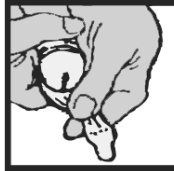
2. During removal from foil, avoid damage to the condom by fingernails, jewelry and etc.



3. Squeeze the reservoir end of the condom gently, between the thumb and the forefinger to expel the air out of the tip, while placing the condom over the head of the erect penis. This must be done before any contact occurs between the penis and the partner's body to assist in the prevention of sexually transmitted infectious and pregnancy.



4. While still holding the reservoir tip, unroll the condom over the entire length of the erect penis with the other hand.



5. Stop and check if the condom slipping off or tightening excessively onto the penis as this might lead to breakage.



6. Soon after ejaculation, hold on the rim of the condom and slowly withdraw the penis while it is still erect so that the condom does not slip off.

7. Remove the condom from your penis by sliding it off slowly. It is important not to permit the penis or used condom to touch the vagina area after withdrawal.

8. Wrap the used condom and dispose it hygienically in a closed rubbish bin.

	Store in a cool, dry place		Keep away from sunlight		Use by date
	Batch code		Do not reuse		Consult instruction for use
	Medical device		Unique Device Identifier		Manufacturer
	Importer		European authorized representative		Date of Manufacture
	Latex free				

*Remark: Add in definition of any other symbols used on the packaging*



**LIST OF POSSIBLE PRODUCT CLAIMS**

*Remark: These claims may appear on primary packaging or secondary packaging.*

- World's first synthetic nitrile male condom
- Well lubricated, thinner and lighter which provide good sensation and stimulation than regular latex condoms.
- Unique non-latex material that is sensitive, clear, odourless.
- Comfort during use.
- Feels like not wearing a condom.
- Conform to your shape.




Document History


Version	Date	Description
0	12.04.2022	Initial release.
1	17.06.2022	<b>Secondary packaging/consumer box – front panel</b> Added “World’s first synthetic nitrile latex male condom” and “Well lubricated, thinner and lighter which provide good sensation and stimulation than regular latex condoms”. <b>Left and right side panels</b> Added “SUITABLE FOR LATEX SENSITIVE USERS” and “Unique non-latex material that is sensitive, clear, odourless, and safe with oil-based lubricants. DO NOT USE WATER-BASED LUBRICANTS, as it may damage the condom”. <b>Back panel</b> Added “Synthetic nitrile latex male condoms do not contain natural rubber latex and are suitable choice for people who have known or suspected allergy to natural rubber latex. Unlike natural rubber latex condoms, synthetic nitrile latex male condoms may be used with oil-based lubricants” and “Comfort during use”. <b>Instruction for use (IFU) – Front</b> Revised the warnings/safety precautions.
2	20.06.2022	<b>Back panel</b> Added “Feels like not wearing a condom” and “Conform to your shape”.
3	22.08.2022	Change running number from K-IFU-13 to K-IFU-14
4	20.09.2022	<b>Instruction for use (IFU)</b> Added “Intended use”, “Intended user”, “Indication”, “Clinical benefits”. Revised warnings/safety precaution
5	30.11.2023	Removed “latex” from “synthetic nitrile latex male condom”. <b>Left and right panels</b> Revised to “Safe with silicone oil-based and mineral oil lubricants or use lubricants that labelled as compatible with nitrile condoms. DO NOT USE WATER BASED LUBRICANTS, as it may damage the condom”. <b>Back panel</b> Revised to “Carex® [Types/ Texture] condoms are designed for pleasure and reliability”. Revised to “Synthetic nitrile male condoms may be used with silicone oil-based or mineral oil lubricants or use lubricants that labelled as compatible with nitrile condoms”. <b>Back</b> Add symbol for date of manufacturer.
6	15.03.2024	Secondary packaging, left and right side panels - Revised the warning to “Only use silicone oil-based or use lubricants that labelled as compatible with nitrile condoms. <b>DO NOT USE WATER BASED LUBRICANTS.</b> ” Back panel - Removed the warning. IFU Revised the warning and safety precautions. Added latex free symbol.
7	29.03.2024	IFU - Revised the warning and safety precautions.
8	29.11.2024	Rearrange to new format. Revised the lubricant compatibility statement. Revised warnings/safety precaution. Revised definition table.



**PRIMARY PACKAGING/ INDIVIDUALLY SEALED CONTAINER**

Brand Name or Identity of Manufacturer/Importer

“LOT” and/or  : *(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





**SECONDARY PACKAGING/ CONSUMER BOX**

*Remark: Equivalent statement may be used to convey the information in this secondary packaging; however, it shall carry the same meaning*

**FRONT PANEL**

**Brand Name [logo]  
[Sub-brand/ Types]  
No. of condoms contain in the package**

**BACK/LEFT SIDE/RIGHT SIDE PANELS**

Brand Name® logo  
[Types]

[With reservoir tip]  
[Nominal width]  
[Smooth, Parallel sided]  
[Lubricated]  
[Clear]  
[Odourless]  
[Drawing of a condom] (*Optional to convey all above information*)

Brand Name® [Types/ Texture] condoms are designed for pleasure and reliability.

- Condom is a medical device
- Conform to ISO 23409:2011

When used correctly every time you have sex, condom intended for contraception and prevention of sexually transmitted infections.

**SUITABLE FOR LATEX SENSITIVE USERS**

Synthetic nitrile male condoms do not contain natural rubber latex and are suitable choice for people who have known or suspected allergy to natural rubber latex.



Condom is medical device



Use each condom only once



For maximum benefit, carefully follow the condom instructions inside this package.



Store in a cool, dry place away from direct sunlight.



\* Only use silicone oil-based lubricants.  
**DO NOT USE WATER BASED LUBRICANTS.**

100% ELECTRONICALLY TESTED

QUALITY  
ASSURANCE  
[logo]



“Manufacturer”

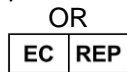


**Innolutex (Thailand) Limited**  
E1-6, Export Processing Zone,  
Southern Industrial Estate,  
Village 4, Chalung Sub-district,  
Hat Yai District, Songkhla 90110,  
Thailand.

**CE mark**

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

“EU Authorized  
Representative”



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

“Importer”



**XXX company & address**



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)*

**BOTTOM PANEL**

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

“EXP” and/or : YYYY-MM or YYYY/MM



**INSTRUCTION FOR USE (IFU)**

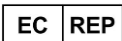
*Remark: Equivalent statement may be used to convey the information in this IFU; however, it shall carry the same meaning.*

INTENDED USE	Intended for contraception and prevention of sexually transmitted infections.
INTENDED USER	Intended to be used by lay persons, adult male or female.
INDICATION	Condom is a medical device used for prevention unwanted pregnancy and sexually transmitted infections.
CLINICAL BENEFITS	Prevent unwanted pregnancy. Prevent and reduce the risk of spreading sexually transmitted infections, including human immunodeficiency virus (HIV).
* WARNINGS/ SAFETY PRECAUTION	<ul style="list-style-type: none"><li>• For maximum benefit, carefully follow the condom instructions inside this package.</li><li>• If extra lubricant is needed, only use silicone oil-based lubricants. <b>DO NOT USE WATER BASED LUBRICANTS</b>, as these may damage the condom.</li><li>• Consult a doctor or pharmacist about the compatibility of topical medicines that are applied to the penis or vagina and might come in contact with the condom, as these may also damage the condom.</li><li>• Do not use the condom if the materials are sticky or brittle. If the individual container is obviously damaged, discard that condom and use a new one from an undamaged package.</li><li>• Seek medical assistance as soon as possible, at least within 72 hours should a condom leak or burst during use.</li><li>• Condoms are for single use only; reused condom could increase the risk of breakage and infection.</li><li>• When used correctly every time you have sex, condom helps prevent pregnancy, reduce the risk of transmitting HIV/AIDS and other sexually transmitted infectious.</li><li>• No method of contraception can provide 100% protection against pregnancy or transmission of HIV and STIs. If you suspect that you or your partner may have become pregnant or infected, consult your doctor immediately.</li><li>• Synthetic nitrile male condoms do not contain natural rubber latex and are suitable choice for people who have known or suspected allergy to natural rubber latex.</li><li>• Some highly sensitive individuals may however experience allergic reactions to ingredients in these condoms. If you or your partner experience itching, irritation, discharge, rash, pain, swelling and/or burning sensation, to some extent causing infection of the vagina or penis, discontinue use and seek medical advice.</li><li>• Store in a cool dry place away from direct sunlight.</li><li>• Keep away from children.</li><li>• There is a risk of choking using a condom orally.</li><li>• Report any serious incident occurred on the condom to the manufacturer and the relevant national competent authority.</li></ul>



**Innolates (Thailand) Limited**  
E1-6, Export Processing Zone,  
Southern Industrial Estate,  
Village 4, Chalung Sub-district,  
Hat Yai District, Songkhla 90110,  
Thailand

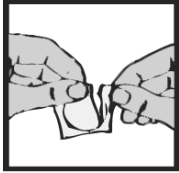
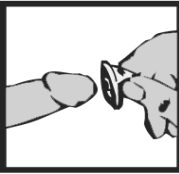
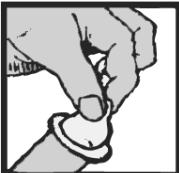



**CE mark**  
Revision Date: 01.08.2024  
Master reference information: T-IFU-05 (v.4)  
ISO 23409:2011
















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



**BACK**

<p><b>Instruction For Use</b></p>   	<ol style="list-style-type: none"> <li>Carefully tear off foil pack, making sure not to damage the condom.</li> <li>During removal from foil, avoid damage to the condom by fingernails, jewelry and etc.</li> <li>Squeeze the reservoir end of the condom gently, between the thumb and the forefinger to expel the air out of the tip, while placing the condom over the head of the erect penis. This must be done before any contact occurs between the penis and the partner's body to assist in the prevention of sexually transmitted infectious and pregnancy.</li> </ol>	  	<ol style="list-style-type: none"> <li>While still holding the reservoir tip, unroll the condom over the entire length of the erect penis with the other hand.</li> <li>Stop and check if the condom slipping off or tightening excessively onto the penis as this might lead to breakage.</li> <li>Soon after ejaculation, hold on the rim of the condom and slowly withdraw the penis while it is still erect so that the condom does not slip off.</li> <li>Remove the condom from your penis by sliding it off slowly. It is important not to permit the penis or used condom to touch the vagina area after withdrawal.</li> <li>Wrap the used condom and dispose it hygienically in a closed rubbish bin.</li> </ol>
---	---	--	--

	Store in a cool, dry place		Keep away from sunlight		Use by date
	Batch code		Do not reuse		Consult instruction for use
	Latex free		Medical device		Unique Device Identifier
	Manufacturer		Date of Manufacturer		Importer
	European authorized representative				

*Remark: Add in definition of any other symbols used on the packaging*



**LIST OF POSSIBLE PRODUCT CLAIMS**

*Remark: These claims may appear on primary packaging or secondary packaging.*

- World's first synthetic nitrile male condom
- Well lubricated, thinner and lighter which provide good sensation and stimulation than regular latex condoms.
- Unique non-latex material that is sensitive, clear, odourless.
- Comfort during use.
- Feels like not wearing a condom.
- Conform to your shape.



---

**Document History**

<b>Version</b>	<b>Date</b>	<b>Description</b>
1	30.11.2023	Initial draft.
2	28.03.2024	Secondary packaging, left and right side panels <ul style="list-style-type: none"><li>- Revised the warning to “Only use silicone oil-based or use lubricants that labelled as compatible with nitrile condoms. <b>DO NOT USE WATER BASED LUBRICANTS.</b>”</li></ul> Back panel <ul style="list-style-type: none"><li>- Removed the warning.</li><li>- Added latex free symbol.</li></ul> IFU <ul style="list-style-type: none"><li>- Revised the warning and safety precautions.</li></ul>
3	21.05.2024	Revised ITL address in back panel and IFU.
4	01.08.2024	Rearrange to new format. Revised the lubricant compatibility statement. Revised warnings/safety precaution.