



PRIMARY PACKAGING/ INDIVIDUALLY SEALED CONTAINER

Brand Name or Identity of Manufacturer/Importer

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



: YYYY-MM or YYYY/M

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

Wingman logo
[Types]

[With reservoir tip]
[Nominal width]
[Shape and Texture]
[Lubricated or Dry]
[Coloured or Natural]
[Flavours] *(Required if flavoured)*
[Nominal Length] *(Required if less than 160mm)*
[Drawing of a condom] *(Optional to convey all above information)*

Wingman [Types/ Texture] condoms are designed for pleasure and reliability.

- Conform to ISO 4074

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

This product contains natural rubber latex which may cause allergic reactions including anaphylactic shock if the user is allergic to 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



DO NOT USE OIL-BASED LUBRICANTS, such as petroleum jelly, vegetable/mineral oils or cold cream, as these may damage the latex condom.

100% ELECTRONICALLY TESTED

QUALITY
ASSURANCE
[logo]



Manufacturer
OR



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

CE mark

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

EU Authorized
Representative
OR



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

Importer
OR




: **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 K-WI-QA-02)



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



INSTRUCTION FOR USE



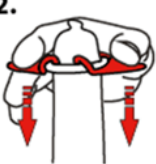
















Remark: Information or statements in this IFU may be rephrased accordingly; however, it shall carry the same meaning.

FRONT

<p>IMPORTANT POINTS TO KNOW BEFORE USING A CONDOM</p> <ol style="list-style-type: none">1. If extra lubrication is needed, use water-based lubricants.2. DO NOT USE OIL BASED LUBRICANTS such as petroleum jelly, mineral oil and cold cream, as they may weaken the condom and cause subsequent failure of the product. So can some topical medicines that are applied to the penis or vagina. If you are not sure about the effect of the medicines you're using on condoms, ask your doctor or pharmacist.3. Do not use the condom if the rubber materials are sticky or brittle. If the individual container is obviously damaged, discard that condom and use a new one from an undamaged package.4. Seek medical assistance as soon as possible, at least within 72 hours should a condom leak or burst during use.5. The condoms and the wings are for single use only; reused condom could increase the risk of breakage and infection.6. When used correctly, the wings will not break or damage the condom. We recommend only touching the wings to minimize the risk of damaging the condom.7. The applicator is intended to ease the donning of condom.8. When used correctly every time you have sex, latex condoms help prevent pregnancy, reduce the risk of transmitting HIV/AIDS and other sexually transmitted infectious.9. 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.10. This product contains natural rubber latex which may cause allergic reactions including anaphylactic shock. If you are allergic to natural rubber latex products, consult your doctor for advice before use.11. Store in a cool dry place away from direct sunlight.12. Keep away from children.13. There is a risk of choking using a condom orally.14. The use of additional lubricants during anal sex can reduce the risk of breakage.15. Condom is a medical device to be used by lay persons - adult male or female.16. Report any serious incident occurred from using the device to the manufacturer and the relevant national competent authority.17. These condoms conform to International standards ISO 4074/ EN ISO 4074. <p>Karex Industries Sdn. Bhd. PTD 7906 & 7907, Taman Pontian Jaya, Batu 34, Jalan Johor, 82000 Pontian, Johor Darul Takzim, Malaysia.</p> <p>Advena Limited Tower Business Centre, 2nd Flr., Tower Street, Swatar, BKR 4013 Malta.</p>	<p>Wingman [logo]</p> <p>Instruction For Use</p> <p>CE mark <i>(minimum height of 5 mm with notified body's number and correct font, to be placed beside manufacturer's detail)</i></p> <p>Revision Date : 5th November 2024 (v.5) Master reference information : K-IFU-04 (v.5)</p>
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BACK

<p>Instruction For Use</p>  <p>1. Carefully tear off foil pack, making sure not to damage the condom.</p>  <p>2. During removal from foil, avoid damage to the condom by fingernails, jewelry and etc.</p>  <p>3. Position the condom over the head of the erect penis with the logo on the wings facing upwards.</p> <p>4. Carefully push both wings down using one or two hands to unroll the condom as far as it will go.</p> <p>5. Remove the wings from the condom by turning them away from the body at the point where the wings join. The condom is now ready for use.</p>		 <p>6. Stop and check if the condom slipping off or tightening excessively onto the penis as this might lead to breakage.</p>  <p>7. Soon after ejaculation, and while the penis is still erect, hold the condom at the base of the penis and withdraw carefully.</p>  <p>8. 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.</p> <p>9. Wrap the used condom and wings, and dispose it hygienically in a closed rubbish bin, not the toilet.</p>			
	Store in a cool, dry place		Keep away from sunlight		Use by Date
	Contains natural rubber latex		Manufacturer		Consult Instruction for Use
	Do not use if Package is damaged		Do not reuse		Batch Code
	Importer		Medical device		Unique Device Identifier
	European authorized representative				
<p><i>Remark: Add in definition of any other symbols used on the packaging</i></p>					

**Document History**

Version No	Author	Date	Description of Change
2	Nurafiqah Nordin	04/03/2021	-Information not available-
3	Nurafiqah Nordin	10/06/2021	a) Update Warnings/Precautions - include the wings (applicator) in statement for single use - Statement for the correct use of the wings (applicator) - Include statement that the applicator is intended for the donning of condom
4	Nurafiqah Nordin	24/01/2022	a) Rearrange IFU symbol b) Update information on the condoms i.e., dimension, shape, flavours etc. c) Rearrange symbol for Latex d) Add in symbol for "Medical Device" e) Add symbol for UDI and Importer f) Update symbol for EC REP g) Add remark for Instruction for Use h) Remove CE and caution symbols from the definition table i) Include definition symbol for Importer, Medical Device, UDI and EC REP symbol
5	Aimi Amirah	11/10/2024	a) Rearrange format draft label b) Include additional picture in the Instruction for Use c) Update correct symbol for "manufacturer", "LOT", and "EC REP"