WHOPAR part 5 Suppliers submission of the SRA approved text

MINIMUM STATEMENTS ON BLISTER PACKS OR FOIL STRIPS {PVC/PE.EVOH.PE/PCTFE/Aluminum} 1. NAME OF THE MEDICINAL PRODUCT Microgynon 28 $150 \,\mu g / 30 \,\mu g$ coated tablets Levonorgestrel / Ethinylestradiol 2. NAME OF THE PHARMACEUTICAL COMPANY Jenapharm 3. **Expiry date** Use by: 4. Batch designation < DISPENSER AND PRODUCT CODE> Batch 5. **OTHER STATEMENTS** Bayer cross

WORDING ON OUTER PACKAGING

{Folding box}

1. NAME OF THE MEDICINAL PRODUCT

Microgynon 28

150 micrograms / 30 micrograms coated tablets

Levonorgestrel / Ethinylestradiol

2. ACTIVE PHARMACEUTICAL INGREDIENT(S)

21 beige tablets, each containing 150 micrograms levonorgestrel and 30 micrograms ethinylestradiol

7 white placebo tablets

3. OTHER CONSTITUENTS

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Contains lactose and sucrose. Refer to package insert for further information.

4.	DOSAGE FORM AND CONTENT
3x28 d	ated tablets coated tablets coated tablets
5.	NOTES AND METHOD(S) OF APPLICATION
	gestion. the package insert.
6.	WARNING THAT THE MEDICINAL PRODUCT IS TO BE KEPT OUT OF CHILDREN'S REACH AND SIGHT
Keep	medicines out of the reach of children.
7.	ADDITIONAL WARNINGS, WHERE NECESSARY
8.	EXPIRY DATE
Can b	e used until:
9.	SPECIAL NOTES ON STORAGE
10.	ANY SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINES OR WASTE DERIVING THEREFROM
11.	NAME AND ADDRESS OF THE PHARMACEUTICAL COMPANY
	harm GmbH & Co. KG Schott-Strasse 15 Jena
12.	MARKETING AUTHORISATION NUMBER(S)
MA N	To.: 6929523.00.00
13.	batch number
Batch	
14.	SALES RESTRICTIONS

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Prescription mandatory.

15.	NOTES ON USE	
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16. INFORMATION IN BRAILLE

Microgynon 28

17. UNIQUE IDENTIFIER – 2D BARCODE

2D barcode carrying the unique identifier.

18. UNIQUE IDENTIFIER – HUMAN READABLE DATA

PC: SN:

NN:

ADDITIONAL PARTICULARS (national specifics / "Blue Box statements")

Original pack	Wording
28 coated tablets	Company logo
3x28 coated tablets	Barcode
6x28 coated tablets	'PZN' (Packaging material drawing)
Sample	Wording
28 coated tablets	Company logo
	Sample not for sale containing 1 x 28 coated
	tablets