

RESTART- levonorgestrel tablet Winx Health Inc.

The image shows the front and back panels of the Restart Morning-After Pill packaging. The front panel is pink and white, featuring the product name 'restart morning-after pill' in a stylized font. Below it, it says 'Emergency Contraceptive' and 'Take within 3 days of unprotected sex'. A central graphic shows a white tablet with the text 'One tablet, one step Reduces the chance of getting pregnant Levonorgestrel tablet, 1.5 mg'. The Winx Health logo is at the bottom, with a comparison to Plan B One-Step. The back panel is also pink and white, containing a 'Drug Facts' table, a barcode, and distribution information.

Drug Facts

Active ingredient	Purpose
Levonorgestrel 1.5 mg	Emergency contraceptive

Use for women to reduce chance of pregnancy after unprotected sex (if a contraceptive failed or if you did not use birth control)

Warnings
Allergy alert: Do not use if you have ever had an allergic reaction to levonorgestrel

Sexually transmitted diseases (STDs) alert: This product does not protect against HIV/AIDS or other STDs

Do not use

- if you are already pregnant (because it will not work)
- for regular birth control

Ask a doctor or pharmacist before use if you are taking efavirenz (HIV medication) or rifampin (tuberculosis treatment) or medication for seizures (epilepsy). These medications may reduce the effectiveness of levonorgestrel.

When using this product you may have

- menstrual changes
- tiredness
- breast pain
- dizziness
- lower stomach (abdominal) pain
- headache
- vomiting
- nausea

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control center right away +1 888-222-1222

Directions

- take as soon as possible within 72 hours (3 days) after unprotected sex. The sooner you take it, the better it will work.
- if you vomit within 2 hours of taking the medication, call a healthcare professional to find out if you should repeat the dose

Other information

- read the instructions, warnings, and enclosed product leaflet before use
- do not use if carton is open or blister seal is broken or missing
- store at 20° to 25°C (68° to 77°F)

Inactive ingredients
colloidal silicon dioxide, FD&C Yellow No. 6 aluminum lake, lactose monohydrate, magnesium stearate, and pregelatinized starch

Distributed by
Winx Health, Beaverton, OR, 97008
Hellowinx.com
Made in Germany

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- Tiredness
- Breast pain
- Nausea

- Headache
- Vomiting
- Lower stomach (abdominal) pain
- Dizziness

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Colloidal Silicon Dioxide, Corn Starch, Lactose Monohydrate, Magnesium Dtearate, Povidone

For women to reduce chance of pregnancy after unprotected sex (if a contraceptive failed or if you did not use birth control)

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Emergency Contraceptive

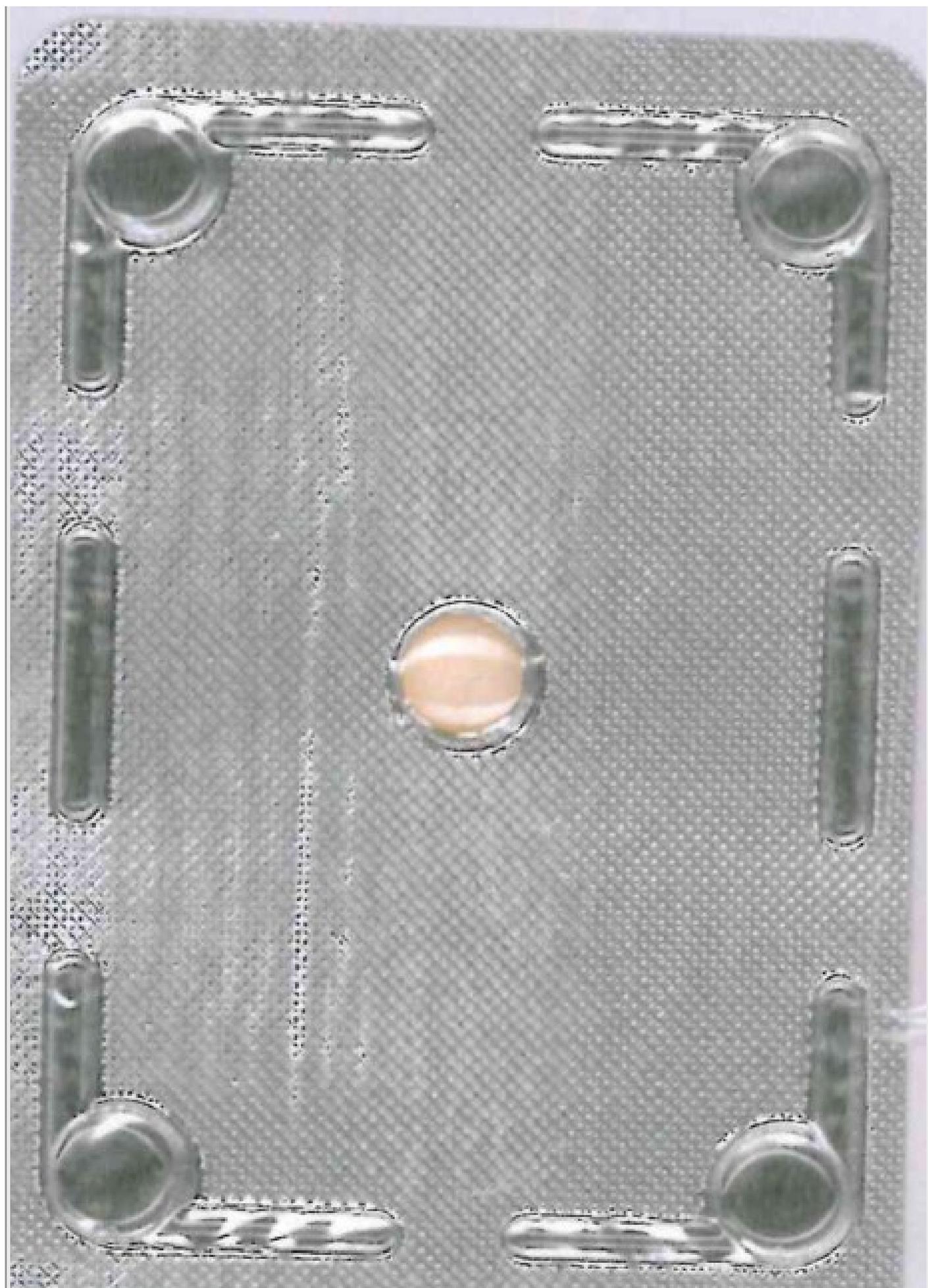
Levonorgestrel 1.5 mg

RESTART			
levonorgestrel tablet			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:80584-103
Route of Administration	ORAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
LEVONORGESTREL (UNII: 5W7SIA7YZW) (LEVONORGESTREL - UNII:5W7SIA7YZW)		LEVONORGESTREL	1.5 mg
Inactive Ingredients			
Ingredient Name			Strength
MAGNESIUM STEARATE (UNII: 70097M6I30)			
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)			
TALC (UNII: 7SEV7J4R1U)			
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)			
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)			
STARCH, CORN (UNII: O8232NY3SJ)			
Product Characteristics			
Color	orange (Light peach)	Score	no score
Shape	ROUND	Size	8mm

Flavor		Imprint Code	17
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80584-103-01	1 in 1 CARTON	10/08/2024	
1		1 in 1 BLISTER PACK; Type 0: Not a Combination Product		





Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA207660	10/08/2024	

Labeler - Winx Health Inc. (117116737)

Establishment

Name	Address	ID/FEI	Business Operations
Naari Pharma Private Limited		915787058	manufacture(80584-103) , analysis(80584-103) , label(80584-103) , pack(80584-103)

Revised: 8/2025

Winx Health Inc.