# MORNING AFTER PILL- levonorgestrel tablet Cadence Health Inc

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## **Drug Facts**

## **Active ingredient**

Levonorgestrel 1.5 mg

## **Purpose**

**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
- nausea
- lower stomach (abdominal) pain
- tiredness
- headache
- dizziness

- breast pain
- vomiting

**Keep out of reach of children.** In case of overdose, get medical help or contact a Poison Control center right away 1-800-222-1222

#### **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

## **Questions or comments?**

Call 1-877-862-7455 Monday - Friday 8 AM - 5 PM CST or visit us at cadenceotc.com

Manufactured for: Cadence OTC

Oakland CA, 94612

NDC 73436-2859-1

Product made in Germany Issued: September 2023

1. NDC 73436-2859-1

Morning After Pill TM

Levonorgestrel 1.5 mg

Emergency contraceptive

Reduces chance of pregnancy after unprotected sex

Not for regular birth control

Won't interefere with your ability to get pregnant later

• The sooner you take it, the more effective it will be

- Take as soon as possible within 72 hours (3 days) after unprotected sex
- Will not harm an existing pregnancy

#### 1 TABLET LEVONORGESTREL 1.5MG



## **MORNING AFTER PILL**

levonorgestrel tablet

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:73436-2859
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	<b>Basis of Strength</b>	Strength
LEVONORGESTREL (UNII: 5W7SIA7YZW) (LEVONORGESTREL - UNII:5W7SIA7YZW)	LEVONORGESTREL	1.5 mg
Inactive Ingredients		

Inactive Ingredients		
Ingredient Name	Strength	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)		

SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
STARCH, CORN (UNII: O8232NY3SJ)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	

Product Characteristics			
Color	orange (Light peach)	Score	no score
Shape	ROUND (convex)	Size	8mm
Flavor		Imprint Code	17
Contains			

P	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73436- 2859-1	1 in 1 CARTON	10/01/2023	
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	ANDA202380	10/01/2023	

## Labeler - Cadence Health Inc (116830263)

## Registrant - Naari Pte. Limited (659345996)

Establishment			
Name	Address	ID/FEI	Business Operations
Haupt Pharma Muenster GmbH		344172564	analysis(73436-2859), manufacture(73436-2859), pack(73436-2859)

Revised: 9/2023 Cadence Health Inc