

LEVONORGESTREL- levonorgestrel tablet
Naari Pte Limited

Levonorgestrel Tablet 1.5 mg

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

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control center right away.

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 after 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 tear strip is removed or blister seal is broken or missing**
- store at 20-25°C (68-77°F)

Inactive ingredients

colloidal anhydrous silica, corn starch, lactose monohydrate, magnesium stearate, potato starch and purified talc

Questions?

If you have questions or need more information, call our toll-free number, x-xxx-xxx-xxxx.

Manufactured for:

Naari Pte Limited
36 Robinson Road, #13-06
City House, Singapore 068877
NDC 79929-016-01
Rev. January 2023

PRINCIPAL DISPLAY PANEL

FOR CLINIC USE ONLY.
NOT FOR RETAIL SALE.

NDC 79929-016-01

levonorgestrel 1.5 mg

emergency contraceptive

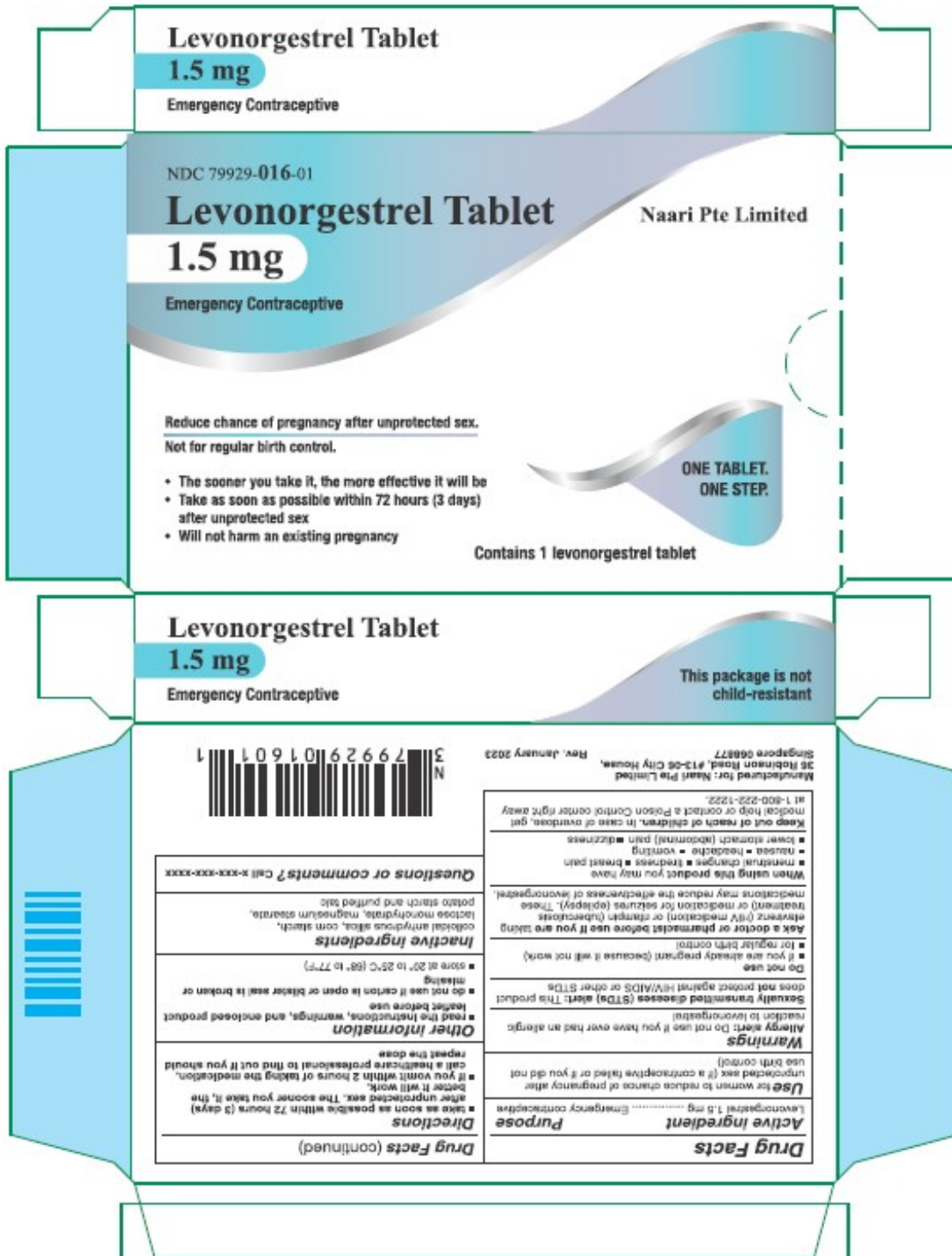
Reduces chance of
pregnancy after
unprotected sex.

Not for regular birth control.

One Tablet.

One Step.

1 Tablet Levonorgestrel 1.5 mg



LEVONORGESTREL

levonorgestrel tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:79929-016
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LEVONORGESTREL (UNII: 5W7SIA7YZ W) (LEVONORGESTREL - UNII:5W7SIA7YZ W)	LEVONORGESTREL	1.5 mg

Inactive Ingredients

Ingredient Name	Strength
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STARCH, POTATO (UNII: 8I089SAH3T)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
TALC (UNII: 7SEV7J4R1U)	
STARCH, CORN (UNII: O8232NY3SJ)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	

Product Characteristics

Color	white	Score	no score
Shape	ROUND	Size	8mm
Flavor		Imprint Code	EE1
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79929-016-01	1 in 1 BOX, UNIT-DOSE	02/16/2023	
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	ANDA207660	02/16/2023	

Labeler - Naari Pte Limited (659345996)**Registrant** - Naari Pte Limited (659345996)**Establishment**

Name	Address	ID/FEI	Business Operations
Naari Pharma Private Limited		915787058	manufacture(79929-016) , analysis(79929-016) , pack(79929-016)

