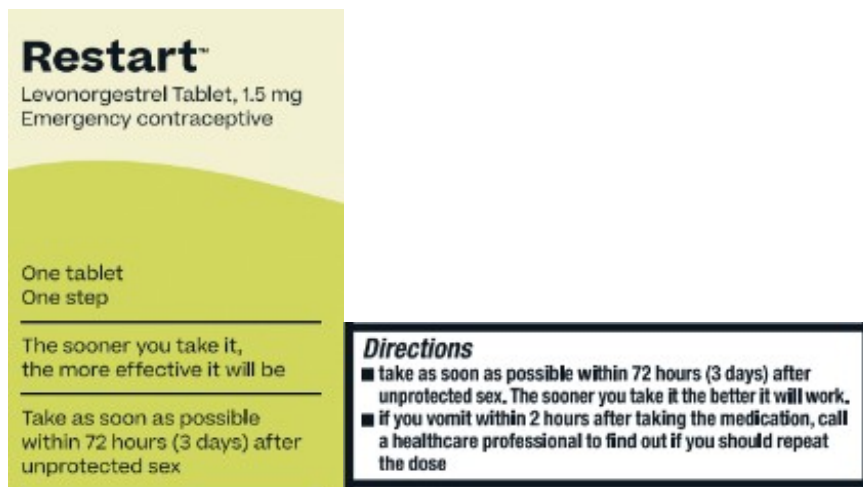


STIX RESTART- levonorgestrel tablet

Get Stix Inc



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 (1-800-222-1222).

Inactive ingredients

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

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

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).

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)

Drug Facts

Active ingredient	Purpose
Levonorgestrel 1.5 mg.....	Emergency contraceptive

STIX RESTART

levonorgestrel tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:80584-102
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:80584-102-13	1 in 1 CARTON	01/01/2024	
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	09/13/2022	

Labeler - Get Stix Inc (117116737)

Establishment

Name	Address	ID/FEI	Business Operations
Naari Pharma Private Limited		915787058	manufacture(80584-102) , analysis(80584-102) , label(80584-102) , pack(80584-102)

Revised: 3/2024

Get Stix Inc