LEVONORGESTREL- levonorgestrel tablet
Ohm Laboratories Inc.

Levonorgestrel

Drug Facts

Active ingredient

Levonorgestrel, USP 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 (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 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**
- this product works mainly by preventing ovulation (egg release). It may also prevent fertilization of a released egg (joining of sperm and egg) or attachment of a fertilized egg to the uterus (implantation).
- **do not use if carton is open or tear strip is removed or blister seal is broken or missing**
- store at 20° to 25°C (68° to 77°F)

Inactive ingredients

colloidal silicon dioxide, corn starch, hypromellose, lactose monohydrate, magnesium stearate, talc

Questions or comments?

For more information, call toll free 1-800-818-4555 weekdays

Distributed by:
Ohm Laboratories Inc.
New Brunswick, NJ 08901

PRINCIPAL DISPLAY PANEL - 1.5 mg Tablet Blister Pack Carton

FDA
APPROVED

NDC 51660-999-11

YOUR
CHOICE™

LEVONORGESTREL TABLET 1.5 MG

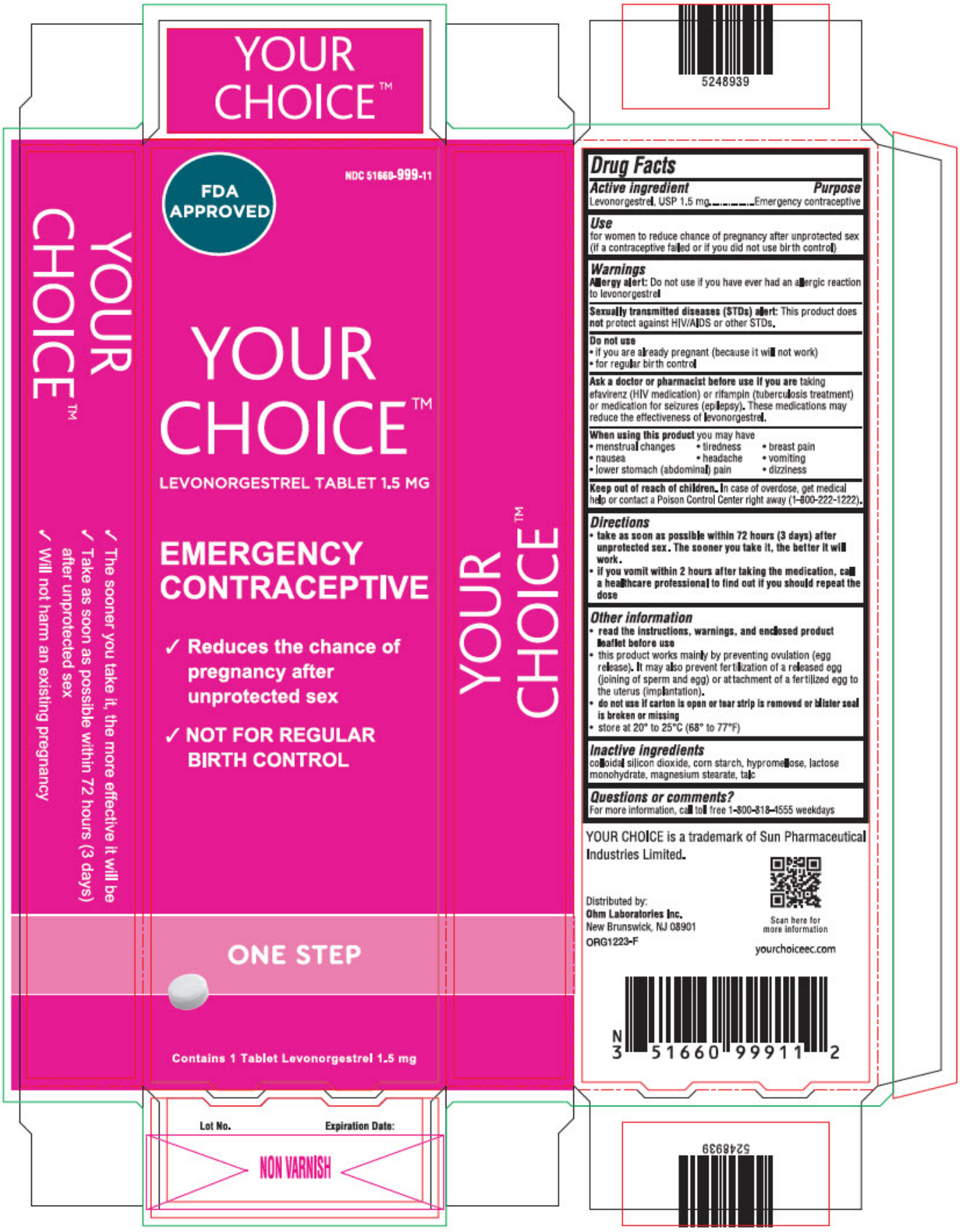
EMERGENCY
CONTRACEPTIVE

- ✓ Reduces the chance of pregnancy after unprotected sex

- ✓ NOT FOR REGULAR BIRTH CONTROL

ONE STEP

Contains 1 Tablet Levonorgestrel 1.5 mg



LEVONORGESTREL

levonorgestrel tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:51660-999
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**
silicon dioxide (UNII: ETJ7Z6XBU4)	
starch, corn (UNII: O8232NY3SJ)	
hypromellose, unspecified (UNII: 3NXW29V3WO)	
lactose monohydrate (UNII: EWQ57Q8I5X)	
magnesium stearate (UNII: 70097M6I30)	
talc (UNII: 7SEV7J4R1U)	

Product Characteristics			
Color	WHITE	**Score**	no score
Shape	ROUND	**Size**	8mm
Flavor		**Imprint Code**	
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:51660-999-11	1 in 1 CARTON	11/01/2017	
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	ANDA202635	11/01/2017	

Labeler - Ohm Laboratories Inc. (184769029)

Establishment

Name	Address	ID/FEI	Business Operations
Sun Pharmaceutical Industries Limited		725959238	MANUFACTURE(51660-999)