LEVONORGESTREL- levonorgestrel tablet
H.J. Harkins Company, Inc.

1164 LEVONORGESTREL

Levonorgestrel USP 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).

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 the reach of children.

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

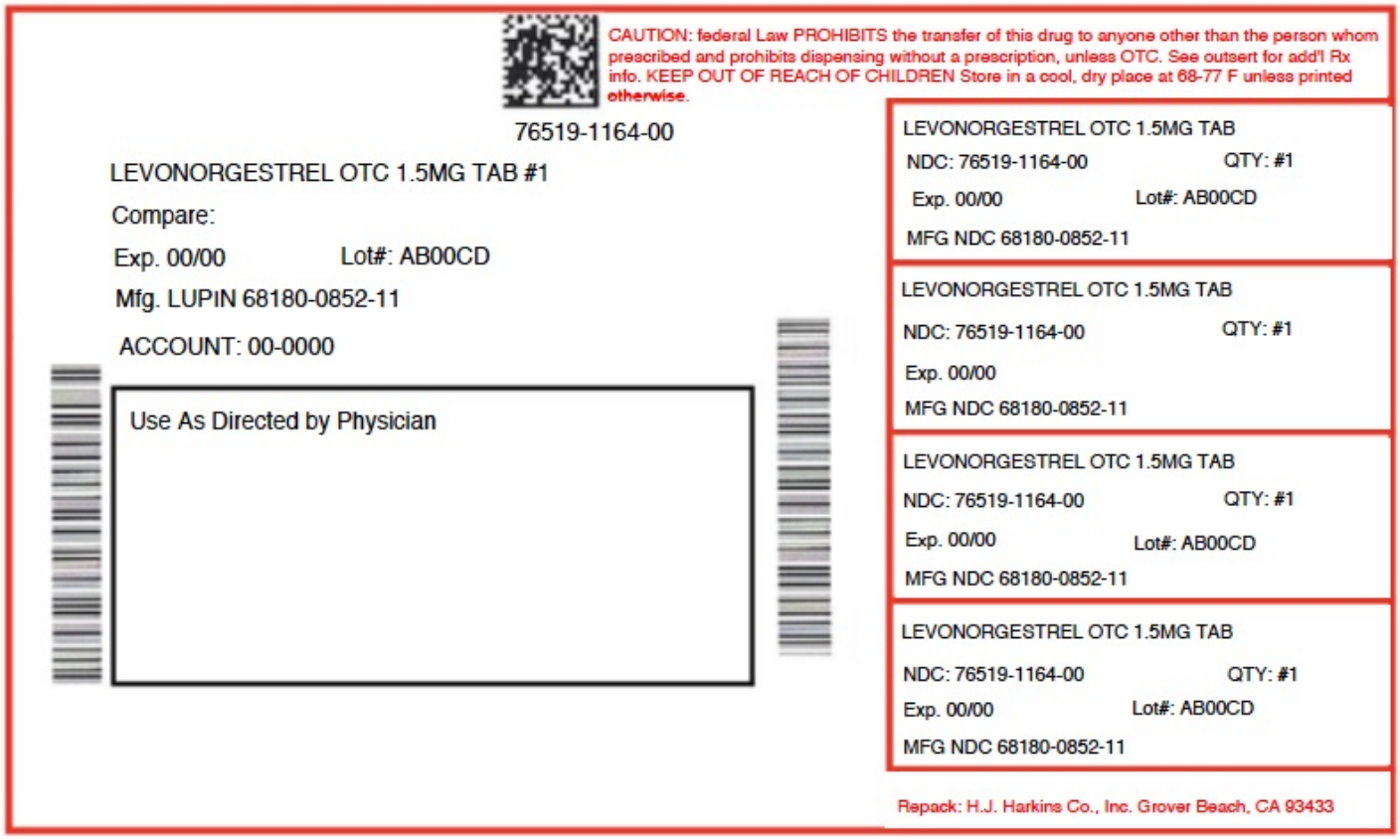
Directions

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 .
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 blister seal is broken or missing .
store at 25°C (77°C); excursions permitted to 15 to 30°C (59 to 86°C) [see USP Controlled Room temperature].

colloidal silicon dioxide, corn starch, lactose monohydrate, magnesium stearate, and povidone.



LEVONORGESTREL

levonorgestrel tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:76519-1164
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**
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POVIDONE K30 (UNII: U725QWY32X)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STARCH, CORN (UNII: O8232NY3SJ)	

Product Characteristics			
Color	white	**Score**	no score
Shape	ROUND	**Size**	9mm

Flavor		**Imprint Code**	LU;S25
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:76519-1164-0	1 in 1 BOX; Type 0: Not a Combination Product	11/15/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA201446	11/15/2017	

Labeler - H.J. Harkins Company, Inc. (147681894)

Establishment

Name	Address	ID/FEI	Business Operations
H.J. Harkins Company, Inc.		147681894	manufacture(76519-1164) , relabel(76519-1164) , repack(76519-1164)

Revised: 9/2019 H.J. Harkins Company, Inc.