

## **PLAN B ONE-STEP- levonorgestrel tablet**

### **A-S Medication Solutions**

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## **Plan B One-Step®**

### ***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 silicon dioxide, corn starch, lactose monohydrate, magnesium stearate, potato starch, talc

### **Questions?**

Call **1-800-330-1271** or visit [www.PlanBOneStep.com](http://www.PlanBOneStep.com)

Distributed by:  
Foundation Consumer Healthcare, LLC. (FCH)  
Pittsburgh, PA 15205

### **HOW SUPPLIED**

Product: 50090-5978

NDC: 50090-5978-0 1 TABLET in a BLISTER PACK / 1 in a BOX, UNIT-DOSE

### **levonorgestrel**



## PLAN B ONE-STEP

levonorgestrel tablet

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:50090-5978(NDC:69536-162)
<b>Route of Administration</b>	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

<b>Color</b>	WHITE	<b>Score</b>	no score
<b>Shape</b>	ROUND	<b>Size</b>	8mm
<b>Flavor</b>		<b>Imprint Code</b>	G00
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date

<b>1</b>	NDC:50090-5978-0	1 in 1 BOX, UNIT-DOSE	05/05/2022	
<b>1</b>		1 in 1 BLISTER PACK; Type 0: Not a Combination Product		
<b>Marketing Information</b>				
<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>		<b>Marketing Start Date</b>	<b>Marketing End Date</b>
NDA	NDA021998		05/10/2018	

**Labeler** - A-S Medication Solutions (830016429)

<b>Establishment</b>			
<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
A-S Medication Solutions		830016429	RELABEL(50090-5978)

Revised: 10/2023

A-S Medication Solutions