# NEXT CHOICE ONE DOSE- levonorgestrel tablet Foundation Consumer Healthcare LLC

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Next Choice One Dose®

**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 **1-888-919-0780** 

Manufactured by:

Gedeon Richter, Ltd, Budapest, Hungary

### PRINCIPAL DISPLAY PANEL - 1.5 mg Tablet Blister Pack Box

NDC 69536-133-88

One Tablet, One Dose

Next Choice

ONE DOSE®

Levonorgestrel 1.5 mg

**Emergency Contraceptive** 

Reduces the chance of pregnancy after unprotected sex.

Not for regular birth control.

1

Tablet

Levonorgestrel 1.5 mg

NDC 69536-133-88

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# Next Choice ONE DOSE®

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# **Emergency Contraceptive**

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Use for women to reduce chance of pregnancy after



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One Tablet, One Dose

One Tablet, One Dose

Next Choice

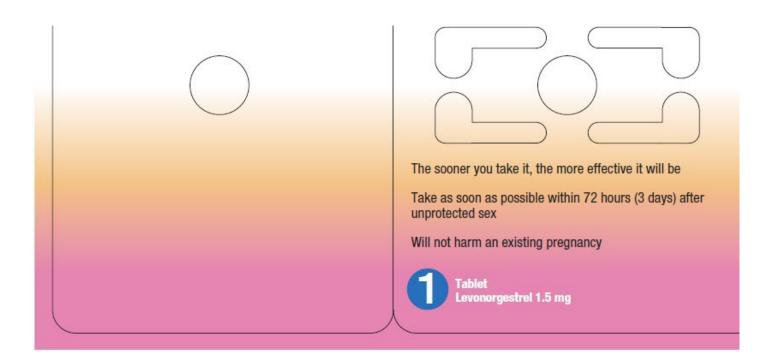
**Emergency Contraceptive** 

Levonorgestrel 1.5 mg

Next Choice

Levonorgestrel 1.5 mg

Emergency Contraceptive



## **NEXT CHOICE ONE DOSE**

levonorgestrel tablet

| Product Information     |                |                    |               |
|-------------------------|----------------|--------------------|---------------|
| Product Type            | HUMAN OTC DRUG | Item Code (Source) | NDC:69536-133 |
| Route of Administration | ORAL           |                    |               |

# **Active Ingredient/Active Moiety**

| Ingredient Name               |                                | Basis of Strength | Strength       |  |
|-------------------------------|--------------------------------|-------------------|----------------|--|
| LEVONORGE CERTICAL CONTRACTOR | FIATCHATIATIAN ALEXANDESCENTED |                   | LEVONOBOECEDEL |  |

**LEVONORGESTREL** (UNII: 5W7SIA7YZW) (LEVONORGESTREL - UNII:5W7SIA7YZW) LEVONORGESTREL 1.5 mg

| Inactive Ingredients                   |          |  |  |
|--|----------|--|--|
| Ingredient Name                        | Strength |  |  |
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4)     |          |  |  |
| STARCH, POTATO (UNII: 81089SAH3T)      |          |  |  |
| 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 | G00      |  |
| Contains                |       |              |          |  |
|                         |       |              |          |  |

| Packaging |                      |  |                         |                       |
|-----------|----------------------|--|-------------------------|-----------------------|
| #         | Item Code            | Package Description                                    | Marketing Start<br>Date | Marketing End<br>Date |
| 1         | NDC:69536-133-<br>88 | 1 in 1 BOX, UNIT-DOSE                                  | 06/15/2019              |                       |
| 1         |                      | 1 in 1 BLISTER PACK; Type 0: Not a Combination Product |                         |                       |

| Marketing Information     |   |                         |                       |
|---------------------------|---|-------------------------|-----------------------|
| Marketing<br>Category     | Application Number or Monograph<br>Citation | Marketing Start<br>Date | Marketing End<br>Date |
| NDA AUTHORIZED<br>GENERIC | NDA021998                                   | 06/15/2019              |                       |
|                           |   |                         |                       |

# **Labeler -** Foundation Consumer Healthcare LLC (079675882)

Revised: 2/2023 Foundation Consumer Healthcare LLC