

**JULIE- levonorgestrel tablet**  
**Julie Products, Inc**

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**Julie™**

**(Levonorgestrel Tablet, 1.5 mg)**

**Emergency Contraceptive**

***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
- nausea
- lower stomach (abdominal) pain
- tiredness
- headache
- dizziness
- breast pain
- vomiting

## **Keep out of reach of children.**

In case of overdose, get medical help or contact a Poison Control center right away at 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**
- **do not use if carton is open or blister seal is broken or missing**
- store at 20° to 25°C (68° to 77°F)

### ***Inactive ingredients***

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

### ***Questions or comments?***

**Call 1-888-213-1399. Monday- Friday 9 AM- 6 PM EST.**

Julie Products, Inc.,  
New York 10013

Product made in Germany

NDC 82791-332-01

Rev. May 2023

### ***Patient Information***

**Julie™**

**LEVONORGESTREL TABLET 1.5 MG**

- **Emergency Contraceptive**
- **One Tablet. One Step.**
- **What You Need To Know**

### **What is Julie™?**

Julie™ is emergency contraception that helps prevent pregnancy after birth control failure or unprotected sex. It is a **backup** method of preventing pregnancy and should not be used as regular birth control.

**What Julie™ is not.**

Julie™ will not work if you are already pregnant and will not affect an existing pregnancy. Julie™ will not protect you from HIV infection (the virus that causes AIDS) and other sexually transmitted diseases (STDs).

### **When should I use Julie™?**

The sooner you take emergency contraception, the better it works. You should use Julie™ within 72 hours (3 days) **after you have had unprotected sex.**

Julie™ is a backup or emergency method of birth control you can use when:

- your regular birth control was used incorrectly or failed
- you did not use any birth control method

### **When not to use Julie™.**

Julie™ should not be used:

- as a regular birth control method, because it's not as effective as regular birth control.
- if you are already pregnant, because it will not work.
- if you are allergic to levonorgestrel or any other ingredients in Julie™.

### **When should I talk to a doctor or pharmacist?**

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 Julie™ and increase your chance of becoming pregnant. Your doctor may prescribe another form of emergency contraception that may not be affected by these medications.

### **How does Julie™ work?**

Julie works before release of an egg from the ovary. As a result, Julie usually stops or delays the release of an egg from the ovary. Julie is one tablet that contains a higher dose of levonorgestrel than birth control pills and works in a similar way to prevent pregnancy.

### **How can I get the best results from Julie™?**

You have 72 hours (3 days) to try to prevent pregnancy after birth control failure or unprotected sex. **The sooner you take Julie™, the better it works.**

### **How effective is Julie™?**

If Julie™ is taken as directed, it can significantly decrease the chance that you will get pregnant. About 7 out of every 8 women who would have gotten pregnant will not become pregnant.

### **How will I know Julie™ worked?**

You will know Julie™ has been effective when you get your next period, which should come at the expected time, or within a week of the expected time. If your period is delayed beyond 1 week, it is possible you may be pregnant. You should get a pregnancy test and follow up with your healthcare professional.

### **Will I experience any side effects?**

- some women may have changes in their period, such as a period that is heavier or

lighter or a period that is early or late. **If your period is more than a week late, you may be pregnant.**

- if you have severe abdominal pain, you may have an ectopic pregnancy, and should get immediate medical attention.
- when used as directed, Julie™ is safe and effective. Side effects may include changes in your period, nausea, lower stomach (abdominal) pain, tiredness, headache, dizziness, and breast tenderness.
- if you vomit within 2 hours of taking the medication, call a healthcare professional to find out if you should repeat the dose.

### **What if I still have questions about Julie™ ?**

If you have questions or need more information, call our toll free number, 1-888-213-1399. Monday- Friday 9 AM- 6 PM EST.

### **Other Information**

#### **Keep out of reach of children:**

In case of overdose, get medical help or contact a Poison Control Center right away at 1-800-222-1222.

#### **Do not use if the blister seal is opened.**

Store at room temperature 20°-25°C (68° to 77°F).

**Active ingredient:** levonorgestrel 1.5 mg

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

**If you are sexually active, you should see a healthcare provider for routine checkups. Your healthcare provider will talk to you about and, if necessary, test you for sexually transmitted diseases, teach you about effective methods of routine birth control, and answer any other questions you may have.**

#### **Manufactured for:**

Julie Products, Inc.,  
New York 10013

Product made in Germany

NDC 82791-332-01

Rev. May 2023

### **PACKAGE LABEL.PRINCIPAL DISPLAY PANEL**

Julie™

Levonorgestrel Tablet 1.5 mg

Emergency Contraceptive

Reduces chance of pregnancy after unprotected sex.

Not for regular birth control.

ONE TABLET. ONE STEP.

Contains 1 levonorgestrel tablet



## JULIE

levonorgestrel tablet

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:82791-332
<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
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<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>STARCH, CORN</b> (UNII: O8232NY3SJ)	
<b>LACTOSE MONOHYDRATE</b> (UNII: EWQ57Q8I5X)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>FD&amp;C YELLOW NO. 6</b> (UNII: H77VEI93A8)	

### Product Characteristics

<b>Color</b>	orange (Light peach)	<b>Score</b>	no score
<b>Shape</b>	ROUND	<b>Size</b>	8mm
<b>Flavor</b>		<b>Imprint Code</b>	17
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:82791-332-01	1 in 1 CARTON	12/27/2022	
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	ANDA202380	12/27/2022	

**Labeler** - Julie Products, Inc (118628472)

**Registrant** - Naari Pte. Limited (659345996)

### Establishment

Name	Address	ID/FEI	Business Operations
Haupt Pharma Muenster GmbH		344172564	analysis(82791-332) , manufacture(82791-332) , pack(82791-332)

Revised: 5/2023

Julie Products, Inc