

REACT- levonorgestrel tablet
Wockhardt USA, LLC

React™

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

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.

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 20-25°C (68-77°F)

Inactive ingredients

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

Questions or comments

Call 1-800-346-6854, or

Visit our Web site at www.ReactContraceptive.com

React™

Levonorgestrel Tablet 1.5 mg

Emergency Contraceptive

One Tablet. One Dose

What You Need to Know

What is React™?

React™ 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 React™ is not.

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

When should I use React™?

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

React™ 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 React™.

React™ 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 React™.

How does React™ work?

React™ is one tablet with levonorgestrel, a hormone that has been used in many birth control pills for several decades. React™ contains a higher dose of levonorgestrel than birth control pills, but works in

a similar way to prevent pregnancy. It works mainly by stopping the release of an egg from the ovary. It is possible that React™ may also work by preventing fertilization of an egg (the uniting of sperm with the egg) or by preventing attachment (implantation) to the uterus (womb).

How can I get the best results from React™?

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

How effective is React™?

If React™ 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 React™ worked?

You will know React™ 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, React™ 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 React™?

If you have questions or need more information, call our toll-free number, 1-800-346-6854 or visit our website at www.ReactContraceptive.com.

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 (68–77°F).

Active ingredient: levonorgestrel 1.5 mg

Inactive ingredients: colloidal silicon dioxide, corn starch, lactose monohydrate, magnesium stearate, povidone, talc

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.

Distributed by:
Wockhardt USA LLC
Parsippany, NJ 07054, USA

Manufactured by
Lotus Pharmaceutical Co., Ltd. Nantou Plant

No. 30 Chenggong 1st Rd., Sinsing Village, Nantou City, Nantou County 54066, Taiwan
20050
Rev. 05/2016

PRINCIPAL DISPLAY PANEL - 1 Tablet Blister Pack Carton

Over the Counter
NDC-64679-050-02

React™

levonorgestrel
1.5 mg tablet

emergency contraceptive

Reduces chance of
pregnancy after
unprotected sex.
Not for regular birth control.

**Compare to*
Plan B One Step®
Active ingredient

Actual Size

One Tablet.
One Dose.

Contains 1 Tablet 1.5mg

emergency contraceptive
One Tablet. One Dose.

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React™

emergency contraceptive
One Tablet. One Dose.

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React™



Void of Color and Aqueous



**One Tablet.
One Dose.**

The sooner you take it, the more effective it will be

Take as soon as possible within 72 hours (3 days) after unprotected sex

Will not harm an existing pregnancy



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05/2016

5-50-0050-02

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*This product is not manufactured nor distributed by Teva Pharmaceuticals, distributor of Plan B One Step. Registered trademarks are held by respective owners

Drug Facts

Active Ingredient

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www.ReactContraceptive.com

Void of Color and Aqueous



REACT

levonorgestrel tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:646 79-050
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)	
Lactose Monohydrate (UNII: EWQ57Q8I5X)	
Magnesium Stearate (UNII: 70097M6I30)	
Povidones (UNII: FZ989GH94E)	
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:64679-050-02	1 in 1 CARTON	04/13/2016	
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	ANDA202246	04/13/2016	

Labeler - Wockhardt USA, LLC (170508365)

Revised: 7/2016

Wockhardt USA, LLC