

FALLBACK SOLO- levonorgestrel tablet
LUPIN LIMITED

Fallback Solo™
(levonorgestrel) Tablet, 1.5 mg

Fallback Solo™
(levonorgestrel) Tablet, 1.5 mg

Drug Facts

Active Ingredient

Levonorgestrel USP 1.5 mg

Purpose

Emergency contraceptive

Indications

Use for women 17 years of age and older 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

This package is not child resistant. Keep this and all medication out of the reach of children.

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

Directions

- **women 17 years of age and older:**
 - **take tablet 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).
- **tablet is enclosed in wallet seal. Do not use if the wallet seal is broken .**
- store at 25°C (77°C); excursions permitted to 15 to 30°C (59 to 86°C) [see USP Controlled Room temperature].

Inactive Ingredients

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

Questions or comments ?

For more information call **1800-399-2561** or visit our website at www.birthcontrolhealth.com.

Fallback Solo™

(levonorgestrel) Tablet, 1.5 mg

Emergency Contraceptive

One Tablet. One Dose.

What You Need to Know

What is Fallback Solo™?

Fallback Solo™ 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 Fallback Solo is not.

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

When should I use Fallback Solo?

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

Fallback Solo 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 Fallback Solo?

Fallback Solo 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 Fallback Solo.

How does Fallback Solo work?

Fallback Solo is one tablet with levonorgestrel, a hormone that has been used in many birth control pills for several decades. Fallback Solo 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 Fallback Solo 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 Fallback Solo?

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

How effective is Fallback Solo?

If Fallback Solo 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 Fallback Solo worked?

You will know Fallback Solo 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, Fallback Solo 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 Fallback Solo?

If you have questions or need more information, call our toll-free number, 1800-399-2561 or visit our website at www.birthcontrolhealth.com.

Other Information

Keep this and all medication 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 wallet seal is opened.

Store at 25°C (77°F); excursions permitted to 15 to 30°C (59 to 86°F). [see USP Controlled Room Temperature].

Active Ingredient: levonorgestrel 1.5 mg

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

Fallback Solo™ is a trademark of Lupin Pharmaceuticals, Inc.

Distributed By:

Lupin Pharmaceuticals, Inc.

Baltimore, Maryland 21202

United States

Manufactured by:

Lupin Limited

Pithampur (M.P.) - 454 775

INDIA

June 2014

ID#: 231975

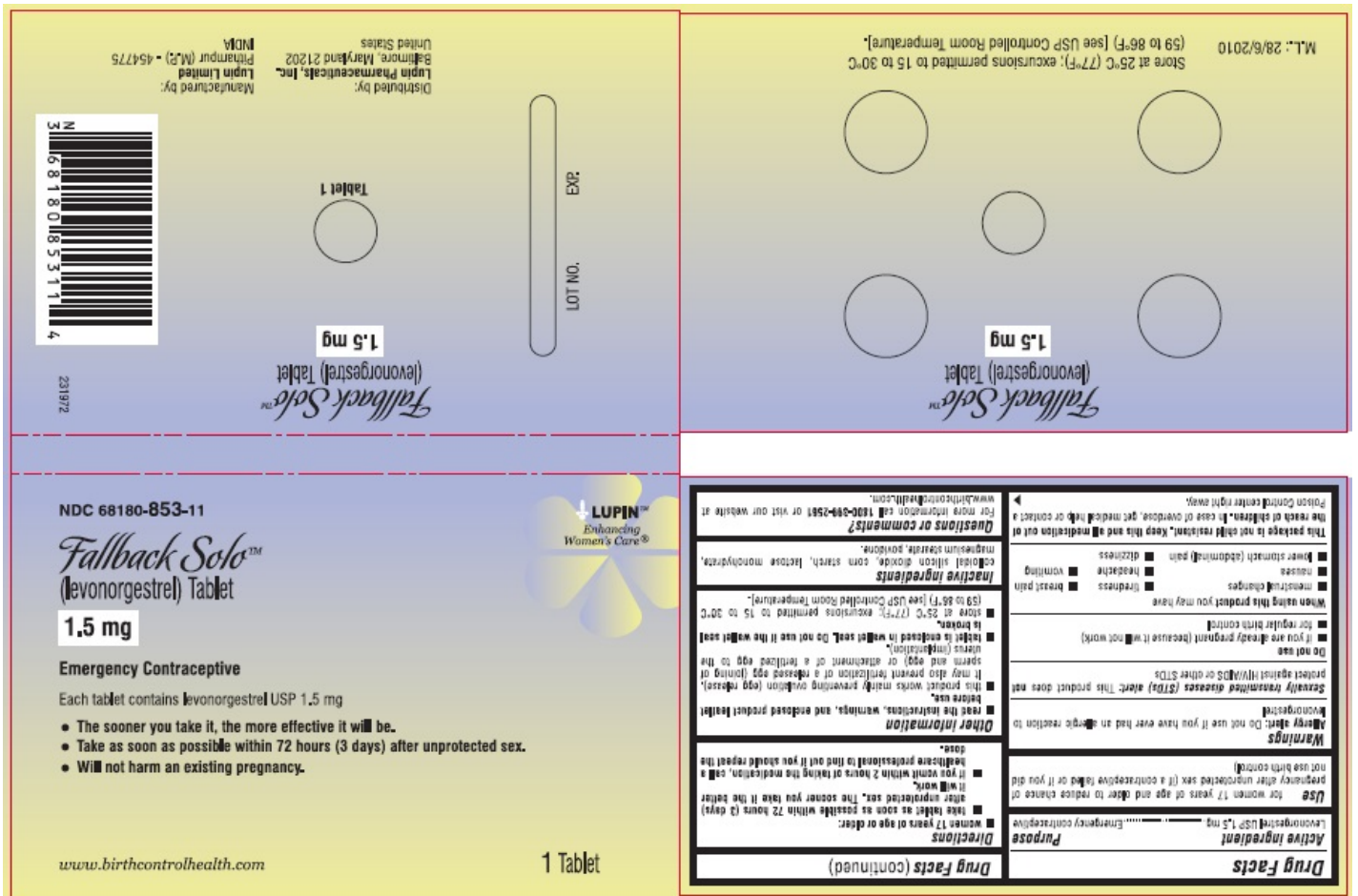
If you are sexually active, you should see a healthcare provider for routine checkups. Your healthcare provider will talk to you about and, if necessary, test you for sexually transmitted diseases, teach you about effective methods of routine birth control, and answer any other questions you may have.

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

Fallback Solo™ (levonorgestrel) Tablet, 1.5 mg

NDC 68180-853-11

Wallet Label: 1 Tablet



Fallback Solo™ (levonorgestrel) Tablet, 1.5 mg

NDC 68180-853-13

Carton Label: 1 Tablet

Drug Facts

Active ingredient
Levonorgestrel USP 1.5 mg.....Emergency contraceptive

Purpose
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Warnings
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Sexually transmitted diseases (STDs) alert: This product does not protect against HIV/AIDS or other STDs

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When using this product you may have

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- nausea
- menstrual changes
- tiredness
- breast pain
- vomiting
- headache
- dizziness

Questions or comments?
For more information call 1800-399-2561 or visit our website at www.birthcontrolhealth.com.

Other information

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- this product works mainly 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).
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- store at 25°C (77°F); excursions permitted to 15 to 30°C (59 to 86°F) [see USP Controlled Room Temperature].

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

Directions

- women 17 years of age or older:
- take tablet 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 of taking the medication, call a healthcare professional to find out if you should repeat the dose.

Drug Facts (continued)

LOT NO.
EXP.

NDC 68180-853-13
Fallback Solo[™]
(levonorgestrel) Tablet
1.5 mg

Each tablet contains levonorgestrel USP 1.5 mg.
Store at 25°C (77°F); excursions permitted to 15 to 30°C (59 to 86°F). [see USP Controlled Room Temperature]

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NDC 68180-853-13
Fallback Solo[™]
(levonorgestrel) Tablet

1.5 mg

LUPIN[™]
Enhancing Women's Care[®]

One Tablet
One Dose

Emergency Contraceptive

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

www.birthcontrolhealth.com

1 Tablet

NDC 68180-853-13
Fallback Solo[™]
(levonorgestrel) Tablet
1.5 mg

Distributed by:
Lupin Pharmaceuticals, Inc. Lupin Limited
Baltimore, Maryland 21202 Pithampur (M.P.) - 454775, INDIA
United States M.L.: 28/6/2010



NDC 68180-853-13
Fallback Solo[™]
(levonorgestrel) Tablet
1.5 mg

LUPIN[™]
1 Tablet

FALLBACK SOLO
levonorgestrel tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:57297-853	
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	
	COLLOIDAL SILICON DIOXIDE (UNII: ETJ7Z6XBU4)			
	LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)			
	MAGNESIUM STEARATE (UNII: 70097M6I30)			
	POVIDONE K30 (UNII: U725QWY32X)			
	STARCH, CORN (UNII: O8232NY3SJ)			
Product Characteristics				
Color	WHITE (white to off white)	Score	no score	
Shape	ROUND (round biconvex)	Size	9mm	
Flavor		Imprint Code	LU;S25	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:57297-853-13	1 in 1 CARTON		
1	NDC:57297-853-11	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	ANDA201446	07/22/2014		

Labeler - LUPIN LIMITED (675923163)

Registrant - LUPIN LIMITED (675923163)

Establishment

Name	Address	ID/FEI	Business Operations
LUPIN LIMITED		650582310	manufacture(57297-853) , pack(57297-853)