

What you should know about Keflex Powder for Oral Suspension 125mg/5ml and 250mg/5ml cefalexin (as monohydrate)

Please read this leaflet carefully before you start to take your medicine. It does not contain all the information about your medicine that you may need to know, so please ask your doctor or pharmacist if you have any questions. This leaflet only applies to Keflex suspension.

What is in your medicine?

Your medicine is called Keflex Powder for Oral Suspension which is a brand of cefalexin. Its active ingredient is cefalexin. The powder is dispersed in water by your pharmacist to form a suspension. Keflex suspension comes in 100 millilitre (ml) bottles of fruit-flavoured liquid, which is red in colour. Each 5ml of the 125mg/5ml Keflex suspension contains 125mg of cefalexin. Each 5ml of the 250mg/5ml Keflex suspension contains 250mg of cefalexin. Keflex suspension also contains water, sucrose, imitation fruit flavouring, allura red AC, sodium laurilsulfate, methylcellulose 15, dimeticone, xanthum gum and pregelatinised starch. Each 5ml spoonful of these medicines contains 3g of sucrose. This should be taken into account in patients with diabetes mellitus.

Keflex is one of a group of antibiotics called cephalosporins. Antibiotics help your body fight infections. Keflex works by destroying certain bacteria that cause infection.

Keflex suspension is made and released onto the market by Facta Farmaceutici SpA, Via Laurentina, Km 24,730 Pomezia 00040, Rome, Italy. The marketing authorisation is held by Flynn Pharma Ltd Alton House, 4 Herbert Street, Dublin 2, Eire.

Why Keflex Suspension?

Keflex treats bacterial infections of the ears, nose and throat. It is also used to treat bronchitis and pneumonia; cystitis, kidney and prostate infections; bone and joint infections; dental abscesses and skin infections such as boils and infected wounds.

Before taking your medicine

Make sure it is safe for you or your child to take Keflex.

If you answer YES to any of the following questions, or you are not sure, tell your doctor or pharmacist.

- Have you ever had a rash or other allergic reaction to antibiotics such as penicillin or cephalosporins, to any other type of medicine, or to any of the ingredients listed above? (An allergic reaction may include a rash, itching, swelling or problems with your breathing.)
- Are you pregnant or could you be?
- Are you breast-feeding?
- Do you have kidney trouble?
- Has your doctor told you that you have an intolerance to some sugars or are you diabetic? (Keflex can interfere with some urine sugar tests.)
- Are you taking any other medicines (for example probenecid or metformin)?

If you need a blood test, tell your doctor you are taking this medicine before you have the test.

Please read the back of this leaflet

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FRONT

**CODICE LAETUS
715/011001100**

IMPIANTO DI PROPRIETÀ DELLA THIS ARTWORK IS PROPERTY OF		PRODOTTI: INS-Keflex 125mg-250mg/5ml (100 ml) os PAESE: FLYNN ROI COUNTRY:		MATTE: MATERIAL: g/m ² : 60 g/sq. est. ANIMA: BOBINA: 70 mm	
Facta Farmaceutici S.p.A.		ETO PUSTELLA: FCT1005	MIS. (mm): 180 x 254	(Falt)	
COD. PRODOTTO: F5100067		BOZZA N.: 02	MEAS. (mm): BOBINA	(Folded)	
COLORE COLOUR		DATA EMISSIONE: 29-01-07	2/S CODE:		
Nero Black			COLORE: Print Sheet	Date	
F 976			INTIRE: Spacing	18-01-07	R1007
				29-01-07	R1002
<small>N.B. per bozze a colori le simulazioni computerizzate. PASTICINI di questa bozza potranno dare effetti diversi rispetto alla stampa finale. VIETATA LA MANOMISSIONE DEGLI IMPIANTI WARNING: Print colour may not reflect true Pantone® colour FILM TAMPERING NOT ALLOWED</small>		<small>IMPIANTO REALIZZATO DA</small> grafifarma <small>ARTWORK REALIZED BY</small> <small>Advertising e Comunicazione</small>		Draft Date 18-01-07 29-01-07 R1007 R1002	SELLA DATA 0.C

What you should know about Keflex suspension - continued

Taking your medicine

- Follow your doctor's instructions. Check the label for how much to take and how often to take it.

Usual doses

- **Children:** The dose will depend on your child's weight. Children aged 5 or over will usually have one 5ml spoonful of the 250mg strength suspension 3 times a day. Children under 5 years old will usually have one 5ml spoonful of the 125mg strength suspension 3 times a day. Occasionally your doctor may tell you to give a larger dose.
- **Adults:** For most infections the dose will be two 5ml spoonfuls of the 250mg suspension 3 times a day.
For less serious infections such as sore throats or cystitis you may be told to take:
 - one spoonful of the 250mg suspension 4 times a day, or
 - 2 spoonfuls of the 250mg suspension twice a day.

Occasionally your doctor may tell you to take more.

If you are not sure how much to take, ask your doctor or pharmacist.

- Shake the bottle well before you take Keflex suspension.
- Your pharmacist may give you a syringe instead of a spoon. It is easier for you to give the right dose to a baby or small child with a syringe. Ask your pharmacist how to use it and make sure that you wash it well after you give each dose.
- Space the doses out as far as possible over 24 hours.
- You must take the medicine for as long as your doctor has told you to. Do not stop taking these doses when you feel better, because you may get worse again.
- If you miss a dose, take one as soon as you can. If you have missed several doses, tell your doctor.
- Do not take more medicine than your doctor tells you to.



If you ever take too much, go to the nearest hospital casualty department or tell your doctor immediately.

While taking your medicine

- This medicine may cause side-effects such as diarrhoea (which may be bloody or have mucus in it), vaginal discharge or itching of the genitals and anus, dizziness or tiredness. Occasionally a child has become hyperactive while taking Keflex. Tell your doctor if you notice any of these effects and they are bothering you.
- If your skin itches or gets red or swollen, or if you have pain in your joints, difficulty breathing or a weak feeling, stop taking the medicine and tell your doctor at once.
- A few patients feel sick or are sick, get indigestion or stomach ache, have headaches or become confused or have other nervous conditions such as feeling agitated. Rarely, tests have shown temporary changes in how the kidneys and liver function (including jaundice, signs of which include yellowing of the skin and the whites of the eyes) and also changes in the numbers of cells in the blood which might cause abnormal bleeding or abnormal bruising. Extremely rarely, patients have had serious allergies affecting their mouth or skin or they have had hallucinations.

If you have these or any other side-effects, tell your doctor. He or she has more information about Keflex and will tell you what to do.

How to store your medicine

- Your pharmacist should not store bottles of Keflex above 25°C and should keep the bottles tightly closed and protected from light. The bottles should be dispensed before the 'Use before' date printed on the carton and bottle.
- You should keep the medicine in the fridge (2°-8°C). After 10 days, throw away any suspension that you haven't used.
- Keep the medicine where children cannot see or reach it.
- If your doctor tells you to stop taking the medicine please take it back to the pharmacist.

Remember: This medicine is for you. Only a doctor can prescribe it for you. Never give it to others. It may harm them, even if their symptoms are the same as yours.

Date this leaflet was written: January 2007.

Keflex is a registered trademark of Eli Lilly and Company Limited.

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BACK

CODICE LAETUS
715/011001100

IMPIANTO DI PROPRIETÀ DELLA THIS ARTWORK IS PROPERTY OF Facta Farmaceutici S.p.A.		PRODOTTO: PRODUCT: INS-Keflex 125mg-250mg/5ml (100 ml) os		MATLLE: MATERIAL: g/m ² : 60	
PAESE: COUNTRY: FLYNN ROI		FTO PUSTELLA: PUNCH SIZE: FCT1005		ANIMA BOBINA: 70 mm	
COD. PRODOTTO: PRODUCT CODE: F5100067		BOZZA N.º: DRAFT N.º: 02		DATA EMISSIONE: ISSUE DATE: 29-01-07	
COLORE COLOUR: Nero Black		MIS. (mm): MEAS. (mm): 180 x 254		CODICE 2/5: 2/5 CODE:	
N.B. per essere a colori: le simulazioni computerizzate FANTONE di questa bozza potranno dare effetti diversi rispetto alla stampa finale. VIETATA LA MANOMISSIONE DEGLI IMPIANTI WARNING: Proof colour may not reflect true Pantone® colour FILM TAMPERING NOT ALLOWED		IMPPIANTO REALIZZATO DA NETWORK REALIZED BY: grafifarma		Draft Date 1- 18-01-07 RI007 2- 29-01-07 RI002 3- 4- 5- 6-	

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Make sure it is safe for you or your child to take Keflex.

If you answer YES to any of the following questions, or you are not sure, tell your doctor or pharmacist.

Have you ever had a rash or other allergic reaction to antibiotics such as penicillin or cephalosporins, to any other type of medicine, or to any of the ingredients listed above? (An allergic reaction may include a rash, itching, swelling or problems with your breathing.)

Are you pregnant or could you be?

Are you breast-feeding?

Do you have kidney trouble?

Has your doctor told you that you have an intolerance to some sugars or are you diabetic? (Keflex can interfere with some urine sugar tests.)

Are you taking any other medicines (for example probenecid or metformin)?

If you need a blood test, tell your doctor you are taking this medicine before you have the test.

Please read the back of this leaflet

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PAESE: COUNTRY: FLYNN ROI		ETO FUSTELLA: PUNCH SIZE: FCT1005		MIS. (mm): MEAS. (mm): 180 x 254 (Flat) BOBINA (Folded)	
COD. PRODOTTO: PRODUCT CODE: F5100067		BOZZA N.º: DRAWING N.º: 02		DATA EMISSIONE: ISSU. DATE: 29-01-07	
COLORE: COLOUR: Nero Black		CODICE 2/5: 2/5 CODE: 19-01-07		Date: 19-01-07	
N.B. per bozze a colori le simulazioni computerizzate PANTONE di questo bozza potranno dare effetti diversi rispetto alla stampa finale. VIETATA LA MANOMISSIONE DEGLI IMPIANTI WARNING: Final colour may not reflect true Pantone® colour FILM TAMPERING NOT ALLOWED		IMPianto REALIZZATO DA: ARTWORK REALIZED BY: grafifarma <small>Immagini e Comunicazione</small>		Date: 19-01-07 RI007 RI002	

What you should know about Keflex Powder for Oral Suspension 125mg/5ml and 250mg/5ml cefalexin (as monohydrate)

What is in your medicine?

Why Keflex Suspension?

Before taking your medicine

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COD. PRODOTTO: PRODUCT CODE: F5100067		BOZZA N. ORAL N.: 02		DATA EMISSIONE: ISSUE DATE: 29-01-07	
COLORE COLOUR: P. 376		CORDO: Fast Size: INTERL. Spacing:		Date 1: 18-01-07 R1007 2: 29-01-07 R1002 3: 4: 5: 6:	
N.B. per bozze a colori: le simulazioni computerizzate FANTONE di questa bozza potranno dare effetti diversi rispetto alla stampa finale. VIETATA LA MANOMISSIOE DEGLI IMPIANTI WARNING: Final colour may not reflect final Pantone® colour FILM TAMPERING NOT ALLOWED				IMPIANTO REALIZZATO DA ARTWORK REALIZED BY grafifarma Immagini e Comunicazione	

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Usual doses

Children: The dose will depend on your child's weight. Children aged 5 or over will usually have one 5ml spoonful of the 250mg strength suspension 3 times a day.

Children under 5 years old will usually have one 5ml spoonful of the 125mg strength suspension 3 times a day. Occasionally your doctor may tell you to give a larger dose.

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ETO FUSTELLA: PUNCH SIZE: FCT1005		(Flat) (Folded) BOBINA			
COD. PRODOTTO PRODUCT CODE: F510067		BOZZA N. DRAFT N.: 02		DATA EMISSIONE ISSUE DATE: 29-01-07	
COLORE COLOUR: Nero Black		CODICE 2/3 2/3 CODE: 18-01-07		Date 18-01-07	
		COLORE FUSTELLA INTERE: Spacing: 29-01-07		Date R007 R002	
N.B. per bozze a colori, le simulazioni computerizzate (PANTONE) di questo bozza potranno dare effetti diversi rispetto alla stampa finale. VIETATA LA MANOMISSIONE DEGLI IMPIANTI WARNING: Proof colour may not reflect true Pantone® colour FILM TAMPERING NOT ALLOWED					
				IMPIANTO REALIZZATO DA ARTWORK REALIZED BY grafifarma Designing e Comunicazione	

What you should know about Keflex suspension - continued

Taking your medicine

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While taking your medicine

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How to store your medicine

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<small>PAESE: COUNTRY:</small>		<small>FLYNN ROI</small>		<small>g/m²: g/sq. mt:</small> 60	
<small>ETO FUSTELLA: PUNCH SIZE:</small> FCT1005		<small>MIS. (mm): MEAS. (mm):</small> 180 x 254		<small>(Flat) (Folded)</small> BOBINA	
<small>ANIMA BOBINA:</small> 70 mm		<small>CODICE 2/3: 2/3 CODE:</small>		<small>Date</small>	
<small>COD. PRODOTTO: PRODUCT CODE:</small> F5100067		<small>BOZZA N. DRAFT N.:</small> 02		<small>DATA EMISSIONE ISSUE DATE:</small> 29-01-07	
<small>COLORE COLOUR</small>		<small>P. 376</small>		<small>CORPO: Front Size:</small>	
<small>INTERI: Spacing:</small>		<small>1:</small> 18-01-07 R1007		<small>2:</small> 29-01-07 R1002	
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<small>6:</small>		<small>6:</small>		<small>6:</small>	
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