



Package leaflet: Information for the user
Flucloxacillin 250 mg and 500 mg Capsules

flucloxacillin sodium

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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2. What you need to know before you take Flucloxacillin Capsules
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1. What Flucloxacillin Capsules are and what they are used for

Flucloxacillin is an antibiotic used to treat infections by killing the bacteria that can cause them. It belongs to a group of antibiotics called “penicillins”.

Flucloxacillin Capsules are used to treat:

- chest infections
- throat or nose infections
- ear infections
- skin and soft tissue infections
- heart infections
- bone and joint infections
- meningitis
- digestive system infections
- blood infections
- kidney, bladder or urethra (the tube which carries urine from the bladder) infections

Flucloxacillin Capsules may also be used to prevent infections during major surgery, particularly heart or orthopaedic surgery.

2. What you need to know before you take Flucloxacillin Capsules

Do not take Flucloxacillin Capsules:

- If you are allergic to flucloxacillin or any other penicillin antibiotics (see symptoms in section 4).
- If you are allergic to any of the other ingredients of this medicine (listed in section 6).
- If you have suffered previously from liver problems (e.g. jaundice) after taking flucloxacillin.
- If you have had an allergic reaction to β -lactam antibiotics (e.g. penicillins, cephalosporins).

Warnings and precautions

Talk to your doctor or pharmacist or nurse before taking Flucloxacillin Capsules:

- If you suffer from kidney problems, as you may require a lower dose than normal (convulsions may occur very rarely in patients with kidney problems who take high doses)
- If you suffer from liver problems, as this medicine could cause them to worsen
- If you are 50 years of age or older
- If you have other serious illnesses (apart from the infection this medicine is treating)
- If you are taking this medicine for a long time as regular tests of liver and kidney function are advised
- If you are on a sodium-restricted diet.
- If you are giving this medicine to a newborn child.
- If you are taking or will be taking paracetamol

There is a risk of blood and fluid abnormality (high anion gap metabolic acidosis) which occurs when there is an increase in plasma acidity, when flucloxacillin is used concomitantly with paracetamol, particularly in certain groups of patients at risk, e.g. patients with severe renal impairment, sepsis or malnutrition, especially if the maximum daily doses of paracetamol are used. High anion gap metabolic acidosis is a serious disease that must have urgent treatment.

The use of flucloxacillin, especially in high doses, may reduce the potassium levels in the blood (hypokalaemia). Your doctor may measure your potassium levels regularly during the therapy with higher doses of flucloxacillin.

Other medicines and Flucloxacillin Capsules

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. Especially:

- probenecid or sulfinpyrazone (used to treat gout)
- methotrexate (a chemotherapy drug)
- oral typhoid vaccine (antibiotics can make this less effective)
- sugammadex (used with general anaesthetics)
- piperacillin (an antibiotic taken by injection)
- warfarin (medicine to prevent blood clotting)
- paracetamol
- other antibiotics (used to treat infections)
- voriconazole (used against fungal infections)

Pregnancy, breast feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Tests

Regular monitoring of liver and kidney function should be performed whilst taking Flucloxacillin Capsules.

Tell your doctor that you are taking Flucloxacillin if you are having urine tests or blood tests because Flucloxacillin may affect the results.

Driving and using machines

Flucloxacillin Capsules should not affect your ability to drive or operate machinery.

Flucloxacillin Capsules contain sodium

For 250mg capsules:

This medicine contains less than 1 mmol sodium (23 mg) per dosage unit, that is to say essentially ‘sodium-free’.

For 500mg capsules:

This medicine contains 26.33 mg sodium (main component of cooking/table salt) in each dosage unit. This is equivalent to 1.32% of the recommended maximum daily dietary intake of sodium for an adult.

3. How to take Flucloxacillin Capsules

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Take this medicine when your stomach is empty. This means an hour before food or 2 hours after food. To reduce the risk of pain in your oesophagus (the tube that connects your mouth with your stomach) swallow capsules with a full glass of water (250 ml) and do not lie down immediately after taking your capsules.

It is important that you take your medicine at the right times.

The recommended dose is:

The dose will depend on the patient and will be decided by your doctor. However, the usual doses for each age group are:

Adults (including elderly) - one 250 mg capsule four times a day, your doctor may prescribe a different dose for severe infections.

- Joint infections (osteomyelitis) or heart infections (endocarditis) - up to 8g daily in divided doses, six to eight hourly.
- To prevent infection due to surgery - 1 to 2g by injection into a vein, at the same time as the anaesthetic, followed by 500mg six hourly either by mouth or injection into a vein or muscle for up to 72 hours.





Use in children and adolescents

- Children aged 10-18 years - 250mg four times daily.
- Children aged 2-10 years: 125mg four times daily.
- Children under 2 years: 62.5mg four times daily.
- Premature or babies less than 4 weeks old: Not recommended.
- Severe kidney disease: your doctor may reduce your dose.

If you still feel unwell after finishing the treatment, speak to your doctor.

If you take more Flucloxacillin Capsules than you should

If you (or someone else) swallow a lot of capsules at the same time, or you think a child may have swallowed any contact your nearest hospital casualty department or tell your pharmacist or doctor immediately. Symptoms of an overdose include feeling or being sick and diarrhoea.

If you forget to take Flucloxacillin Capsules

Do not take a double dose to make up for a forgotten dose. If you forget to take a dose take it as soon as you remember it and carry on as before, try to wait about four hours before taking the next dose.

If you stop taking Flucloxacillin Capsules

Do not stop treatment early because some bacteria may survive and cause the infection to come back.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Stop taking Flucloxacillin Capsules and contact your doctor at once if you experience any of the following:

- hypersensitivity or severe allergic reaction including itchy rash, itching, sore mouth or eyes, swelling of the face, lips, throat or tongue or breathing problems.
- severe bloody diarrhoea (pseudomembranous colitis).
- jaundice (yellow colour in the skin and white of the eyes), hepatitis (liver inflammation) - sometimes these effects on the liver can be delayed for up to 2 months after finishing treatment
- severe skin rash with flushing, fever, blisters or ulcers (Stevens-Johnson syndrome)
- severe rash with reddening, peeling and swelling of the skin that looks like a burn (toxic epidermal necrolysis).
- changes in numbers of blood cells (causing unexplained bleeding, bruising or skin discolouration),

Tell your doctor if you notice any of the following side effects or notice any other effects not listed:

Common (occurs in less than 1 in 10 users): minor stomach disturbances e.g. stomach upset or diarrhoea

Very rare (Occurs in less than 1 in 10,000 people): inflammation of the kidney, anaemia, skin rash with circular, red patches (Erythema multiforme). Joint or muscle pain or fever, may develop after 2 days or more from the start of treatment with Flucloxacillin Capsules. Very rare cases of blood and fluid abnormality (high anion gap metabolic acidosis) which occurs when there is an increase in plasma acidity, when flucloxacillin is used concomitantly with paracetamol, generally in the presence of risk factors (see section 2).

Some of these reactions can be delayed for up to two months after finishing the treatment.

Not known (frequency cannot be estimated from the available data)

Serious skin reactions - A red, scaly rash with bumps under the skin and blisters (exanthematous pustulosis). Contact a doctor immediately if you get any of these symptoms.

- Low potassium levels in the blood (hypokalaemia), which can cause muscle weakness, twitching or abnormal heart rhythm.
- Pain in oesophagus (the tube that connects mouth with stomach) and other related symptoms, such as difficulties in swallowing, heartburn, throat irritation or chest pain.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: <http://www.mhra.gov.uk/yellowcard> or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Flucloxacillin Capsules

Keep this medicine out of the sight and reach of children.

Do not use Flucloxacillin Capsules after the expiry date which is stated on the carton or label. The expiry date refers to the last day of that month.

Do not store above 25°C. Store in the original pack.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Flucloxacillin Capsules contain

- The active substance is flucloxacillin sodium. Each capsules contain either 250mg or 500mg of the active ingredient.
- The other ingredients are colloidal anhydrous silica, magnesium stearate, gelatin, black iron oxide (E172), titanium dioxide (E171), iron oxide red (E172), iron oxide yellow (E172). The white ink contains titanium dioxide (E171), Shellac, Tween 80.

What Flucloxacillin Capsules look like and contents of the pack

Flucloxacillin 250 mg Capsules are caramel body and black cap printed with the words 'FLU250MIL'

Flucloxacillin 500 mg Capsules are caramel body and black cap with the words 'FLU500MIL'

Flucloxacillin 250 mg Capsules are available in blister packs containing 28 Capsules. Flucloxacillin 500 mg Capsules are available in blister packs containing 20 or 28 Capsules

Marketing Authorisation Holder and Manufacturer:

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POM

This leaflet was last revised in May 2025

**To request a copy of this leaflet in large print please call,
0208 831 1580 (UK only)**

Please be ready to give the following information:

Product name	Reference number
Flucloxacillin 250mg Capsules	PL 21880/0017
Flucloxacillin 500mg Capsules	PL 21880/0018



Colours:

 Red 032 C

 Black

Font Type & Size	Times NR - Bold
	Heading - 12 pts
	Body - 9 pts
Version	V-3

Unit 1 & 8

MEDREICH LIMITED				Title: Art Work Approval Form			
Product	Flucloxacillin Capsules - 250mg & 500mg - S/L - English - PIL SAP Descr: FLUCLOXACILLIN CAPS PIL S/L ENG WOA-MDUK			Specification:	Printed on 56 - 60 GSM Maplitho Paper.		
Customer	MEDREICH PLC, UK						
Reason for Issue	AWR No.: 1000AW2510104/105 Old Code: 1227090-V1 a) Revision of text from customer b) Revised leaflet instructions to include for the information if Capsules stuck in throat			Colours:	2 - Red 032 C and Black		
Related FG Codes	1301899 / 1301900 / 1303456 / 1304385	Pharmacode No.	3594	Dimensions:	285 x 190 mm (Open size) to be packed in auto cartonator		
Item Code	1229284-V1	Blister Layout No.	RPE Ultra 600 20171185-22B	No. of Folds (only for PIL)	NA	Artwork made to	100%
		Carton Layout No.	NA				
		PIL Layout No.	NA				
Verified By				Approved By			
PDC:		PDC:		Regulatory:		CQA:	