



PATIENT INFORMATION LEAFLET: INFORMATION FOR THE USER

RONAKFLUCLOX DS SUSPENSION (Flucloxacillin Oral Solution BP 250 mg/5 ml)

Read all of this leaflet carefully before you start RONAKFLUCLOX DS SUSPENSION using

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your health care provider.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects becomes serious, or if you notice any side effects not listed in this leaflet, please tell your health care provider.

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1. What RONAKFLUCLOX DS SUSPENSION is and what it is used for
2. Before you take RONAKFLUCLOX DS SUSPENSION
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4. Possible side effects
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1. WHAT RONAKFLUCLOX DS SUSPENSION AND WHAT IT IS USED FOR

Flucloxacillin sodium belongs to a class of antibiotics called “penicillinase-resistant penicillins” and is used to treat bacterial infections including:

- Skin and soft tissue infections
- Boils, abscesses, carbuncles (A painful localized bacterial infection of the skin and subcutaneous tissue that usually has several openings through which pus is discharged)
- Cellulitis (inflammation of tissue below the skin)
- Infected wounds, infected burns
- Protection for skin grafts
- Infected skin condition e.g. ulcer, eczema and acne
- Furunculosis, (A skin condition characterized by the development of recurring boils)
- Impetigo (a contagious skin disease, esp. of children, usually caused by streptococcal bacteria, marked by a superficial pustular eruption, particularly on the face)
- Respiratory tract infections
- Pneumonia (inflammation of the lungs with congestion), lung abscess, empyema (a collection of pus in a body cavity, especially in the lung cavity)
- Sinusitis (inflammation of a sinus or the sinuses)
- Pharyngitis (inflammation of the mucous membrane of the pharynx; sore throat)
- Tonsillitis (inflammation of the tonsils).
- Otitis media (inflammation of the middle ear)
- Otitis Externa (Inflammation of the external auditory canal)

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- Quinsy (tonsillar abscess)
- Other infections
- Osteomyelitis (affecting the bone and bone marrow)
- Enteritis (affecting the intestinal tract, especially the small intestine)
- Endocarditic (inflammation of the lining of the heart and its valves)
- Urinary tract infections
- Meningitis (a serious disease characterised by inflammation of the membranes around the brain or spinal cord)
- Septicaemia (blood poisoning). Flucloxacillin can also be used to prevent infections during major surgery, particularly heart or orthopaedic surgery.

2. BEFORE YOU TAKE RONAFLUCLOX DS SUSPENSION

Do not take this medicine if you:

- Are allergic (hypersensitive) to penicillins/ flucloxacillin sodium or any of the other ingredients in the product.

Have previous history of liver problems from taking flucloxacillin.

- Have had an allergic reaction to β -lactam antibiotics (e.g. penicillins, cephalosporins). Warnings and precautions Talk to your doctor or pharmacist before taking this medicine 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)
- suffer from liver problems
- are 50 years of age or older
- have other serious illness (apart from the infection this medicine is treating)
- 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.

Other medicines and Flucloxacillin Powder For Oral Solution Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

- Probenecid (used in the treatment of gout)
- Other antibiotics (used to treat infections)
- 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)
- Sulfinpyrazone (used in the treatment of gout) Some medicines may affect the way others work.

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





medicines. This means medicines you have bought yourself as well as medicines on prescription from a doctor. Taking this medicine with food and drink The solution should be taken half to one hour before meals. Pregnancy and breast-feeding This medicine should only be used by pregnant women if considered essential by doctor. Flucloxacillin passes into breast milk. 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 for a long period of time. Tell your doctor that you are taking flucloxacillin if you are having urine tests or blood tests because it may affect the results. Driving and using machines This medicine is not expected to affect your ability to drive or operate machinery.

3. HOW TO TAKE YOUR MEDICINE

Always take your medicine exactly as your doctor or pharmacist has told you. Their directions may differ from the information contained in this leaflet. The pharmacist's label should tell you how much to take and how often. Check with your doctor or pharmacist if you are not sure. How much of your medicine to take and when to take it The dose will depend on the patient and will be decided by your doctor. However, the usual doses for each age group are –

Adults and children over 10 years: 10ml four times a day Children 2-10 years: 5ml four times a day. Flucloxacillin Oral Solution is not recommended for premature or babies less than four weeks old. Children under 2 years: 2.5ml four times a day. Endocarditis or Osteomyelitis: up to 320ml daily in divided doses six to eight hourly.

Severe kidney disease: your doctor may reduce your dose, the maximum dose in adults is 1g every 8 to 12 hours. Make sure you complete your prescribed course; do not stop taking this medicine if you feel better.

When to take your medicine:

For oral use only. Take your medicine on an empty stomach, at least thirty minutes to one hour before meals/food. It is important that you take your medicine at the right times.

If you take more of your medicine than you should:

Contact your doctor or nearest hospital casualty department if you or a child have swallowed too much medicine. Take this leaflet and any remaining solution with you, if possible. Symptoms of overdose include nausea, vomiting, diarrhea

If you forget to take your medicine :

If you miss a dose, take the solution as soon as you remember and carry on as before. If it is almost time for your next dose, skip the forgotten dose and continue as usual.

If you stop taking your medicine :

Keep taking your medicine until your doctor tells you to stop. Do not stop taking it just because you feel better. If you stop taking the medicine, your infection may return or get worse. If you are still unwell after taking all the medicine, go and see your doctor. If you have any further questions on the use of this medicine, ask your doctor or pharmacist



4. POSSIBLE SIDE EFFECTS

STOP taking flucloxacillin and contact your doctor if you experience:

- Allergic reaction, symptoms of which includes rash, itching, difficulty in breathing or swelling of the face, lips, throat or tongue
- Jaundice (yellow colour in the skin and whites of the eyes)
- Severe skin rash with itching, fever, blisters or ulcers (StevensJohnson syndrome) or a severe rash with reddening, peeling and swelling of the skin that looks like a burn (toxic epidermal necrolysis)
- Severe, bloody diarrhoea
- A red, scaly rash with bumps under the skin and blisters (exanthematous pustulosis) (frequency not known). Contact a doctor immediately if you get any of these symptoms.

Tell your doctor if you notice any of the following effects

COMMON: (may affect up to 1 in 10 people)

- Minor gastrointestinal disturbances (e.g. diarrhoea, nausea & vomiting)

UNCOMMON: (may affect up to 1 in 100 people)

- Urticaria (itchy skin eruption) • Purpura (brownish-red spots on the skin)

VERY RARE: (may affect up to 1 in 10,000 people)

- Change in number of blood cells i.e. neutropenia and thrombocytopenia (might cause bleeding, easy bruising or skin discolouration)
- haemolytic anaemia
- increase in the number of white blood cells in the blood (eosinophilia).
- Anaphylactic Shock (severe allergic reaction)
- Angioneurotic Oedema (rapid swelling)
- Pseudomembranous colitis (inflammation of the colon with abdominal cramps, diarrhoea, bloody stools)
- Inflammation of the kidney or liver (hepatitis)
- Changes in liver function tests

OTHER SIDE EFFECTS: (frequency not known)

- Serious skin reactions
- A red, scaly rash with bumps under the skin and blisters (exanthematous pustulosis).

5. HOW TO STORE RONAFLUCLOX DS SUSPENSION

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

Unopened bottle: Do not store above 25°C. Store in the original container and keep tightly closed. Do not use after the expiry date is stated on the label. Once reconstituted (mixed) by the pharmacist, store the solution at 2°C to 8°C in a refrigerator and use within 7 days. Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.





6. FURTHER INFORMATION

What **RONAKFLUCLOX DS SUSPENSION** contains:

- The active pharmaceutical ingredient(s) are Flucloxacillin Sodium BP.
- The other ingredient(s) are Sodium benzoate, Sodium citrate, Sugar, Flavour pineapple Dry mix & Aspartame.

What **RONAKFLUCLOX DS SUSPENSION looks like and contents of the pack:** White to off white colored granular powder after reconstitution gives colourless solution, with pineapple flavor.

100 ml Amber Colored Glass bottle placed in a carton with pack insert.

Manufacturer

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