

Oracyn-K[®]

Phenoxymethylpenicillin Potassium BP



PRESENTATION

Oracyn-K 250 Tablet: White, flat, round tablet with bevelled edge, one side engraved with “Oracyn-K 250” and reverse side with score line. Each tablet contains Phenoxymethylpenicillin Potassium BP equivalent to Phenoxymethylpenicillin 250mg.

Oracyn-K 500 Tablet: White circular shape tablet with bevelled edge and both sides are plain. Each tablet contains Phenoxymethylpenicillin Potassium BP equivalent to Phenoxymethylpenicillin 500mg.

Oracyn-K Syrup: Off-white free flowing powder with when reconstituted forms pinkish red with characteristic (Black-berry) flavored syrup. After reconstitution, each 5ml contains Phenoxymethylpenicillin Potassium BP equivalent to Phenoxymethylpenicillin 125mg.

INDICATIONS

For the treatment of mild to moderately severe bacterial infections, if these are due to penicillin susceptible pathogens and respond to therapy with oral penicillin, such as:

- infections of the ear, nose and throat regions, e.g., tonsillitis, pharyngitis, laryngitis, otitis media, sinusitis.
- infections of the lower respiratory tract, e.g., bronchitis and pneumonia, bronchopneumonia.
- infections due to beta-haemolytic streptococci of group A, e.g., scarlet fever, erysipelas, rheumatic fever.
- skin infections, e.g., pyoderma, furunculosis, phlegmon, erysipeloid, erythema migrans, insofar as the micro-organisms are penicillin-susceptible.
- lymphadenitis and lymphangitis of bacterial origin.
- infections of the buccal cavity, gums or jaws, e.g., inflammatory infiltrates, delayed dentition stages II and III, antral fistulae, secondary bacterial infection with Gram-positive pathogens following virus-induced gingivitis or stomatitis.

For prophylaxis of scarlet fever; also to prevent recurrences of rheumatic fever.

For prophylaxis of infection after dental and oral surgical procedures or dental extractions in certain high risk patients (e.g. with congenital cardiac defects, artificial heart valves, rheumatic endocarditis).

In some cases, combination with another appropriate antibiotic may be indicated.

DOSAGE AND ADMINISTRATION

Dosage

Infants: 150,000 I.U. 3 times daily (equivalent to a daily dose of 450,000 I.U.).

Young children: 300,000 I.U. 3 times daily (equivalent to a daily dose of 900,000 I.U.).

Children aged 6 to 15 years: 600,000 I.U. 3 times daily (equivalent to a daily dose of 1.8 mega I.U.).

Adolescents: 600,000 to 1.2 mega I.U. 3 times daily (equivalent to a daily dose of 1.8 to 3.6 mega I.U.).

Adults: 1.2 mega I.U. 3 times daily (equivalent to a daily dose of 3.6 mega I.U.).

In patients with anuria, it is advisable to lengthen the interval between doses to 12 hours.

It is recommended to continue treatment for at least three days after the temperature has returned to normal. When dealing with infections by beta-haemolytic streptococci, treatment must be continued for at least 10 days.

Administration

Oracyn-K is best taken on an empty stomach, preferably one hour before meals.

The tablets are swallowed without chewing with sufficient amounts of liquid.

Before each use of Oracyn-K, the bottle has to be shaken vigorously.

CONTRAINDICATIONS

Oracyn-K must not be administered in **patients with hypersensitivity to penicillins or any of the excipients of Oracyn-K.**

Oracyn-K must not be used to treat patients with severe gastrointestinal disorders accompanied by vomiting and diarrhea.

WARNINGS

The possibility of **cross-allergy between cephalosporins and penicillins** must be considered.

When treating patients with heart diseases or serious electrolyte disturbances of other origin, the potassium content of Oracyn-K may have to be considered.

PRECAUTIONS

Administration of antibiotics, especially if prolonged, **may lead to the proliferation of resistant micro-organisms. The patient's condition must therefore be checked at regular intervals.** If a secondary infection occurs, appropriate measures must be taken.

In patients with diabetes mellitus, the sugar content of Oracyn-K syrup must be taken into consideration.

DRIVING A VEHICLE OR PERFORMING OTHER HAZARDOUS TASKS

There is no indication of impaired ability to drive, or to operate machinery.

INTERACTIONS

Food

Concurrent intake of food leads to a reduction in the rate of absorption. Therefore, Oracyn-K is best taken on an empty stomach, preferably one hour before meals, in order to reach the highest possible rate of absorption.

Drug interactions

Precautions for use

Concomitant administration of penicillins may lead to increased levels of methotrexate in serum and potentiate its toxic effects. Monitoring of methotrexate serum levels is therefore necessary.

Take into account

If diarrhoea occurs as a consequence of treatment with Oracyn-K, the absorption of other orally administered drugs may be disturbed and their efficacy may consequently be impaired.

If penicillins are combined with bacteriostatic chemotherapeutics or antibiotics (e.g., tetracyclines, chloramphenicol), **the activity of penicillins may be attenuated or abolished.**

Concurrent administration of probenecid inhibits the renal excretion of penicillins. Concurrent use of indomethacin, phenylbutazone, salicylates or sulfonpyrazone may cause elevated and prolonged serum levels of phenoxymethylpenicillin.

Administration of penicillins may cause a transient reduction in plasma concentrations of oestrogens and gestagens. The effectiveness of oral contraceptives is therefore uncertain.

The absorption of Oracyn-K may be reduced where intestinal sterilization with aminoglycosides (e.g. neomycin) has just been performed or is still in progress.

INTERFERENCE WITH LABORATORY AND DIAGNOSTIC TESTS

Non-enzymatic urine glucose determinations and tests for urobilinogen may give false-positive results.

PREGNANCY

Phenoxymethylpenicillin crosses the placenta. Given the appropriate indication, Oracyn-K may be used at any time throughout pregnancy.

LACTATION

Phenoxymethylpenicillin passes into the breast milk in small amounts. Oracyn-K may be used during lactation; however, diarrhoea and yeast colonization of mucous membranes may occur in the infant.

ADVERSE REACTIONS

Occasionally, **hypersensitivity reactions involving the skin** (e.g. urticaria, morbilliform or scarlatiniform rashes, pruritus), **eosinophilia or more serious allergic reactions, e.g. drug fever, vasculitis, serum sickness or interstitial nephritis**, may develop. **Anaphylactic or anaphylactoid reactions accompanied by, e.g- angioneurotic oedema, oedema of the larynx, bronchial spasm and shock** may occur.

In the event of signs pointing to anaphylactic/anaphylactoid reactions, the treatment must be terminated immediately.

In occasional instances, there may be skin rashes or inflammation of mucous membranes, especially in the region of the mouth (**stomatitis**); **dryness of the mouth and disorders of taste** may rarely occur.

The occurrence of **severe bullous skin reactions** - usually involving the mucosae – has been reported in isolated cases (**Stevens-Johnson syndrome, Lyell's syndrome**).

Gastrointestinal disturbances with, e.g., nausea, vomiting, abdominal pain, loose stools, or diarrhoea may develop. Diarrhoea may sometimes be a symptom of **enterocolitis which may, in some cases, be haemorrhagic.**

A particular form of enterocolitis that can occur with antibiotics is **pseudomembranous colitis** (in most cases due to Clostridium difficile). This **must be considered in patients in whom severe, persistent diarrhoea occurs during treatment or in the initial weeks thereafter. Even if pseudomembranous colitis is only suspected, administration of Oracyn-K must be halted immediately.** This type of colitis requires immediate and appropriate treatment by a physician. Drugs that inhibit intestinal peristalsis must not be taken in such cases.

In isolated cases, particularly after high doses and prolonged administration, **changes in blood picture such as reduction in the number of white blood cells** (e.g.,leucopenia, granulocytopenia, **agranulocytosis**), **erythrocytes (e.g., due to haemolytic anaemia), thrombocytes, or pancytopenia** and **myelosuppression** may occur.

During treatment for spirochaetal infections, **Herxheimer's reaction** characterized by the occurrence or worsening of general symptoms such as fever, chills, headache, and joint pains may develop.

In isolated cases, **drug-induced aseptic meningitis** may occur.

In extremely rare cases, transient **discolouration of the teeth** may be seen during treatment with Oracyn-K.

Administration of antibiotics, especially if prolonged, may lead to the **proliferation of resistant micro-organisms.**

OVERDOSE

The toxicity of phenoxymethylpenicillin is low, and it has a broad therapeutic range.

When a multiple therapeutic dose is taken orally once only, phenoxymethylpenicillin has no acute toxicity.

With oral administration, it is practically impossible to attain concentrations capable of inducing neurotoxic symptoms.

Special measures in the event of overdosage, other than discontinuation of the medication, are not required. Elimination of phenoxymethylpenicillin can be accomplished through haemodialysis.

Storage: Store in a cool and dry place, protect from light

PACKAGE QUANTITY

Oracyn-K 250 Tablet: Box of 30 X 10 X 250mg in Blister pack.

Oracyn-K 500 Tablet: Box of 25 X 10 X 500mg in Blister pack.

Oracyn-K Syrup: Bottle of 50 ml.

Manufactured by:



Synovia Pharma PLC., Station Road, Tongi, Gazipur.

A Subsidiary of BEXIMCO PHARMACEUTICALS LTD.

544545

Direction Slip artwork legend

Product Name	:	Oracyn K
Code number	:	544545
Dimension	:	L 10.75 x W 11.5 inches
Min. size of text	:	8 pt
Used Colors	:	Black C Pantone 186 C