VITAMED
REKAH GROUP
Pharmaceutical Industries LTD

רופא/ה נכבד/ה,
רוקח/ת נכבד/ה,

CEFUROXIME – VIT

חברת ויטמד מבקשת להודיע על עדכונים בעלון לרופא של התכשיר שבנדון.

התווית התכשיר:

Cefuroxime – Vit is indicated for the treatment of the infections caused by susceptible microorganisms, prophylaxis against post operative infections in a variety of operations.

מרכיב פעיל: cefuroxime (as sodium) 750mg

צורת המתן של התכשיר :

I.M , I.V

עלון לרופא):

4.3) Contraindications:

History of severe hypersensitivity (e.g. anaphylactic reaction) to any other type of beta-lactam antibacterial agent (penicillins, monobactams and carbapenems).

4.4 Special warnings and precautions for use

Overgrowth of non-susceptible microorganisms

Use of cefuroxime may result in the overgrowth of *Candida*. Prolonged use may also result in the overgrowth of other non-susceptible microorganisms (e.g. enterococci and *Clostridium difficile*), which may require interruption of treatment (see section 4.8).

Antibacterial agent–associated pseudomembranous colitis has been reported with use of cefuroxime and may range in severity from mild to life threatening. This diagnosis should be considered in patients with diarrhoea during or subsequent to the administration of cefuroxime (see section 4.8). Discontinuation of therapy with cefuroxime and the administration of specific treatment for *Clostridium difficile* should be considered. Medicinal products that inhibit peristalsis should not be given.

Intracameral use and eye disorders

Cefuroxime - Vit is not formulated for intracameral use. Individual cases and clusters of serious ocular adverse reactions have been reported following unapproved intracameral use of cefuroxime sodium compounded from vials approved for intravenous/intramuscular administration. These reactions included macular oedema, retinal oedema, retinal detachment, retinal toxicity, visual impairment, visual acuity reduced, vision blurred, corneal opacity and corneal oedema.

4.5 Interactions with other medicinal products and other forms of interaction

Cefuroxime may affect the gut flora, leading to lower oestrogen reabsorption and reduced efficacy of combined oral contraceptives.

Cefuroxime is excreted by glomerular filtration and tubular secretion. Concomitant use of probenecid is not recommended. Concurrent administration of probenecid prolongs the excretion of the antibiotic and produces an elevated peak serum level.

Other Interactions

Determination of blood/plasma glucose levels: refer to section 4.4.

Concomitant use with oral anticoagulants may give rise to increased international normalised ratio (INR).

4.6 Fertility, pregnancy and lactation

Breastfeeding

A decision must be made whether to discontinue breast-feeding or to discontinue/abstain from cefuroxime therapy taking into account the benefit of breast feeding for the child and the benefit of therapy for the woman.

4.8 Undesirable effects

System organ class	Common	Uncommon	Not known
Infections and infestations			overgrowth of *Clostridium difficile*
Blood and lymphatic system disorders			thrombocytopenia, haemolytic anaemia
Immune system disorders			cutaneous vasculitis
Skin and subcutaneous tissue disorders			toxic epidermal necrolysis angioneurotic oedema

VITAMED
REKAH GROUP
Pharmaceutical Industries LTD

4.9 Overdose

Overdose can lead to neurological sequelae including encephalopathy, convulsions and coma. Symptoms of overdose can occur if the dose is not reduced appropriately in patients with renal impairment (see sections 4.2 and 4.4).

<u>השינויים המודגשים ברקע צהוב מהווים החמרה. בעלון בוצעו שינויים נוספים אשר מהווים תוספת מידע.</u>

העלון מפורסם במאגר התרופות שבאתר משרד הבריאות: https://data.health.gov.il/drugs/index.html#!/byDrug
ניתן לקבלו מודפס באמצעות פניה לבעל הרישום, חברת ויטמד

בברכה,

מירי חזן
רוקחת ממונה