Products

LEVOFLOX: Armed with Excellence

Quinolones are a very important family of antibacterial agents that are widely prescribed for the treatment of infections in humans. Since their discovery in the early 1960s, the quinolone group of antibacterial has generated considerable clinical and scientific interest.

Levofloxacin is a synthetic chemotherapeutic antibiotic of the quinolone drug class and is used to treat severe or life-threatening bacterial infections or bacterial infections that have failed to respond to other antibiotic classes. It is a trusted and accepted molecule for treating various respiratory tract as well as urinary tract infections. Recently, a high-dose, short-course regimen (750 mg once daily for 5 days) of levofloxacin has been developed with the aim of enhancing concentration-dependent bactericidal activity and reducing the potential for the emergence of resistance. The c onvenient once-daily dosing is of particular benefit in those patients who may not be compliant. Levofloxacin is rapidly bactericidal and has a broad spectrum of activity, with a better safety and tolerability profile compared to other quinolones. Excellent bioavailability with both orally and intravenously available forms advances its use for treating various difficult-to-treat infections.

Levofloxacin is one of the respiratory fluoroquinolones that is recommended by international guidelines like IDSA, ATS and ERS for treating various respiratory tract infections. The molecule, due to its excellent tissue concentrations in the urinary tract, is also recommended by the European Association of Urology (EAU) for treating various complicated and uncomplicated urinary tract infections. Levofloxacin is approved for treating nosocomial and community-acquired pneumonia, acute bacterial sinusitis, acute bacterial exacerbation of chronic bronchitis, complicated/uncomplicated skin and skin structure infections, chronic bacterial prostatitis, complicated/uncomplicated urinary tract infections, acute pyelonephritis, and inhalational anthrax (post-exposure).

LEVOFLOX (Levofloxacin) is currently available as 250 mg, 500 mg and 750 mg oral tablets, and a 500 mg intravenous (I.V.) infusion. The usual dose of levofloxacin tablets is one tablet every 24 hours, while the I.V. solution is to be administered by slow infusion over 60 minutes every 24 hours.

Cefoprox CV: The extra whenever you need

The most important concern in the management of upper respiratory tract infections (URTIs) is Antibiotic resistance.

Worldwide evidence suggests that inappropriate antibiotic use for non-severe URTIs, most of which are viral, adds to the overall burden of antibiotic resistance, a phenomenon which is becoming more prevalent. This resistance to antibiotics constitutes a major threat to public health. Nowadays, the resistance pattern for Cefpodoxime in India for various pathogens is on the increasing trend such as for *E.coli* (85%), *K. pneumoniae* (65%), *S. aureus* (60%), *P. aeruginosa* (100%), *A. baumanni* i (67%) etc.

Therefore reintroduction of currently available penicillins and cephalosporins along with other agents such as ß-lactamase inhibitors is an attractive opportunity for many reasons: Well established safety and efficacy profile, Production of ß-lactamase is the most common mechanism of resistance to ß-lactam antibiotics, especially in gram negative bacteria, Convenience of use, and more essentially an understanding that using such combination empirically may help in not only overcome therapeutic failures due to resistant bacteria but will also delay resistance development in susceptible bacteria.

Hence the combination of Cefpodoxime (3 rd generation cephalosporin) and Clavulanic acid (ß-lactamase inhibitor) provides a solution for treatment of bacterial infections caused by beta lactam resistant pathogens.

CEFOPROX CV is a combination of a third generation ß-lactam antibiotic Cefpodoxime proxetil 200 mg along with a ß-lactamase inhibitor Clavulanic acid 125 mg.

DOSAGE AND INDICATIONS

Adults and Adolescents (aged 12 years and older)			
Type of infections	Total daily dose	Dose frequency	Duration
Pharyngitis and/or tonsillitis	200 mg	100 mg q12 hours	5-10 days
Acute community-acquired pneumonia	400 mg	200 mg q12 hours	14 days
Acute bacterial exacerbations of chronic bronchitis	400 mg	200 mg q12 hours	10 days
Skin and skin structure	800 mg	400 mg q12 hours	7-14 days

Acute maxillary sinusitis	400 mg	200 mg q12 hours	10 days
Uncomplicated urinary tract infection	200 mg	100 mg q12 hours	7 days
*Dose of **CEFOPROX CV Tablets** is based on the cefpodoxime component.			

KEY HIGHLIGHTS

1. More potent *in vitro* activity in comparison to amoxicillin+ clavulanic acid against ß-lactamase producing strains of Gram-positive and Gram-negative bacteria.
2. ≥8-fold reduction in MIC against ESBL-positive organism has been observed.
3. The combination extends the antibiotic spectrum and enhances the activity of cefpodoxime.
4. Highly effective combination in Switch Therapy.

April 2011

Montair FX: For an Active, Non-Sedative Day in AR

Allergic Rhinitis (AR) is a common disease worldwide, affecting about 10–50% of the population. It exacts a toll on a patient's quality of life, cognitive and learning functions, decision-making and self-perception and, if left untreated, can contribute to co-morbidities, including asthma, sinusitis and otitis media with effusion or the development of nasal polyps.

MONTAIR FX is a combination of an antileukotriene montelukast 10 mg with the second generation antihistamine fexofenadine 120 mg.

Montelukast is a selective and orally active leukotriene receptor-antagonist that inhibits CysLT $_1$ with 24-hour action. It has been shown to decrease the number of eosinophils in the blood of patients with AR, suggesting a decrease in the inflammation and improvement in daytime and night-time symptoms as well as to improve the disease-related quality of life.

Fexofenadine hydrochloride, a second-generation antihistamine, is the pharmacological metabolite of terfenadine and a potent and selective antagonist of peripheral H 1 -receptors. It has an early onset of action as compared to levocetirizine, and causes a significantly higher reduction in the wheal size after 3 to 6 hours when compared to desloratadine. Fexofenadine is as effective as the popular antihistamine, cetirizine, but it lacks the sedating effects associated with cetirizine. This is because of its inability to cross the blood–brain barrier. Fexofenadine is also superior to loratadine in improving nasal congestion, ocular symptoms and the quality of life for patients with AR.

The combination of montelukast and fexofenadine has been shown to be superior to monotherapy in a randomized, double-blind, multicentred, prospective study with 275 adult patients in terms of reduction in nasal obstruction, nasal resistance as well as in daily symptoms and also offered higher patient satisfaction.

Thus with the introduction of **MONTAIR FX** , there opens up another treatment option for patients with AR who want complete control along with no sedation.

March 2011

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ROKFOS: Infusing life into Bones

Osteoporosis is a progressive systemic disease resulting in increased bone fragility and susceptibility to fractures at vertebral and nonvertebral sites.

Therapeutic adherence is a key factor influencing the effectiveness of treatment in chronic diseases where the effects of the therapy can only be seen after a long-term application of drugs or are subjectively not perceived at all.

The situation is even more complicated in chronic asymptomatic diseases like hypertension or osteoporosis.

Once yearly dosing with Zoledronic acid is a new alternative in the therapy of osteoporosis and represents an important step towards an improvement in the adherence to treatment.

Cipla introduces **ROKFOS** , once yearly Zoledronic acid 5 mg for the management of osteoporosis.

ROKFOS is indicated for:

- Treatment and Prevention of post-menopausal osteoporosis. of post-menopausal osteoporosis
- Treatment to increase bone mass in men with osteoporosis.
- Treatment of Paget's disease of the bone.
- Prevention & treatment of glucocorticoid induced osteoporosis.

The recommended dose is a single intravenous infusion of 5 mg Zoledronic acid administered once a year given over no less than 15 minutes. However, for prevention of postmenopausal osteoporosis, the recommended dose is a 5 mg infusion given once every 2 years intravenously over no less than 15 minutes.

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VANLID 250: Hands down Victory against MRSA

Staphylococcus aureus (*S. aureus)* is an important pathogen that frequently causes clinical disease in children. A wide array of illnesses can be caused by this common pathogen ranging from non-invasive skin infections to severe, life-threatening sepsis. Additionally, as antibacterials have been used to eradicate *S. aureus* , it has developed resistance to these important therapeutic agents. Growing bacterial resistance means that what were once effective and inexpensive treatments for infections caused by these bacteria are now being seriously questioned.

Methicillin-resistant S. aureus (MRSA) has become an increasing problem in pediatric patients over the past decade. A new type of staphylococcus, usually termed community-acquired MRSA (CA-MRSA), which is resistant to fewer antibiotics compared to the HA-MRSA, has also emerged in the paediatric age group.

Vancomycin was introduced in 1958 and has been a useful antibiotic for about 50 years. The recent advent of MRSA has provided a renaissance for this glycopeptide. Over the years, vancomycin has become the mainstay of MRSA infection therapy and thus, is the primary therapeutic option in severe, life-threatening invasive MRSA infections.

Several literatures have shown vancomycin to be clinically and microbiologically (including the resistant Gram-positive organisms) consistently very effective across all infections caused by presumed or documented resistant Gram-positive pathogens across all paediatric age groups, including neonates. Vancomycin is well-tolerated and safe in paediatric patients including in the critically ill neonates.

VANLID 250 is ***India's First*** vancomycin I.V. with the right strength of 250 mg for paediatric patients. **VANLID 250** is a chromatographically purified and lyophilized product.

VANLID 250 is indicated for the treatment of staphylococcal infections like lower respiratory tract infections (like pneumonia), septicaemia, skin and soft tissue infections and osteomyelitis. It is also indicated for treatment of endocarditis caused by Staphylococci, *Streptococcus viridans** or *Streptococcus bovis** and Enterococci (e.g. *E.faecalis*),** and Diphtheroids , for the treatment of early-onset prosthetic valve endocarditis caused by *Staphylococcus epidermidis* or diphtheroids $ and as prophylaxisagainst endocarditis in patients at risk from dental or surgical procedures.

In paediatric patients, the usual I.V. dosage of 10 mg/kg per dose is recommended every 6 hours (total daily

dosage 40 mg/kg of body weight). In neonates and young infants, an initial dose of 15 mg/kg is suggested, followed by 10 mg/kg every 12 hours in the first week of life and every 8 hours thereafter until 1 month of age. Longer dosing intervals may be necessary in premature infants. Each dose should be administered over a period of at least 60 minutes.

Parenteral form of vancomcin can be administered orally for treatment of antibiotic-associated pseudomembranous colitis produced by C. difficile and Staphylococcal enterocolitis.

Orally, **VANLID 250 I.V.** can be administered using 40 mg/kg body weight in three or four divided doses for 7–10 days. The total daily dose should not exceed 2 g.

Dosage adjustment must be made in patients with impaired renal function.

**Vancomycin alone or in combination with an aminoglycoside*
***Vancomycin only in combination with an aminoglycoside*
$ Vancomycin in combination with either rifampin or an aminoglycoside or both

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VC 15: Healthy Skin Expert

Vitamins such as A, C and E are naturally present in human skin. These vitamins are part of a complex system of enzymatic and non-enzymatic antioxidants that protect the skin from harmful reactive oxygen species. However, the skin is subjected to substantial environmental free radical stress from sunlight, pollution and smoking, all of which deplete the dermal stores of naturally occurring antioxidants. To replenish these losses, vitamins should be applied topically on the skin.

Vitamin C (L-ascorbic acid) is the body's major aqueous phase antioxidant and is vital for life. Oral supplementation with Vitamin C does little to increase skin concentration because active transport of vitamin C from the gastrointestinal tract is limited. Therefore, topical application of vitamin C is the preferred method to increase its presence in the skin.

Vitamin C is an excellent antioxidant that sequentially donates electrons, thereby neutralizing free radicals present in the aqueous compartment of the cell. Along with its antioxidant property it has also got photoprotective, depigmenting and anti-inflammatory properties. Vitamin C also provides the additional advantages of replenishing vitamin E and stimulating dermal collagen synthesis, a major target in chronic photoaging.

VC 15 contains L-ascorbic acid at a concentration of 15%. It is a stable formulation with a pH of 2.7. **VC 15** promises to be non-irritating and non-comedogenic. It is available in a bottle of 15 ml along with a dropper.

VC 15 is indicated for photodamaged/ aging skin, melasma/ hyperpigmentation, acne and acne scars and post procedure inflammation.

Properties supporting clinical uses of topical vitamin C (VC 15)

Clinical Uses	Properties
Photodamaged/Aging skin	
• Dry skin	Moisturization
• Dull complexion, rough texture	Photoprotection and antioxidant
• Fine lines and deep wrinkles	Collagen synthesis and antioxidant
• Age spots	Depigmentation and photoprotection
Melasma/hyperpigmentation	Depigmentation and photoprotection
Acne and acne scars	Antioxidant, anti-inflammatory and collagen synthesis
Post-procedure inflammation	Antioxidant and anti-inflammatory

VC 15 should be used once daily in the morning. With the help of the dropper, take 7 to 10 drops of VC 15 onto your fingertips. Then, dab the serum onto your face and neck and gently massage until it is completely absorbed.

VC 15 should be used within one month after opening the bottle.

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ENTAVIR: Persistent Efficacy in Treating Chronic Hepatitis B

Chronic hepatitis B is a worldwide public health challenge, approximately 2 billion people worldwide have been infected by hepatitis B virus, and more than 350 million are chronic carriers.

The primary goal in chronic hepatitis B treatment is to reduce serum HBV DNA level to the lowest possible level (undetectable) and thereby decrease the risk of developing liver cirrhosis and liver cancer.

Entecavir (ETV), a guanosine nucleoside analogue, is a potent and selective inhibitor of hepatitis B virus replication with around 94% patients continuing to remain HBV DNA undetectable and 80% patients with normalization of liver enzymes at the end of 5 years of continuous entecavir therapy. Entecavir resistance is rare in nucleoside-naïve patients, around 1.2% after 6 years of treatment. It is recommended as a first line treatment in lamivudine-naïve chronic hepatitis B patients.

Long-term entecavir therapy leads to potent suppression of HBV DNA, normalization of ALT and improvement in liver histology with accompanying regression of fibrosis, including those with advanced fibrosis or cirrhosis at baseline. Recent studies have shown that entecavir has also been successful in preventing acute liver failure in patients of acute hepatitis B and progression to chronic hepatitis B. It can also be safely and effectively used in HBV infected patients pre or post renal transplant without any renal compromise.

ENTAVIR (entecavir) is a film coated tablet for oral use and is available in two dose strengths of 0.5 mg and 1.0 mg which have specific indications in patients of chronic hepatitis B as mentioned below.

ENTAVIR tablets are indicated for the treatment of chronic hepatitis B virus infection in adults(= 16 years of age) with evidence of active viral replication and either evidence of persistent elevations in serum aminotransferases (ALT or AST) or histologically active disease.

ENTAVIR tablets should be administered on an empty stomach (at least 2 hours after a meal and 2 hours before the next meal).

Recommended Dosage

Compensated Liver Disease

- The recommended dose of entecavir for chronic hepatitis B virus infection in nucleoside treatment-naïve

adults and adolescents 16 years of age and older is 0.5 mg once daily.

- The recommended dose of entecavir in adults and adolescents (at least 16 years of age) with a history of hepatitis B viremia while receiving lamivudine or known lamivudine or telbivudine resistance mutations rtM204I/V with or without rtL180M, rtL80I/V, or rtV173L is 1 mg once daily.

Decompensated Liver Disease

- The recommended dose of entecavir for chronic hepatitis B virus infection in adults with decompensated liver disease is 1 mg once daily.

Dosage adjustment is recommended for patients with creatinine clearance less than 50 mL/min, including patients on hemodialysis or continuous ambulatory peritoneal dialysis (CAPD).

The optimal duration of treatment with entecavir for patients with chronic hepatitis B virus infection and the relationship between treatment and long-term outcomes such as cirrhosis and hepatocellular carcinoma are unknown.

January 2011

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FORACORT AUTOHALER- Make a Smarter Choice

Foracort Autohaler is the world's first breath-actuated inhaler containing a combination of formoterol with budesonide.

Foracort Autohaler contains 6 mcg of formoterol and 200 mcg of budesonide. This combination is an effective and convenient option for the maintenance treatment of patients with asthma in whom dual asthma maintenance therapy is warranted. The use of formoterol with budesonide for both daily maintenance therapy and as-needed relief of breakthrough symptoms using a single inhaler is a new approach to asthma management and is indicated in patients with persistent asthma. This treatment strategy significantly reduces the rate of severe asthma exacerbations compared with the traditional approach of using an inhaled corticosteroid with long-acting beta agonist (ICS/LABA) with a short-acting beta agonist (SABA) and achieves equivalent daily symptom control compared with high dose of ICS/LABA plus separate SABA for relief.

Foracort is already available as a dry powder inhaler (DPI) in the form of Rotacaps to be used with a Rotahaler or a Revolizer and as a pressurised metered dose inhaler (pMDI).

The Autohaler overcomes the key problem of the pMDI viz. coordination of actuation with inhalation and does not rely on the patient`s inspiratory effort to aerosolize the dose of medication unlike dry powder inhalers. Autohaler is activated at low flow rates of 22-30 l/sec. Studies have shown that the **Autohaler** is easier to use and to teach as compared to pMDIs and some of the DPIs. It can also be used by children who are wheezing, older patients with severe airflow obstruction and those with arthritis. Autohaler contains 300 doses, which ensures long term medication for the patient, thus offers better adherence and compliance.

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MOXICIP KT: Where power Breeds Safety

India has experienced an exponential increase in the number of cataract surgeries. An estimated 0.5 million cataract surgeries were done in 1981–1982; this increased to 4.8 million in 2006 with 90% intraocular lens acceptance. Inflammation has always been accepted as a natural consequence of the cataract surgical procedures and also these procedures are associated with a risk of infection. These consequences are generally treated with anti-inflammatory (steroids) and anti-infective eye drops. But the adverse consequences associated with long term use of steroids and the resistance and efficacy issues associated with the use of older generation anti-infectives warrants the need for a combination wherein **Power Will Breed Safety.**

MOXICIP KT contains Moxifloxacin, a genetically smart, broad spectrum fluoroquinolone and Ketorolac a potent anti-inflammatory and analgesic non steroidal anti inflammatory. The combination of these drugs has positive therapeutic effect on postoperative inflammation and prevention of postoperative infection following cataract surgery. Also the presence of an anti-inflammatory and antibiotic agent in a single ophthalmic product overcomes any potential 'washout effect' that may be seen when separate medications are used. In addition, the combination also leads to better compliance, patient comfort and safety. The reduced number of administrations with this combination may be of particular benefit for elderly patients, who make up the majority of cataract surgery cases.

MOXICIP KT contains Moxifloxacin 0.5% (anti-infective) and Ketorolac 0.5% (anti-inflammatory non steroidal). It is the World's first antibiotic and NSAID combination to be preservative free and with HEC (Hydroxyethyl cellulose). HEC is a polymer which acts as a viscosity enhancer improving the retention time of the drug.

INDICATIONS

For NSAID-responsive inflammatory ocular conditions for which a NSAID is indicated and where bacterial infection or a risk of bacterial ocular infection exists.

The use of a combination drug with an anti- infective component is indicated where the risk of superficial ocular infection is high or where there is an expectation that potentially dangerous numbers of bacteria will be present in the eye.

DOSAGE AND ADMINISTRATION

One drop in affected eye three times a day

MOXICIP KT: Highlights

- First a Combination of
    - Moxifloxacin: A broad spectrum, potent, 8 methoxy fluoroquinolone.
    - Ketorolac: A potent anti inflammatory and analgesic agent
- A combination with HEC advantage which increases the drug retention time
- A combination with no preservative which results in No corneal toxicity
- A combination which can be used for wide array of indications
- A combination which will provide Patient compliance and Long term usage.

December 2010

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LACSYP: Differences Do Matter

Constipation affects almost everyone at one time or another and is a symptom caused by various factors that are not always discernable. Constipation is marked by a multitude of presentations, ranging from an inability to pass stools to less than three stools in a week. Patients often include difficulty in passing stools, hard stools, and the sensation of incomplete bowel movement as constipation.

Although constipation is more often than not a temporary condition, it affects around 30% of the population at some point of time. Very commonly, constipation is caused due to lifestyle choices such as inactivity, low fiber, ignoring the urge, or even dehydration. However, medication, surgeries and pregnancies are also common causes of constipation. Though the symptoms associated with constipation are often intermittent and mild, they may be chronic, difficult to treat and debilitating.

Lacsyp (lactitol) is a second-generation disaccharide agent used frequently as a laxative. Described first in 1979, this pleasant tasting, non-absorbable sugar is used as an artificial sweetener in food preparations. Like its analog, lactulose, lactitol too is used for the treatment of hepatic encephalopathy and constipation. Both have been shown to be equally efficacious; however, lactitol is without certain discomforts associated with lactulose. Although effective, many patients are intolerant to lactulose because of its nauseatingly sweet taste and, quite often, the intestinal discomfort associated with bloating and abdominal pain adds an unnecessary burden on patients.

The predictable cathartic effect of lactitol, unlike lactulose, has made it the clear choice of patients in comparative trials. Rapid resolution of hepatic encephalopathy, an end-stage liver disease complication, extends the benefits of this non-absorbable sugar beyond patient tolerability and palatability. Being non-absorbable, the potential for systemic side effects are limited. Dosing with this agent has no effect on the blood sugar levels even in patients with diabetes.

Lacsyp offers a sweet and preferred option to manage conditions from as troublesome as constipation to serious conditions like hepatic encephalopathy.

December 2010

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Vertipress - Suppressing Vertigo, Balancing Lives

Vertipress - Suppressing Vertigo, Balancing Lives

Vertigo or giddiness is a disturbance of the sense of equilibrium and movements, where the person feels that either his surroundings are going round him or he himself is rotating. The symptoms of vertigo are due to dysfunction of the vestibular system in the inner ear. Definitive treatment of vertigo depends on treating the underlying cause.

Vertipress (Betahistine hydrochloride) is a drug indicated in the treatment of Meniere's disease and more generally of peripheral vertigo disorders of different origins. Additionally, betahistine also takes care of tinnitus and deafness associated with Meniere's disease.

The mechanism of action of betahistine is based on its interaction with H_1 and H_3receptors. Betahistine has a weak H_1 receptor agonist action and a potent antagonistic effect on H_3 receptors.

Dosage and administration: Initial oral treatment is 8 to 16 mg three times daily, taken with food.

Maintenance doses are generally in the range of 24 mg to 48 mg daily.

Vertipress is not recommended for use in individuals below 18 years of age.

December 2010

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Febucip – The Selective, Non-purine XO inhibitor

Gout is a disorder of purine metabolism and results from urate crystal deposition in and around the joints caused by longstanding hyperuricaemia.

Febuxostat is a xanthine oxidase inhibitor and achieves its therapeutic effect by decreasing serum uric acid (sUA). It is the first agent approved in the United States for the treatment of gout since allopurinol was first marketed in 1964. It is –

- **Non-purine analogue** - does not structurally resemble purines and pyrimidines.
- **Selective** – selectively inhibits xanthine oxidase and not the other additional enzymes of the purine and pyrimidine pathway.
- **Potent** – inhibits both the oxidized and reduced forms of xanthine oxidase.

Febuxostat is indicated for the chronic management of hyperuricaemia in patients with gout.

For the treatment of hyperuricaemia in patients with gout, **FEBUCIP** is recommended at a dosage of 40 mg or 80 mg once daily.

The recommended starting dose is 40 mg once daily. For patients who do not achieve a sUA < 6 mg/dL after 2 weeks with 40 mg, **FEBUCIP** 80 mg is recommended. **FEBUCIP**can be taken without regard to food or antacid use.

Gout flares may occur after initiation of **FEBUCIP** due to changing sUA levels, resulting in mobilization of urate from tissue deposits. Flare prophylaxis with an NSAID or colchicine is recommended upon initiation of therapy with **FEBUCIP** . Prophylactic therapy may be beneficial for up to 6 months. If a gout flare occurs during **FEBUCIP** treatment, they need not be discontinued. The gout flare should be managed concurrently, as appropriate for the individual patient.

Febuxostat is contraindicated in patients being treated with azathioprine, mercaptopurine or theophylline.

No dose adjustment is necessary in patients with mild or moderate renal and hepatic impairment . Caution should

be exercised in severe renal and hepatic impairment patients.

FEBUCIP is available in 2 strengths - 40 mg and 80 mg.

November 2010

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SORNIP cream – Answering the Unanswered

Psoriasis is a lifelong disease that waxes and wanes over time. It affects 1 to 3% of the world's population. People with psoriasis have to live with this chronic disease for which there is no known cure. Adequate treatment can, however, relieve the symptoms and maintain remission. During their lifetime, patients will undergo a range of treatment options to achieve the desired goals.

Varieties of systemic and topical agents are available for the treatment of psoriasis, but the latter remains the mainstay of treatment for most patients, especially those with limited disease. But, many of these agents have certain limitations.

There is a constant research for an optimum therapeutic option. An innovative formulation, **SORNIP cream** which contains the resin extract of the *Boswellia serrata* tree is introduced for the treatment of mild to moderate psoriasis. The active ingredient in**SORNIP cream** is the 3-0-acetyl keto beta boswellic acid.

SORNIP cream has beneficial effects in psoriasis because of its anti-inflammatory and immunomodulatory activity; thus, it slows down or normalizes the excessive keratinocyte proliferation and reduces the inflammation associated with psoriasis.

SORNIP cream can be used as a monotherapy to treat mild and localized psoriasis. It may have a potential to be used as a combination therapy for patients with moderate and severe disease. It can also be used during the "steroid-free holiday periods" and as a maintenance treatment option.

SORNIP cream is required to be applied as a thin layer on the psoriatic lesions three times daily (of which one application should be before bedtime).

It is available in a 30 gm lamitube pack.

October 2010

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Cipla Launches PIRFENEX (Pirfenidone 200 mg) in India for Idiopathic Pulmonary Fibrosis

Idiopathic pulmonary fibrosis (IPF) is an inevitably progressive form of lung disease, with a dismal prognosis for which, until recently, there were no effective and approved treatments.IPF has a median survival from diagnosis of 2.8-4.2 years which is less than many cancers. In idiopathic pulmonary fibrosis, epithelial injury by an unknown inciting agent in a susceptible host and abnormal wound healing leads to fibroproliferative and inflammatory changes in the lungs. Eventually this leads to severe dyspnoea in the patient with most patients dying of respiratory failure.

PIRFENEX (Pirfenidone) is the first and only approved drug for the treatment of IPF. Pirfenidone exerts its effect by down regulating the transcription of key profibrotic growth factors including TGF- ß, reducing inflammatory cytokines such as TNF-α and through reduction in lipid peroxidation and oxidative stress. It is a novel anti-fibrotic drug which through clinical trials has shown to slow down progression of this terminal disease as measured by decline in forced vital capacity over 36-72 weeks and stabilizes lung function. As per a recent Cochrane analysis, pirfenidone is the only drug which improves progression free survival in IPF patients by 30%. In general, in these clinical trials, pirfenidone was safe and well tolerated.

Hence introduction of pirfenidone offers hope and opens up a new path in the treatment of IPF patients.

PANSTAL: Ensures the Real Value of Food

Pancreatic Exocrine insufficiency (PEI) is caused by a generalized reduction in pancreatic enzyme production and delivery, leading to severe impairment in fat absorption with steatorrhoea (greasy foul smelling stools).

PEI is associated with conditions like chronic pancreatitis, after pancreatic or major gastro intestinal surgery, obstruction of pancreatic or common bile duct and cystic fibrosis.

Symptoms and signs other than steatorrhoea include abdominal cramps after meals, abdominal bloating, malabsorption, weight loss and even chronic malnutrition if left untreated. About 80% of patients after pancreatic surgery and 50% of patients with chronic pancreatitis develop PEI associated maldigestion in 10 to 12 years from the onset of the disease. Hence recognition of this condition and an appropriate replacement therapy is highly relevant to avoid malnutrition-related morbidity and mortality.

The management of PEI includes correction of the underlying cause or disease, dietary supervision and oral administration of pancreatic enzyme replacement therapy (PERT).

PERT aims at providing pancreatic enzymes in the duodenal lumen with sufficient active lipase at the time of gastric emptying of nutrients. These pancreatic enzymes then help break down fats, proteins and carbohydrates in food, thereby acting as a replacement for digestive enzymes physiologically secreted by the pancreas.

Key highlights: PANSTAL CAPSULES

- Have enteric-coated granules to avoid acid-mediated inactivation of lipase and ensure gastric emptying of enzymes in parallel with nutrients.
- Release the active pancreatic enzymes within the proximal intestine with a high therapeutic efficacy.
- Are widely accepted as the therapy of choice for maldigestion secondary to pancreatic exocrine insufficiency of any aetiology.

Each capsule contains:
Pancreatin IP ……150 mg equivalent to:
Lipase …….. 10,000 PhEur units
Amylase …… 8,000 PhEur units
Protease …… 600 PhEur units
(as enteric coated granules)

PANSTAL Capsules are indicated for patients with pancreatic exocrine insufficiency, which is often associated with the following: chronic pancreatitis , after pancreatectomy or gastrointestinal bypass surgery, ductal obstruction from a neoplasm (pancreas or common bile duct) and cystic fibrosis.

The dosage of **PANSTAL Capsules** should be individualized based on clinical symptoms, the degree of steatorrhea present, and the fat content of the diet.

Generally for children (below 6 years of age) usual initial starting dosage is up to one**PANSTAL Capsule** per meal or snack. For adults and children (over 6 years of age) the usual initial starting dosage is one to two **PANSTAL Capsules** per meal or snack.

PANSTAL Capsule should be taken **during meals or snacks** , with sufficient fluid. The capsules can be swallowed whole, or for ease of administration they may be opened and the granules taken with fluid or soft food (apple puree or mashed vegetables) but without chewing followed with a glass of water or juice to ensure complete ingestion.

October 2010

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Rosulip-F: A Class Apart Combination

Statin therapy is clearly established as an effective treatment for lowering LDL-C levels and is the cornerstone of dyslipidemia management. However, 60% of vascular complications still occur despite statin therapy. Hence, this means that a particular "residual risk" still persists which we must effectively address to reduce the clinical and economic burden. This residual risk can be effectively tackled with a statin-fibrate combination. Also, statin and fenofibrate therapy have been associated with reduction in the risk of various macrovascular and microvascular complications of diabetes.

Rosuvastatin is the most potent statin with a safety profile comparable to other statins, while fenofibrate is effective in lowering TG and increasing HDL-C. **The combination ofrosuvastatin and fenofibrate therefore constitutes an optimal therapeutic approach for providing optimal treatment of atherogenic dyslipidemia and managing vascularcomplications.**

ROSULIP-F is available in two strengths: **ROSULIP-F5** (5 mg rosuvastatin with 145 mg fenofibrate) and **ROSULIP-F10** (10 mg rosuvastatin with 145 mg fenofibrate).

INDICATIONS

ROSULIP-F is indicated as an adjunct to diet for treatment of mixed dyslipidemia, hypercholesterolemia and hypertriglyceridemia.

DOSAGE AND ADMINISTRATION

Patients should be placed on an appropriate lipid-lowering diet before receiving**ROSULIP-F** , and should continue this diet during treatment. The recommended dosage is one tablet once daily

ROSULIP-F cannot be used to initiate dosing in patients having mild to moderate impaired renal function and should be administered only after evaluating the effects of rosuvastatin and fenofibrate on renal function and lipid levels.

October 2010

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Pararcip: Infusing Relief

Pain is a major concern influencing every aspect of life. Pain is often called the fifth vital sign in conjunction with temperature, pulse, respiration and blood pressure. Though pain serves the useful purpose of warning it imposes several emotional, physical and economical stresses on the patient. Thereby, there is a need to ease the suffering and improve the quality of life of those living with pain.

Introducing **PARACIP** solution for infusion, containing 1g paracetamol for intravenous infusion.

Paracetamol has been widely used for over a century as an effective analgesic and as an antipyretic agent. Its efficacy and tolerability are well established and in contrast to other analgesics, it has a favourable safety profile.

PARACIP can also be used as an effective component in multimodal analgesia in combination with opioids and NSAIDs.

PARACIP solution for infusion is indicated for

- The short-term treatment of moderate pain, especially following surgery
- The short-term treatment of fever, when administration by intravenous route is clinically justified by an urgent need to treat pain or hyperthermia and/or when other routes of administration are not possible.

DOSAGE AND ADMINISTRATION

PARACIP is available as a 100ml solution for infusion containing 1g paracetamol.

PARACIP should be administered as a 15-minute intravenous infusion, and is for single use in one patient only.

PARACIP solution for infusion should not be mixed with other medicinal products

Paracetamol 1 g per administration, i.e. one 100 ml vial, can be used up to four times a day. The minimum interval between each administration must be 4 hours in patients without hepatic impairment. In patients with renal and/or hepatic impairment the minimum interval between doses must not be less than 6 hours.

The maximum daily dose from all sources of paracetamol must not exceed 4 g.

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FLOSOFT: Smart & Safe

Inflammation is the body's protective response to a stimulus it recognizes as offensive. While inflammation is protective for the body as a whole, the inflammatory processes can cause scarring and damage to the surrounding healthy tissue. Corticosteroids are used to preserve the normal structure of the tissues. They were developed in the 1940s, and till date remain the most potent agents for managing inflammation. Fluorometholone is one such steroid used for the management of inflammatory and allergic conditions of the eye.

Earlier fluorometholone was available as an alcohol derivative but now even the acetate derivative is available. The derivatives of steroid base (acetate, alcohol and phosphate) influence the bioavailability i.e. they determine the ability of steroid to penetrate the anterior chamber. Acetate and Alcohol derivatives are soluble in hydrophobic media whereas phosphate derivative is soluble in hydrophilic media. In the normal eye, an acetate derivative penetrates the best through the cornea, followed by alcohols, and then phosphates.

The derivatives of steroid base (acetate, alcohol and phosphate) also influence the bioactivity of that steroid so accordingly fluorometholone acetate shows superior anti inflammatory activity in the cornea than fluorometholone alcohol.

FLOSOFT contains Fluorometholone acetate 0.1%. It is the World's first formulation with SOC (Stabilized Oxychlorocomplex) as the preservative. SOC is introduced as an ophthalmic preservative in 1996. Once it enters the eye, it breaks into water and salt i.e. sodium and potassium ions (NaCl), these components are already found in natural tears. Also it has no effect on mammalian cells. Hence it is more comfortable than other preservatives (Benzalkonium chloride).

INDICATIONS

FLOSOFT (fluorometholone acetate ophthalmic suspension) is indicated for use in the treatment of steroid responsive inflammatory conditions of the palpebral and bulbar conjunctiva, cornea, and anterior segment of the eye.

DOSAGE AND ADMINISTRATION

Shake Well Before Using. One to two drops instilled into the conjunctival sac(s) four times daily. During the initial 24 to 48 hours the dosage may be safely increased to two drops every two hours. If no improvement after two weeks, consult physician. Care should be taken not to discontinue therapy prematurely.

FLOSOFT: Highlights

1. World's first formulation of Fluorometholone acetate with SOC as a preservative
2. Particle Size between 1-3 µ: Uniform Particle distribution and No agglomeration
3. As effective as Prednisolone and Dexamethasone in reducing corneal inflammation
4. Shows superior anti inflammatory effect in the cornea as compared to Fluorometholone alcohol
5. Fluorometholone acetate has low propensity to elevate IOP, therefore
    - Can be given to old age patients suffering from glaucoma
    - Can be given to Steroid responders
    - Can also be given in chronic therapy, requiring longer period of time

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IMUDROPS: TREAT BEYOND THE SURFACE

Dry eye is a multifactorial disease of the tears and ocular surface that results in symptoms of discomfort, visual disturbance and tear film instability with potential damage to the ocular surface. It is accompanied by increased osmolarity of the tear film and inflammation of the ocular surface.

A number of anti-inflammatory agents have been evaluated for treatment of patients with dry eye, including cyclosporine-A, pimecrolimus, tacrolimus, and corticosteroids.

Cyclosporine may represent the first product for dry eye that actually treats the cause and not the symptoms of dry eye.

To improve delivery of cyclosporine to ocular tissues, a microemulsion formulation in castor oil is developed that produces sustained cyclosporine concentrations sufficient for immunomodulation .

IMUDROPS : Technology features

- Unique micro emulsion technology provides cyclosporine particle size of less than 1 micron
- Better, faster absorption and penetration
- Negligible local irritation, burning and stinging reaction

Topical cyclosporine emulsion has also been investigated for the treatment of other ocular surface disorders that may have an immune – based inflammatory component. In these trials , cyclosporine 0.05% ophthalmic emulsion has shown efficacy for management of posterior blepharitis , ocular rosacea , post-L ASIK dry eye , contact lens intolerance , atopic keratoconjunctivitis, graft versus host disease and herpetic stromal keratitis . As these disorders are often refractory to another available treatments , ophthalmic cyclosporine is a welcome non toxic adjunct or replacement to potentially toxic topical or systemic immunosuppressive therapies.

Cyclosporine (IMUDROPS) Key HIGHLIGHTS

- Potent immunomodulator that acts selectively and locally
- US FDA approved treatment for KCS
- Significant breakthrough in the management of dry eyes

- Immunomodulatory, lacrimogenic and mucin enhancing property
- Restores the body's ability to produce natural healthy tears
- Stops the progression of dry eye disease
- Significant decrease in the artificial tears use

IMUDROPS : Indications and Usage

To increase tear production in patients whose tear production is presumed to be suppressed due to ocular inflammation associated with keratoconjunctivitis sicca.

IMUDROPS : Dosage and Administration

- Invert the unit dose vial a few times to obtain a uniform, microemulsion before using.
- Instill one drop of Imudrop ophthalmic microemulsion twice a day in each eye approximately 12 hrs apart.
- Imudrops can be used concomitantly with artificial tears, allowing a 15 minute interval between products.
- Discard vial immediately after use.

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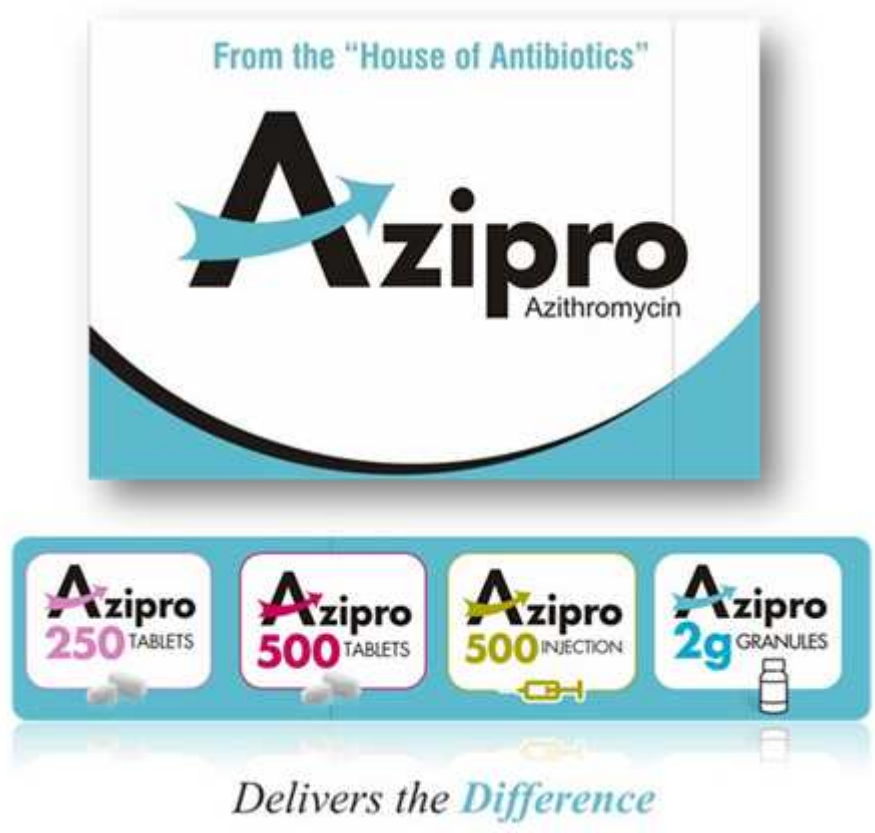
AZIPRO—Delivers the Difference



Community-acquired respiratory tract infections cause considerable morbidity and mortality. Most of these are upper respiratory tract infections with approximately one third of RTI's involving the lower respiratory tract. The use of short-course antimicrobial therapy has potential economic benefits, including reduced acquisition cost, improved adherence (compliance), reduced adverse events, reduced office visits and increased patient satisfaction.

Azithromycin is the sole member of the macrolide sub-class—the azalides. Due to its altered chemical structure, azithromycin is characterized by a broader spectrum of activity (covering gram positive, gram negative, anaerobes, atypicals and many others), lower incidence of adverse events and drug interactions and an excellent pharmacokinetic profile. The patients are also able to complete a course of azithromycin within a shorter timeframe as compared to other antibiotics.

Azithromycin is approved for use in the treatment of acute exacerbations of chronic bronchitis (AECB), mild-to-moderate community acquired pneumonia (CAP), acute bacterial sinusitis, pharyngitis/tonsillitis, uncomplicated skin and skin structure infections and pelvic inflammatory disease (PID).

Azithromycin is available as 250 mg, 500 mg oral tablets, 500 mg IV injection and 2 gms sustained release with

microsphere technology.

Microsphere technology is an advanced drug delivery system that uses microspherical shaped particles to release the drug slowly in the lower GI tract. Azithromycin is embedded in the microspheres, which enable the delivery of azithromycin as a complete course of therapy in a single dose. The microspheres minimize the release of azithromycin in the stomach, thereby minimizing GI side effects; instead, they pass through the stomach immediately and into the small intestine where the active ingredient is slowly released.

Azithromycin demonstrated good clinical and bacteriological efficacy in AECB, CAP, acute bacterial sinusitis, pharyngitis / tonsillitis, uncomplicated skin and skin structure infections and PID and was generally well tolerated. Thus, Azithromycin is a good option for the treatment of adult and adolescent patients.

Dosage and Administration:

Oral tablets in Adults

CAP (mild severity) Pharyngitis/tonsillitis (second line therapy) Skin/skin structure (uncomplicated)	500 mg as a single dose on Day 1, followed by 250 mg once daily on Days 2 through 5.
AECB (mild to moderate)	500 mg OD x 3 days OR 500 mg as a single dose on Day 1, followed by 250 mg once daily on Days 2 through 5.
Acute bacterial sinusitis	500 mg OD x 3 days

Injection in Adults

CAP	500 mg as a single daily dose by the IV route for at least two days. IV therapy should be followed by azithromycin by the oral route at a single, daily dose of 500 mg, administered as two 250-mg tablets to complete a 7- to 10-day course of therapy.
Pelvic inflammatory disease	500 mg as a single daily dose by the IV route for one or two days. IV therapy should be followed by azithromycin by the oral route at a single, daily dose of 250 mg to complete a 7-day course of therapy.

The infusate concentration and rate of infusion for **AZIPRO** (azithromycin for injection) should be either 1 mg/mL over 3 hours or 2 mg/mL over 1 hour.

AZIPRO (azithromycin for injection) should not be given as a bolus or as an intramuscular injection.

Azithromycin sustained release

AZIPRO should be taken as a single 2 g dose.

AZIPRO (azithromycin SR) should be used within 12 hours of mixing (do not refrigerate) and be taken on an empty stomach (at least 1 hour before or 2 hours following a meal)

LEVOLIN AUTOHALER

Experience relief with never before ease

Levolin (levosalbutamol) **Autohaler** is the world's first - easy to use, breath actuated inhaler (BAI).

Levosalbutamol or (R)-salbutamol is the pure, therapeutically active isomer of salbutamol. It is a potent bronchodilator, effective at half the dose of salbutamol with a quick onset of action. The entire bronchodilatory activity of racemic salbutamol is attributable to (R)salbutamol. (S) salbutamol has been shown to have no bronchodilatory or bronchoprotective activity. In fact studies have shown that (S) salbutamol might have pro-inflammatory properties.

Levosalbutamol is available as Levolin rotacaps to be used with Rotahaler/Revolizer, pressurized metered dose inhaler (pMDI), respules to be used with nebulizer. Now levosalbutamol is also available as **Levolin Autohaler.** It is indicated for the treatment or prevention of bronchospasm in adults, adolescents and children with reversible obstructive airway disease.

Levolin Autohaler overcomes the key problem of the pMDI viz. coordination of actuation with inhalation and does not rely on the patient`s inspiratory effort to aerosolize the dose of medication unlike dry powder inhalers. **Levolin Autohaler** is activated at low flow rates of 22-30 l/sec. Studies have shown that the Autohaler TM is easier to use and to teach as compared to pMDIs and some of the DPIs. It can also be used by children who

are wheezing, older patients with severe airflow obstruction and those with arthritis. **Autohaler**TM contains 300 doses, which ensures long term preventive inhalation for the patient, thus offers better adherence and compliance.

Now, **Autohaler** TM is available as a complete therapy for patients, viz. controller and reliever as **Seroflo Autohaler** and **Levolin Autohaler** respectively.

For more information on autohaler device, log onto: www.ciplaautohaler.com

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ZOLMIST: Head to Relief in Minutes

Migraine is a common, frequently incapacitating, headache disorder characterized by episodic attacks of moderate-to-severe headaches, and various combinations of neurological, gastrointestinal and/or autonomic nervous system dysfunction. It is estimated that migraine affects 12% of the general population. It is 3-time more common in females as compared to males; with prevalence of 18% in women and 6% in men. It is a disabling condition and incurs a heavy toll in terms of treatment costs, patient disability, and patient quality of life. In fact, World Health Organization has labeled severe migraine, along with quadriplegia, psychosis and dementia, as the most disabling chronic condition.

Migraine management has two way approach: a) prophylactic therapy – when the patient has frequent migraine attacks (> 2 attacks in a month) medication is used to prevent the future migraine attack; b) abortive therapy – when the patient has rare migraine attacks, drugs are used only after the attack to reduce pain, associated symptoms & improve quality of life.

Triptans are used for abortive treatment of migraine & is a drug which should be used only when the diagnosis of migraine is confirmed as it is a drug specific for migraine treatment. From the class of triptans; sumatriptan, rizatriptan & naratriptan were available in India . Cipla took an initiative not only to introduce a new triptan ie. zolmitriptan in India but it has launched zolmitriptan in nasal form, with brand name**ZOLMIST.** This revolutionary

drug-device combination offers several advantages over oral and parenteral formulations in migraine patients.

The key benefit of using zolmitriptan in nasal formulation is the rapid onset-of-action.Relief from migraine is obtained as early as 10 minutes post-dose of intranasal zolmitriptan. Studies have shown that zomitriptan nasal spray yields consistent and significantly higher headache response rates, relief from migraine symptoms and pain-free rates as compared to placebo and oral zolmitriptan. Besides, higher number of patients were able to return back to their normal routine in just 2 hrs post zolmitriptan use. Apart from the efficacy, patient satisfaction is an important parameter in migraine therapy. Patient satisfaction studies with zolmitriptan nasal spray show that around 70-80% of patients are satisfied with intranasal zolmitriptan. Speed of onset and efficacy were the 2 key factors cited by many patients preferring zolmitriptan nasal spray over their previous therapy. Zolmitriptan has a good tolerability profile with no major adverse event. Both safety & efficacy for intranasal zolmitriptan has been evaluated & established for a period of one year.

In fact, **ZOLMIST** has been studied in Indian patients & it was found to be effective & safe for migraine treatment. Overall 74% of patients in the study were satisfied with **ZOLMIST**& 84% were willing to use it in future.

One vial of **ZOLMIST** contains seven metered doses of zolmitriptan. The recommended dose of **ZOLMIST** is one spray (i.e. 5 mg). If headache returns, the dose may be repeated only after 2 hours. The maximum dosage of **ZOLMIST** should not exceed more than two sprays (i.e. 10 mg) in 24 hours.

Thus, **ZOLMIST** , which is a new addition to the list of *India 's first brands by Cipla* , targets to offer quick & consistent benefits in migraine patients & help migraine patients to ***head towards relief in minutes*** .

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