

especially in those with hypertension, the use of nasal decongestants must be supervised by the physician. The prolonged use of preparations containing vasoconstrictive substances may alter the normal function of the nasal mucosa and of the paranasal sinuses, thus inducing drug addiction. Therefore, repeated applications for long periods may be harmful.

Rinofluimucil should be used with due caution in pediatrics, asthmatic patients, the elderly and subjects suffering from prostatic hypertrophy due to the risk of urinary retention.

Effects on the Ability to Drive or Operate Machinery: There is no evidence that Rinofluimucil can affect attention or reaction time.

Use in pregnancy & lactation: Rinofluimucil should be given to pregnant and lactating women only in case of real need, under medical supervision.

ADVERSE REACTIONS: Frequent administrations of Rinofluimucil at the highest dosage may cause adverse events of sympathomimetic nature eg, increase in excitability, cardiac palpitations, tremor, hypertension, headache and urination troubles.

INTERACTIONS: There is no evidence in literature of clinically significant interactions with the active ingredients of Rinofluimucil. The use of vasoconstrictors is not suggested during the treatment with tricyclic antidepressants.

STORAGE: Shelf-Life: 30 months. After first opening, Rinofluimucil can be used for a period not exceeding 20 days.

SPEDIFEN

CONTENTS: * Ibuprofen as arginine.

PRESENTATION: Tab 400 mg (film-coated) 5 x 6's.

DESCRIPTION: Ibuprofen arginine is a highly soluble salt formed by combining racemic ibuprofen with the amino acid L-arginine. The presence of arginine facilitates the dissolution of ibuprofen (in gastrointestinal tract), permitting more rapid absorption of ibuprofen. The principal effect of this product is more rapid onset of the analgesic and anti-inflammatory actions of ibuprofen.

ACTIONS: Spedifen has analgesic, antipyretic and prominent anti-inflammatory effects. The analgesic effects of ibuprofen are the result of both peripheral and central effects and are distinct from its anti-inflammatory properties.

Similar to other NSAIDs, Spedifen is potent, unspecific inhibitor of the isoenzymes cyclooxygenase-1 (COX-1) and -2 (COX-2) which results in a marked reduction in prostaglandin and thromboxane synthesis. In contrast to salicylates which irreversibly acetylate the cyclooxygenases, propionic derivatives compete with the precursor arachidonic acid at the active site of the enzymes in a reversible manner.

Besides the reduction of prostaglandin and thromboxane formation, ibuprofen arginine also partly inhibits the synthesis of several lipooxygenase products.

Analgesic, antipyretic and anti-inflammatory effects of the inhibition of prostaglandin synthesis prevent their hyperalgetic effect upon sensory nerves; reduction of vasodilator prostanoid formation (PGE₂) diminishes vascularity and fluid transudation, which are main manifestations of inflammation.

Pharmacokinetics: Ibuprofen arginate and the analogous amino acid/ibuprofen salt formulation ibuprofen lysinate produce peak plasma levels considerably earlier and higher than ibuprofen acid, while bioavailability and elimination kinetics remain similar. Peak plasma levels are achieved 0.5-0.6 hr after administration of ibuprofen arginate and 0.55-0.75 hr after administration of ibuprofen lysinate. The systemic bioavailability of ibuprofen lysinate is complete.

INDICATIONS: * Symptomatic relief of pain (eg, headache, toothache, dysmenorrhea, osteoarticular and muscular pain). Fever due to influenza.

DOSAGE & ADMINISTRATION: * **Adults and Children >12 years:** 1 tab 3-4 times a day.

Do not exceed 4 tabs a day. Elderly, in particular, should use the lowest advised dose.

CONTRAINDICATIONS: * Patients who have previously shown hypersensitivity to the components of Spedifen or to other antirheumatic drugs (acetylsalicylic acid, etc).

Patients with active or severe peptic ulceration or other gastropathies.

Patients with severe hepatic or renal impairment.

Use in pregnancy & lactation: Spedifen is contraindicated in pregnant and lactating women.

WARNINGS: After a short period of treatment without appreciable results, consult the physician. In patients whose activity requires surveillance should pay attention if somnolence, dizziness or depression occurs during ibuprofen treatment.

Spedifen cannot be used in haemorrhagic-fever patients.

PRECAUTIONS: * In patients suffering from asthma, Spedifen must be administered only in case of real need and under physician's control.

ADVERSE REACTIONS: * Sometimes cutaneous allergic reaction (erythema, urticaria and pruritus) may be experienced. The most frequent adverse events occurring with ibuprofen are gastrointestinal disturbances. These include dyspepsia, abdominal pain and, sometimes, constipation or diarrhoea. The frequency of nausea and vomiting is rare. Exceptionally, the appearance of ulcers has been reported. These may be accompanied by gastrointestinal bleeding. Such events quickly disappear upon suspension of treatment.

Consult the physician or pharmacist if adverse events, other than those previously mentioned occur.

INTERACTIONS: * Interactions with coumarin-type anticoagulants should occur. Patients undergoing such therapy should consult the physician before treatment with Spedifen. In cases of any concomitant treatment with other drugs, it is advisable to consult the physician before starting with Spedifen.

URFAMYCIN

CONTENTS: Thiamphenicol.

PRESENTATION: Cap 250 mg x 20's, 1000's. 500 mg x 5's, 500's. Vial 0.5 g x 1's, 100's. 0.75 g x 1's.

DESCRIPTION: Urfamycin capsule contains thiamphenicol while the injection contains thiamphenicol glycinate.

Thiamphenicol is D(+)-threo-2-dichloroacetamido-1-(4-methylsulfonylphenyl)propane-1,3-diol.

Empirical Formula: C₁₂H₁₅Cl₂NO₅S.

Molecular Weight: 356.24.