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IBUGESIC TH Tablets (Aceclofenac + Thiocolchicoside)

Composition

IBUGESIC TH 4
Each film-coated tablet contains:
Thiocolchicoside IP ..... 4 mg
Aceclofenac IP.....100 mg
Excipients.....q.s.
IBUGESIC TH 8
Each film-coated tablet contains:
Thiocolchicoside IP ..... 8 mg
Aceclofenac IP.....100 mg
Excipients.....q.s.

Dosage Form

Tablets for oral use

Description

IBUGESIC TH is a fixed-dose combination of the non-steroidal anti-inflammatory drug (NSAID), aceclofenac, with an effective non-sedating muscle relaxant, thiocolchicoside, to treat painful muscle spasms.

Pharmacology

▶ Pharmacodynamics

Aceclofenac
Aceclofenac is a NSAID with marked anti-inflammatory and analgesic properties. The mode of action of aceclofenac is largely based on the inhibition of prostaglandin synthesis. Aceclofenac is a potent inhibitor of the enzyme cyclooxygenase, which is involved in the production of prostaglandins.
Thiocolchicoside
Thiocolchicoside is a glycosulphurated analogue of colchicine. In preclinical studies, the drug was reported to have selective affinity for gamma-aminobutyric acid (GABA) and glycinergic receptors; these properties appear to mediate skeletal muscle relaxant activity. There is evidence that muscle relaxant actions may result from direct activation of the GABA receptor at the spinal level.
Thiocolchicoside has exhibited analgesic and anti-inflammatory activity in animal models.
In a placebo-controlled trial involving healthy volunteers, thiocolchicoside was devoid of any objective or subjective sedative side effects when given in a dose of 16 mg daily for up to 1 week.

▶ Pharmacokinetics

Aceclofenac

Absorption

After oral administration, aceclofenac is rapidly and completely absorbed as unchanged drug. Peak plasma concentrations are reached approximately 1.25 to 3.00 hours following ingestion. Aceclofenac penetrates the synovial fluid, where the concentrations reach approximately 57% of those in plasma.

Distribution

Aceclofenac is highly protein-bound (>99%). The volume of distribution is approximately 25 L.

Metabolism

Aceclofenac circulates mainly as unchanged drug. The main metabolite detected in plasma is 4'- hydroxyaceclofenac. Aceclofenac is partially metabolised to diclofenac.

Excretion

The mean plasma elimination half-life is around 4 hours. Approximately two-thirds of the administered dose is excreted via the urine, mainly as hydroxymetabolites.

Special Population

No changes in the pharmacokinetics of aceclofenac have been detected in the elderly.

Thiocolchicoside

Absorption

After oral administration, no thiocolchicoside is detected in plasma. Only two metabolites are observed: the pharmacologically active metabolite, SL18.0740, and an inactive metabolite, SL59.0955. For both metabolites, maximum plasma concentrations occur 1 hour after thiocolchicoside administration.

After a single oral dose of 8 mg of thiocolchicoside, the C_{max} and AUC of SL18.0740 are about 60 ng/mL and 130 ng.h/mL, respectively. For SL59.0955, these values are much lower: C_{max} around 13 ng/mL and AUC ranging from 15.5 ng.h/mL (until 3 hours) to 39.7 ng.h/mL (until 24 hours).

Distribution

The apparent volume of distribution of thiocolchicoside is estimated around 42.7 L after an intramuscular (IM) administration of 8 mg. No data are available for both metabolites.

Metabolism

After oral administration, thiocolchicoside is first metabolised in the aglycon 3- demethylthiocolchicine or SL59.0955. This step mainly occurs by intestinal metabolism, explaining the lack of circulating unchanged thiocolchicoside by this route of administration. SL59.0955 is then glucuroconjugated into SL18.0740, which has equipotent pharmacological activity to thiocolchicoside and, thus, supports the pharmacological activity after oral administration of thiocolchicoside. SL59.0955 is also demethylated into didemethyl-thiocolchicine.

Excretion

After oral administration, total radioactivity is mainly excreted in faeces (79%) while urinary excretion represents only 20%. No unchanged thiocolchicoside is excreted either in urine or faeces. SL18.0740 and SL59.0955 are found in urine and faeces while the didemethyl-thiocolchicine is only recovered in faeces. After oral administration of thiocolchicoside, the SL18.0740 metabolite is eliminated with an apparent $t_{1/2}$ ranging from 3.2 to 7 hours and the metabolite SL59.0955 has a $t_{1/2}$ averaging 0.8 hours.

Indication

For the treatment of acute inflammation condition associated with spasms in adults only.

Dosage And Administration

One tablet twice daily or as directed by the physician.

Contraindications

▶ Aceclofenac

Hypersensitivity to aceclofenac or to any of the excipients. Active, or a history of, recurrent peptic ulcer/haemorrhage (two or more distinct episodes of proven ulceration or bleeding).
NSAIDs are contraindicated in patients who have previously shown hypersensitivity reactions (e.g. asthma, rhinitis, angio-oedema or urticaria) in response to ibuprofen, aspirin, or other NSAIDs.
Patients with active bleeding or bleeding diathesis.
Severe hepatic failure and renal failure
Established congestive heart failure (NYHA II–IV), ischaemic heart disease, peripheral arterial disease and/or cerebrovascular disease.
History of gastrointestinal (GI) bleeding or perforation, related to previous NSAIDs therapy.
Aceclofenac should not be prescribed during pregnancy, especially during the last trimester of pregnancy, in women attempting to conceive and during lactation unless there are compelling reasons for doing so. The lowest effective dosage should be used.

▶ Thiocolchicoside

Hypersensitivity to thiocolchicoside or to any of the excipients
During the entire pregnancy period
During lactation
In women of childbearing potential not using contraception

Warnings And Precautions

▶ Aceclofenac

Undesirable effects may be minimised by using the lowest effective dose for the shortest duration necessary to control symptoms.
The use of aceclofenac with concomitant NSAIDs, including cyclooxygenase-2 selective inhibitors, should be avoided.
Respiratory Disorders
Caution is required if administered to patients suffering from, or with a previous history of, bronchial asthma since NSAIDs have been reported to precipitate bronchospasm in such patients.
Cardiovascular, Renal and Hepatic Impairment
The administration of an NSAID may cause a dose-dependent reduction in prostaglandin formation and precipitate renal failure. Patients at greatest risk of this reaction are those with impaired renal function, cardiac impairment, liver dysfunction, those taking diuretics and the elderly. Renal function should be monitored in these patients.
Cardiovascular and Cerebrovascular Effects
Patients with congestive heart failure (NYHA-I) and patients with significant risk factors for cardiovascular events (e.g. hypertension, hyperlipidaemia, diabetes mellitus, smoking) should only be treated with aceclofenac after careful consideration. Appropriate monitoring and advice are required for patients with a history of hypertension and/or mild congestive heart failure (NYHA-I) as fluid retention and oedema have been reported in association with NSAID therapy.
As the cardiovascular risks of aceclofenac may increase with dose and duration of exposure, the shortest duration

possible and the lowest effective daily dose should be used. The patient's need for symptomatic relief and response to therapy should be re-evaluated periodically.
Aceclofenac should also be administered with caution and under close medical surveillance to patients with a history of cerebrovascular bleeding.
GI Bleeding, Ulceration and Perforation
GI bleeding, ulceration or perforation, which can be fatal, has been reported with all NSAIDs at any time during treatment, with or without warning symptoms or a previous history of serious GI events.
Close medical surveillance is imperative in patients with symptoms indicative of GI disorders, with a history suggestive of GI ulceration, with ulcerative colitis or with Crohn's disease, bleeding diathesis or haematological abnormalities.
The risk of GI bleeding, ulceration or perforation is higher with increasing NSAID doses, in patients with a history of ulcer, particularly if complicated with haemorrhage or perforation, and in the elderly. These patients should commence treatment on the lowest dose available. Combination therapy with protective agents (e.g. misoprostol or proton-pump inhibitors) should be considered for these patients, and also for patients requiring concomitant low-dose aspirin, or other drugs likely to increase GI risk.
Patients with a history of GI toxicity, particularly when elderly, should report any unusual abdominal symptoms (especially GI bleeding) particularly in the initial stages of treatment.
Caution should be advised in patients receiving concomitant medications that could increase the risk of ulceration or bleeding, such as oral corticosteroids, anticoagulants such as warfarin, selective serotonin-reuptake inhibitors (SSRIs) or antiplatelet agents such as aspirin.
When GI bleeding or ulceration occurs in patients receiving aceclofenac, the treatment should be withdrawn.
NSAIDs should be given with care to patients with a history of GI disease (ulcerative colitis, Crohn's disease) as these conditions may be exacerbated.
Systemic Lupus Erythematosus (SLE) and Mixed Connective Tissue Disease
In patients with SLE and mixed connective tissue disorders, there may be an increased risk of aseptic meningitis.
Dermatological
Serious skin reactions, some of them fatal, including exfoliative dermatitis, Stevens-Johnson syndrome and toxic epidermal necrolysis, have been reported very rarely in association with the use of NSAIDs. Patients appear to be at highest risk for these reactions early in the course of therapy, with the onset of the reaction occurring in the majority of cases within the first month of treatment. Aceclofenac should be discontinued at the first appearance of skin rash, mucosal lesions, or any other sign of hypersensitivity.
Exceptionally, varicella can trigger serious cutaneous and soft tissue infection complications. To date, the contributing role of NSAIDs in the worsening of these infections cannot be ruled out. Thus, it is advisable to avoid use of aceclofenac in case of varicella.
Impaired Female Fertility
The use of aceclofenac may impair female fertility and is not recommended in women attempting to conceive. In women who have difficulties conceiving or who are undergoing investigation of infertility, withdrawal of aceclofenac should be considered.
Hypersensitivity Reactions
As with other NSAIDs, allergic reactions, including anaphylactic/anaphylactoid reactions, can also occur without earlier exposure to the drug.
Haematological
Aceclofenac may reversibly inhibit platelet aggregation. Aceclofenac should be avoided in patients who have developed anaemia, agranulocytosis or thrombocytopaenia secondary to NSAIDs or metamizol.
Long-term Treatment

All patients who are receiving NSAIDs should be monitored as a precautionary measure, e.g. renal failure, hepatic function (elevation of liver enzymes may occur) and blood counts.

Effects on Ability to Drive and Use Machines

Undesirable effects such as dizziness, drowsiness, fatigue and visual disturbances are possible after taking NSAIDs. If affected, patients should not drive or operate machinery.

▶ Thiocolchicoside

Preclinical studies showed that one of thiocolchicoside's metabolites (SL59.0955) induced aneuploidy (i.e. unequal number of chromosomes in dividing cells) at concentrations close to human exposure observed at doses 8 mg twice daily per os. Aneuploidy is considered as a risk factor for teratogenicity, embryo/foeto-toxicity, spontaneous abortion, and impaired male fertility, and a potential risk factor for cancer.

As a precautionary measure, use of the product at doses exceeding the recommended dose or long-term use should be avoided. Patients should be carefully informed about the potential risk of a possible pregnancy and about effective contraception measures to be followed.

Thiocolchicoside should be administered with caution to epileptic patients or patients with a risk of convulsions.

Reduce the dosage of thiocolchicoside, as necessary, in case of diarrhoea. If necessary, the tablets can be taken with an antacid.

Thiocolchicoside, when administered orally, should not be used at higher dose or for longer than 7 days.

Thiocolchicoside is not recommended in flaccid paralysis, muscular hypotonia and renal impairment.

▶ Drug Interactions

Aceclofenac

Other Analgesics, Including Cyclooxygenase-2 Selective Inhibitors: Avoid concomitant use of two or more NSAIDs (including aspirin) as this may increase the risk of adverse effects.

Antihypertensives: Reduced antihypertensive effect. The risk of acute renal insufficiency, which is usually reversible, may be increased in some patients with compromised renal function (e.g. dehydrated patients or elderly patients) when ACE inhibitors or angiotensin II-receptor antagonists are combined with NSAIDs. Therefore, the combination should be administered with caution, especially in the elderly. Patients should be adequately hydrated and consideration should be given to monitoring of renal function after initiation of concomitant therapy, and periodically thereafter.

Diuretics: Reduced diuretic effect. Diuretics can increase the risk of nephrotoxicity of NSAIDs. Although it was not shown to affect blood pressure control when co-administered with bendrofluazide, interactions with other diuretics cannot be ruled out. When concomitant administration with potassium-sparing diuretics is employed, serum potassium should be monitored.

Cardiac Glycosides, e.g. Digoxin: NSAIDs may exacerbate cardiac failure, reduce glomerular filtration rate (GFR) and increase plasma glycoside levels. The combination should be avoided unless frequent monitoring of glycoside levels can be performed.

Lithium: Several NSAIDs drugs inhibit the renal clearance of lithium, resulting in increased serum concentration of lithium. The combination should be avoided unless frequent monitoring of lithium can be performed.

Methotrexate: The possible interaction between NSAIDs and methotrexate should be kept in mind even when low doses of methotrexate are used, especially in patients with decreased renal function. When combination therapy has to be used, the renal function should be monitored. Caution should be exercised if NSAIDs and methotrexate are administered within 24 hours of each other, since NSAIDs may increase plasma levels, resulting in increased toxicity.

Mifepristone: NSAIDs should not be used for 8 to12 days after mifepristone administration as NSAIDs can reduce the effect of mifepristone.

Corticosteroids: Increased risk of GI ulceration or bleeding
Anticoagulants: NSAIDs may enhance the effects of anticoagulants, such as warfarin. Close monitoring of patients on combined anticoagulants and aceclofenac therapy should be undertaken.
Quinolone Antibiotics: Animal data indicate that NSAIDs can increase the risk of convulsions associated with quinolone antibiotics. Patients taking NSAIDs and quinolones may have an increased risk of developing convulsions.
Antiplatelet Agents and SSRIs: Increased risk of GI bleeding.
Cyclosporine, Tacrolimus: Administration of NSAID drugs together with cyclosporine or tacrolimus is thought to increase the risk of nephrotoxicity due to decreased synthesis of prostacyclin in the kidneys. During combination therapy, it is, therefore, important to carefully monitor renal function.
Zidovudine: Increased risk of haematological toxicity is present when NSAIDs are given with zidovudine. There is evidence of an increased risk of haemarthroses and haematoma in HIV(+) haemophiliacs receiving concurrent treatment with zidovudine and ibuprofen.
Antidiabetic Agents: Clinical studies have shown that diclofenac can be given together with oral antidiabetic agents without influencing their clinical effect. However, there have been isolated reports of hypoglycaemic and hyperglycaemic effects. Thus, with aceclofenac, consideration should be given to adjustment of the dosage of hypoglycaemic agents.
Other NSAIDs: Concomitant therapy with aspirin or other NSAIDs may increase the frequency of adverse reactions, including the risk of GI bleeding.
Thiocolchicoside
Alcohol and other CNS depressants: Additive CNS depressant effects may occur.

▶ Renal Impairment

The administration of an NSAID may cause a dose-dependent reduction in prostaglandin formation and precipitate renal failure. The importance of prostaglandins in maintaining renal blood flow should be taken into account in patients with impaired cardiac or renal function, those being treated with diuretics or recovering from major surgery. Effects on renal function are usually reversible on withdrawal of aceclofenac.

▶ Hepatic Impairment

If abnormal liver function tests persist or worsen, clinical signs or symptoms consistent with liver disease develop or if other manifestations occur (eosinophilia, rash), aceclofenac should be discontinued. Close medical surveillance is necessary in patients suffering from mild-to-moderate impairment of hepatic function. Hepatitis may occur without prodromal symptoms.
Use of aceclofenac in patients with hepatic porphyria may trigger an attack.

▶ Pregnancy

There is no information on the use of aceclofenac during pregnancy. Inhibition of prostaglandin synthesis may adversely affect the pregnancy and/or the embryo/foetal development. Data from epidemiological studies suggest an increased risk of miscarriage, cardiac malformation or gastroschisis after use of prostaglandin synthesis inhibitor in early pregnancy. The absolute risk for cardiovascular malformation was increased from less than 1%, up to approximately 1.5%. The risk is believed to increase with dose and duration of therapy.
In animals, administration of a prostaglandin synthesis inhibitor has been shown to result in increased pre- and post-implantation loss and embryo-foetal lethality. In addition, increased incidences of various malformations, including cardiovascular, have been reported in animals given a prostaglandin synthesis inhibitor during the organogenetic period.
During the first and second trimester of pregnancy, aceclofenac should not be given unless clearly necessary. If aceclofenac is used by a woman attempting to conceive, or during the first and second trimester of pregnancy, the dose should be kept as low and duration of treatment as short as possible.

During the third trimester of pregnancy, all prostaglandin synthesis inhibitors may expose the foetus to the following:
- Cardiopulmonary toxicity (with premature closure of the ductus arteriosus and pulmonary hypertension).
- Renal dysfunction, which may progress to renal failure with oligo-hydroamniosis.

The mother and the neonate, at the end of pregnancy, are at risk for the following:
- Possible prolongation of bleeding time, an anti-aggregating effect that may occur even at very low doses.
- Inhibition of uterine contractions resulting in delayed or prolonged labour.

Consequently, aceclofenac is contraindicated during the third trimester of pregnancy
There are limited data on the use of thiocolchicoside in pregnant women. Therefore, the potential hazards for the embryo and foetus are unknown. Studies in animals have shown teratogenic effects. Thiocolchicoside is contraindicated during pregnancy and in women of childbearing potential not using contraception.

▶ Lactation

There is no information on the secretion of aceclofenac to breast milk; there was, however, no notable transfer of radiolabelled (^{14}C) aceclofenac to the milk of lactating rats. The use of aceclofenac should, therefore, be avoided in pregnancy and lactation unless the potential benefits to the other outweigh the possible risks to the foetus.
Since thiocolchicoside passes into the mother’s milk, its use is contraindicated during breastfeeding.

▶ Paediatric Use

There are no clinical data on the use of aceclofenac in children and therefore it is not recommended for use in children.
Thiocolchicoside should not be used in children and adolescents aged below 16 years.

▶ Geriatric Use

The elderly have an increased frequency of adverse reactions to NSAIDs, especially GI bleeding and perforation, which may be fatal. The elderly, who are more likely to be suffering from impaired renal, cardiovascular or hepatic function and receiving concomitant medication, are at increased risk of the serious consequences of adverse reactions. If an NSAID is considered necessary, the lowest effective dose should be used and for the shortest possible duration. The patient should be monitored regularly for GI bleeding during NSAID therapy.

Undesirable Effects

▶ Aceclofenac

GI: The most commonly-observed adverse events are GI events. Peptic ulcers, perforation or GI bleeding, sometimes fatal, particularly in the elderly, may occur. Nausea, vomiting, diarrhoea, flatulence, constipation, dyspepsia, abdominal pain, melaena, haematemesis, ulcerative stomatitis, exacerbation of colitis and Crohn's disease have been reported following administration. Less frequently, gastritis has been observed. Pancreatitis has been reported very rarely.
Hypersensitivity: Hypersensitivity reactions have been reported following treatment with NSAIDs. These may consist of (a) non-specific allergic reactions and anaphylaxis (b) respiratory tract reactivity comprising asthma, aggravated asthma, bronchospasm or dyspnoea, or (c) assorted skin disorders, including rashes of various types, pruritus, urticaria, purpura, angio-oedema and, more rarely, exfoliative and bullous dermatoses (including epidermal necrolysis and erythema multiforme).
Cardiovascular and Cerebrovascular: Oedema, hypertension and cardiac failure have been reported in association with NSAID treatment.
Aceclofenac is both structurally related and metabolised to diclofenac for which a greater amount of clinical and epidemiological data consistently point towards an increased risk of general arterial thrombotic events (myocardial

infarction or stroke, particularly at high doses and in long-term treatment). Epidemiological data has also found an increased risk of acute coronary syndrome and myocardial infarction associated with the use of aceclofenac. Exceptionally, occurrence of serious cutaneous and soft tissues infections complications during varicella has been reported in association with NSAID treatment.

Other adverse reactions reported less commonly include the following:

Renal: interstitial nephritis.

Hepatic: abnormal liver function, hepatitis and jaundice.

Neurological and Special Senses: optic neuritis, reports of aseptic meningitis (especially in patients with existing autoimmune disorders, such as SLE, mixed connective tissue disease), with symptoms such as stiff neck, headache, nausea, vomiting, fever or disorientation, confusion, hallucinations, and drowsiness.

Haematological: agranulocytosis, aplastic anaemia.

Dermatological: bullous reactions, including Stevens-Johnson syndrome and toxic epidermal necrolysis (very rare); photosensitivity.

Within the system organ classes, undesirable effects are listed under headings of frequency, using the following categories: very common ((≥1/10); common (≥1/100 to <1/10); uncommon (≥1/1,000 to <1/100); rare (≥1/10,000 to <1/1,000); very rare (<1/10,000), not known (cannot be estimated from the available data). Within each frequency grouping, undesirable effects are presented in order of decreasing seriousness.

System organ class	Common (≥1/100 to <1/10)	Uncommon (≥1/1,000 to <1/100)	Rare (≥1/10,000 to <1/1,000)	Very rare/isolated reports (<1/10,000)
Blood and lymphatic system disorders			Anaemia	Granulocytopaenia Thrombocytopaenia Neutropaenia Haemolytic anaemia
Immune system disorders			Anaphylactic reaction (including shock) Hypersensitivity	
Metabolism and nutrition disorders				Hyperkalaemia
Psychiatric disorders				Depression Abnormal dreams Insomnia
Nervous system disorders	Dizziness			Paraesthesia Tremor Somnolence Headache Dysgeusia (abnormal taste)
Eye disorders			Visual disturbance	
Ear and labyrinth disorders				Vertigo Tinnitus

Cardiac disorders			Cardiac failure	Palpitations
Vascular disorders			Hypertension	Flushing Hot flush Vasculitis
Respiratory, thoracic and mediastinal disorders			Dyspnoea	Bronchospasm Stridor
GI disorders	Dyspepsia Abdominal pain Nausea Diarrhoea	Flatulence Gastritis Constipation Vomiting Mouth ulceration	Melaena GI haemorrhage GI ulceration	Stomatitis Intestinal perforation Exacerbation of Crohn's disease and Colitis Ulcerative haematemesis Pancreatitis
Hepatobiliary disorders	Hepatic enzyme increased			Hepatic injury (including hepatitis) Jaundice Blood alkaline phosphatase increased
Skin and subcutaneous tissue disorders		Pruritus Rash Dermatitis Urticaria	Angio-oedema	Purpura Severe mucocutaneous skin reaction (including Stevens-Johnson syndrome and toxic epidermal necrolysis)
Renal and urinary disorders		Blood urea increased Blood creatinine increased		Renal failure Nephrotic syndrome
General disorders and administration site conditions				Oedema Fatigue Cramps in legs
Investigations				Weight increase

▶ Thiocolchicoside

Cardiovascular Effects: Hypotension has been reported occasionally following oral or parenteral thiocolchicoside; however, causality has not been clearly established.

Dermatologic Effects: In a pharmaco-epidemiological study involving hospitalised patients (n=5,212) treated with thiocolchicoside (mostly via the IM route), cutaneous erythema was reported in 0.13% and dermatitis in 0.04%. Contact dermatitis and photocontact allergy have been reported rarely after topical application

GI Effects: In a pharmaco-epidemiological study involving hospitalised patients (n=5,212) treated with thiocolchicoside (mostly via the IM route), gastralgia was reported in 0.4%, diarrhoea in 0.15%, nausea 0.07%, and pyrosis in 0.04%.These symptoms have been reported in a small number of cases in other studies too.

Neurologic Effects: Agitation and drowsiness have been occasionally reported after IM administration of thiocolchicoside.
Following Side Effects Have Also Been Reported after Use of the Aceclofenac and Thiocolchicoside Combination
CNS: Lightheadedness, malaise, overstimulation, sedation, blurred or double vision, nervousness and confusion, trembling, weakness, and possible dependence following long-term use, seizure.
Dermatologic: Petechiae, itch, hyperhidrosis.
GI: Dry mouth, heartburn, hiccups, stomach cramps.
If serious adverse reactions occur, the treatment should be discontinued.
If you experience any side effects, talk to your doctor or pharmacist or write to drugsafety@cipla.com. You can also report side effects directly via the National Pharmacovigilance Programme of India by calling on 1800 180 3024.
By reporting side effects, you can help provide more information on the safety of this product.

Overdosage

Management of acute poisoning with aceclofenac essentially consists of supportive and symptomatic measures. Symptoms include headache, nausea, vomiting, epigastric pain, GI irritation, GI bleeding, rarely diarrhoea, disorientation, excitation, coma, drowsiness, dizziness, tinnitus, hypotension, respiratory depression, fainting and, occasionally, convulsions. In cases of significant poisoning, acute renal failure and liver damage are possible. Patients should be treated symptomatically as required. Within 1 hour of ingestion of a potentially toxic amount, activated charcoal should be considered. Alternatively, in adults, gastric lavage should be considered within 1 hour of ingestion of a potentially life-threatening overdose. Specific therapies such as dialysis or haemoperfusion are probably of no help in eliminating NSAIDs due to their high rate of protein-binding and extensive metabolism. Good urine output should be ensured. Renal and liver function should be closely monitored. Patients should be observed for at least 4 hours after ingestion of potentially toxic amounts. In case of frequent or prolonged convulsions, patients should be treated with intravenous diazepam. Other measures may be indicated by the patient's clinical condition. Management of acute poisoning with oral aceclofenac essentially consists of supportive and symptomatic measures for complications such as hypotension, renal failure, convulsions, GI irritation, and respiratory depression.
Overdosage of the aceclofenac and thiocolchicoside combination may also cause vertigo. Acute renal failure and hepatic damage are possible in case of severe intoxication.

Storage And Handling Instructions

Store protected from moisture at a temperature not exceeding 30° C.

Packaging Information

IBUGESIC TH 4 Tablets/IBUGESIC TH 8 Tablets: Blister pack of 10 x 10 tablets
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IBUGESIC TH Tablets

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