

For the use only of a Registered Medical Practitioner or a Hospital or a Laboratory

This package insert is continually updated: Please read carefully before using a new pack.

Ibuprofen and Paracetamol Tablets Combiflam[®] Tablets

COMPOSITION:

Each uncoated tablet of **Combiflam[®]** contains Ibuprofen IP 400 mg and Paracetamol IP 325 mg

INDICATIONS

Management of mild to moderate pain and inflammation in conditions such as dysmenorrhoea, headache, including migraine, post-operative pain, dental pain, musculoskeletal and joint disorders, peri-articular disorders and soft tissue disorders (sprains and strains). It also reduces fever.

DOSAGE AND ADMINISTRATION

Adults: 1 tablet 3 times a day.

Adults and adolescents weighing from 40 kg body weight (aged 12 years and above): Initial dose, 1 tablet of **Combiflam[®]**. If necessary, additional doses of **Combiflam[®]** tablet can be taken. The respective dosing interval should be chosen in line with the observed symptoms and the maximum recommended daily dose. It should not be below 6 hours. A total dose of 3 tablet of **Combiflam[®]** should not be exceeded in any 24-hour period.

For short-term use only.

If **Combiflam[®]** tablet is required in adults for more than 3 days in the case of fever or for more than 4 days for the treatment of pain or if the symptoms worsen the patient is advised to consult a physician.

It is recommended that patients with sensitive stomachs take **Combiflam[®]** tablet with food. If taken shortly after eating, the onset of actions of **Combiflam[®]** tablet may be delayed. If this happens, not more **Combiflam[®]** tablet than recommended within section 4.2 (posology) or until the correct re-dosing interval has passed is to be taken.

SPECIAL POPULATIONS

Pediatric patients

Combiflam[®] tablet is contraindicated in adolescents under 40 kg body weight and children below 12 years of age because of the high active substance content. If in adolescents this medicinal product is required for more than 3 days, or if symptoms worsen a physician should be consulted.

Elderly patients

No special dosage adjustments are required. Due to possible undesirable effect profile, it is recommended to monitor the elderly particularly carefully. (*Refer Special Warning and Precaution for Use Section*)

Hepatic impairment

No dose adjustments are required in patients with mild to moderate impairment to hepatic function (patients with severe hepatic dysfunction). (*Refer Contraindications Section*)

Renal impairment

No dose adjustments is required in patients with mild to moderate impairment to renal function (patients with severe renal insufficiency). (*Refer Contraindications Section*)

CONTRAINDICATIONS

Combiflam[®] tablet is contraindicated in:

- Patients with known hypersensitivity to paracetamol, ibuprofen or any of the excipients.
- In patients with a history of hypersensitivity reactions (eg. bronchospasm, angioedema, asthma, rhinitis or urticaria) associated with acetylsalicylic acid or other non-steroidal anti-inflammatory drugs (NSAIDs).
- In patients with a history of, or an existing gastrointestinal ulceration/ perforation or bleeding, including that associated with NSAIDs.
- Patients with defects in coagulation.
- In patients with severe hepatocellular insufficiency, severe renal failure or severe heart failure.
- Active, or history of recurrent or existing peptic ulcer/haemorrhages (two or more distinct episodes of proven ulceration or bleeding).
- cerebrovascular or other active bleeding
- Adolescents under 40 kg body weight and children below 12 years of age.
- Patients with severe dehydration (caused by vomiting, diarrhoea or insufficient fluid intake).

SPECIAL WARNINGS AND PRECAUTIONS FOR USE

Hepatotoxicity may occur with paracetamol even at therapeutic doses, after short treatment duration and in patients without pre-existing liver dysfunction.

Severe cutaneous adverse reactions (SCARs):

Life-threatening cutaneous reactions Stevens-Johnson syndrome (SJS), and Toxic epidermal necrolysis (TEN) have been reported with the use of **Combiflam**[®] tablet. Patients should be advised of the signs and symptoms and monitored closely for skin reactions. If symptoms or signs of SJS and TEN (e.g. progressive skin rash often with blisters or mucosal lesions) occur, patients should immediately stop **Combiflam**[®] tablet treatment and seek medical advice.

To avoid the risk of overdose:

Check that paracetamol is absent from the composition of other medicinal products taken concomitantly.

Caution is advised in patients with underlying sensitivity to aspirin and/or to non-steroidal anti-inflammatory drugs (NSAIDs).

Combiflam[®] tablet should be used upon medical advice in patients with:

- Glucose-6-phosphate-dehydrogenase deficiency
- Severe renal insufficiency
- Mild to moderate hepatocellular insufficiency
- Gilbert's syndrome
- Chronic alcohol use including recent cessation of alcohol intake
- Low glutathione reserves

Undesirable effects may be minimized by using the lowest effective dose for the shortest duration necessary to control symptoms and by patients taking the dose with food.

Caution is required in patients with certain conditions, which may be made worse:

- Systemic lupus erythematosus and mixed connective tissue disease – increased risk of aseptic meningitis
- Congenital disorder of porphyrin metabolism (e.g. acute intermittent porphyria)
- Gastrointestinal disorders and chronic inflammatory intestinal disease (ulcerative colitis, Crohn's disease)
- Hypertension and/or cardiac impairment as renal function may deteriorate.
- Renal impairment
- Hepatic dysfunction
- Directly after major surgery
- In patients who react allergically to other substances, as an increased risk of hypersensitivity reactions occurring also exists for them on use of **Combiflam**[®] tablet
- In patients who suffer from hayfever, nasal polyps or chronic obstructive respiratory disorders as an increased risk exists for them of allergic reactions occurring. These may present as asthma attacks (so-called analgesic asthma), Quincke's edema or urticaria.

Gastrointestinal effects :

The use of **Combiflam**[®] tablet with concomitant NSAIDs including cyclooxygenase-2 selective inhibitors, increases risk of adverse reactions and should be avoided.

Elderly:

The elderly have an increased frequency of adverse reactions to NSAIDs especially gastrointestinal bleeding and perforation which may be fatal.

Cardiovascular and cerebrovascular effects:

Caution (discussion with physician or pharmacist) is required prior to starting treatment in patients with a history of hypertension and/or heart failure as fluid retention, hypertension and oedema have been reported in association with NSAID therapy.

Clinical studies suggest that use of ibuprofen, particularly at a high dose (2400 mg/day) may be associated with a small increased risk of arterial thrombotic events (for example myocardial infarction or stroke). Overall, epidemiological studies do not suggest that low dose ibuprofen (e.g. \leq 1200 mg/day) is associated with an increased risk of arterial thrombotic events.

Patients with uncontrolled hypertension, congestive heart failure, established ischaemic heart disease, peripheral arterial disease, and/or cerebrovascular disease should only be treated with ibuprofen after careful consideration and high doses (2400 mg/day) should be avoided.

Similar consideration should be made before initiating long term treatment for patients with risk factors for cardiovascular events (Eg. Hypertension, hyperlipidaemia, diabetes mellitus, smoking), particularly if high doses of ibuprofen (2400 mg/day) are required.

Gastrointestinal bleeding, ulceration and perforation:

GI bleeding, ulceration and perforation which can be fatal, has been reported with all NSAIDs at anytime during treatment, with or without warning symptoms or a previous history of serious GI events.

When GI bleeding or ulceration occurs in patients receiving ibuprofen containing products, the treatment should be withdrawn.

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 acetylsalicylic acid, or other drugs likely to increase GI risk.

Patients with a history of GI toxicity, particularly the 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 which could increase the risk of ulceration or bleeding, such as oral corticosteroids, anticoagulants such as warfarin, selective serotonin-reuptake inhibitors or anti-platelet agents such as acetylsalicylic acid

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.

Dermatological:

Serious skin reactions, some of them fatal including exfoliative dermatitis, Steven-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 of these reactions early in the course of therapy, the onset of the reaction occurring in the majority of cases within the first month of treatment. The patient is advised to discontinue the intake of **Combiflam**[®] tablet at the first appearance of skin rash, mucosal lesions, or any other sign of hypersensitivity.

Exceptionally, varicella can be at the origin of serious cutaneous and soft tissues infectious 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 **Combiflam**[®] tablet in case of varicella.

Other notes

Severe acute hypersensitivity reactions (e.g. anaphylactic shock) are observed very rarely. At the first signs of hypersensitivity reaction after taking/administering **Combiflam**[®] tablet therapy must be stopped. Medically required measures, in line with the symptoms, must be initiated by specialist personnel.

Ibuprofen, the active substance of **Combiflam**[®] tablet may temporarily inhibit the blood-platelet function (thrombocyte aggregation). Therefore, patients with platelet disorders should be monitored carefully.

In case of prolonged treatment with ibuprofen, liver and kidney parameters as well as blood picture need to be checked regularly.

Prolonged use of any type of analgesics for headaches can make them worse. If this situation is experienced or suspected, medical advice should be obtained and treatment should be discontinued. The diagnosis of medication overuse headache (MOH) should be suspected in patients who have frequent or daily headaches despite (or because of) the regular use of headache medications.

In general terms, the habitual intake of analgesics particularly on combination of several pain-relieving active substances, may lead to permanent renal damage with the risk of renal failure (analgesic nephropathy). This risk may be increased under physical strain associated with loss of salt and dehydration. Therefore it should be avoided.

Through concomitant consumption of alcohol, active substance-related undesirable effects, particularly those that concern the gastrointestinal tract or the central nervous system, may be increased on use of NSAIDs.

Pediatric population

There is a risk of renal impairment in dehydrated adolescents.

INTERACTIONS WITH OTHER MEDICINAL PRODUCTS AND OTHER FORMS OF INTERACTION

The risk of paracetamol toxicity may be increased in patients receiving other potentially hepatotoxic drugs or drugs that induce liver microsomal enzymes, such as certain antiepileptics (such as phenobarbital, phenytoin, carbamazepine, topiramate), rifampicin and alcohol. The induced metabolism results in an elevated production of the hepatotoxic oxidative metabolite of paracetamol. Hepatotoxicity will occur if this metabolite exceeds the normal glutathione binding capacity.

Paracetamol may increase the risk of bleeding in patients taking warfarin and other antivitamin K. Patients taking paracetamol and antivitamin K should be monitored for appropriate coagulation and bleeding complications.

Co-administration of flucloxacillin with paracetamol may lead to metabolic acidosis, particularly in patients presenting risk factors of glutathione depletion, such as sepsis, malnutrition or chronic alcoholism

This product (like any other paracetamol containing products) is contraindicated in combination with other paracetamol containing products – increased risk of serious adverse effects

The absorption rate of paracetamol may be increased by metoclopramide or domperidone.

Chelating resin can decrease the intestinal absorption of paracetamol and potentially decrease its efficacy if taken simultaneously. In general, there must be an interval of more than 2 hours between taking the resin and taking paracetamol, if possible.

| Concomitant use of ibuprofen with | Possible effects: |
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| Other NSAIDs, including salicylates: | The concomitant administration of several NSAIDs may increase the risk of gastrointestinal ulcers and bleeding due to a synergistic effect. The concomitant use of ibuprofen with other NSAIDs should therefore be avoided. |
| Digoxin: | The concomitant use of Combiflam [®] tablet with digoxin preparations may increase serum level of digoxin. A check of serum-digoxin is not as a rule required on correct use (maximum over 4 days). |
| Corticosteroids: | Corticosteroids as these may increase the risk of adverse reactions, especially of the gastrointestinal tract (gastrointestinal; ulceration or bleeding) . |
| Anti-platelet agents: | Increased risk of gastrointestinal bleeding |
| Acetylsalicylic acid | Concomitant administration of ibuprofen and acetylsalicylic acid is not generally recommended because of the potential of increased adverse effects. Experimental data suggest that ibuprofen may competitively inhibit the effect of low dose acetylsalicylic acid on platelet aggregation when they are dosed concomitantly. Although there are uncertainties regarding extrapolation of these data to the clinical situation, the possibility that regular, long-term use of ibuprofen may reduce the cardioprotective effect of low-dose acetylsalicylic acid cannot be excluded. No clinically relevant effect is considered to be likely for occasional ibuprofen use |
| Anticoagulants: | NSAIDs may enhance the effect of anti-coagulants, such as warfarin |
| Phenytoin: | The concomitant use of Combiflam [®] tablet with phenytoin preparations may increase serum level of phenytoin. A check of serum-phenytoin levels is not as a rule required on correct use (maximum over 4 days). |
| Selective serotonin reuptake inhibitors (SSRIs): | Increased risk of gastrointestinal bleeding |
| Lithium: | The concomitant use of Combiflam [®] tablet with lithium preparations may increase serum level of lithium. A check of serum-lithium is not as a rule required on correct use (maximum over 4 days). |
| Probenecid and sulfinpyrazone: | Medicinal products that contain probenecid or sulfinpyrazone may delay the excretion of ibuprofen. |
| Diuretics, ACE inhibitors, betareceptor-blockers and angiotensin-II antagonists | NSAIDs may reduce the effect of diuretics and other antihypertensive medicinal products. In some patients with compromised renal function (e.g. dehydrated patients or elderly patients with compromised renal function) the co-administration of an ACE inhibitor, betareceptor-blockers or angiotensin-II antagonists and agents that inhibit cyclo-oxygenase may result in further |

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| | deterioration of renal function, including possible acute renal failure, which is usually reversible. 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. |
| Potassium sparing diuretics: | The concomitant administration of Combiflam [®] tablet and potassium-sparing diuretics may lead to hyperkalaemia. |
| Methotrexate: | The administration of Combiflam [®] tablet within 24 hours before or after administration of methotrexate may lead to elevated concentrations of methotrexate and an increase in its toxic effect. |
| Ciclosporin: | The risk of a kidney-damaging effect due to ciclosporin is increased through the concomitant administration of certain nonsteroidal antiinflammatory drugs. This effect also cannot be ruled out for a combination of ciclosporin with ibuprofen. |
| Tacrolimus: | The risk of nephrotoxicity is increased if the two medicinal products are administered concomitantly |
| Zidovudine: | There is evidence of an increased risk of haemarthroses and haematoma in HIV (+) haemophiliacs receiving concurrent treatment with zidovudine and ibuprofen. |
| Sulphonylureas: | Clinical investigations have shown interactions between nonsteroidal anti-inflammatory drugs and antidiabetics (sulphonylureas). Although interactions between ibuprofen and sulphonylureas have not been described to date, a check of blood-glucose values is recommended as a precaution on concomitant intake. |
| 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. |
| CYP2C9 inhibitors: | Concomitant administration of ibuprofen with CYP2C9 inhibitors may increase the exposure to ibuprofen (CYP2C9 substrate). In a study with voriconazole and fluconazole (CYP2C9 inhibitors), an increased S(+)-ibuprofen exposure by approximately 80 to 100% has been shown. Reduction of the ibuprofen dose should be considered when potent CYP2C9 inhibitors are administered concomitantly, particularly when high dose (2400 mg/day) ibuprofen is administered with either voriconazole or fluconazole. |
| Mifepristone: | NSAIDs should not be used for 8-12 days after mifepristone administration as NSAIDs can reduce the effect of mifepristone |

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PREGNANCY LACTATION AND FERTILITY

PREGNANCY:

Inhibition of prostaglandin synthesis may adversely affect the pregnancy and/or the embryo/fetal development.

During the first and second trimester of pregnancy, ibuprofen should not be given unless clearly necessary. If ibuprofen 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 fetus to:
 - 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 to:
 - Possible prolongation of bleeding time, an anti-aggregating effect which may occur even at very low doses
 - Inhibition of uterine contractions resulting in delayed or prolonged labor.Consequently, ibuprofen is contraindicated during the third trimester of pregnancy.

LACTATION:

Ibuprofen and its metabolites can pass in low concentrations into the breast milk. No harmful effects to infants are known to date. Therefore, for short-term treatment with the recommended dose for pain and fever, interruption of breast-feeding would generally not be necessary.

FERTILITY

There is some evidence that drugs which inhibit cyclo-oxygenase/ prostaglandin synthesis may cause impairment of female fertility by an effect on ovulation. This is reversible on withdrawal of treatment

DRIVING A VEHICLE OR PERFORMING OTHER HAZARDOUS TASKS

As central nervous undesirable effects such as tiredness and dizziness may occur on use of **Combiflam**[®] tablet at higher dosage, the ability to react and the ability to take part actively in road traffic and to operate machines may be impaired in isolated cases. This applies to a greater extent in combination with alcohol

ADVERSE REACTIONS

Paracetamol

The following CIOMS frequency rating is used, when applicable:

Very common $\geq 10\%$; Common ≥ 1 and $< 10\%$; Uncommon ≥ 0.1 and $< 1\%$;
 Rare ≥ 0.01 and $< 0.1\%$; Very rare $< 0.01\%$; Not known (cannot be estimated from available data).

Blood and lymphatic system disorders

Very rare: thrombocytopenia, neutropenia, leucopenia

Not known: agranulocytosis, haemolytic anaemia in patients with underlying glucose 6-phosphate-dehydrogenase deficiency

Immune system disorders

Not known: Hypersensitivity such as anaphylactic shock, angioedema

Cardiac disorders:

Not Known: Kounis syndrome

Respiratory, thoracic and mediastinal disorders

Not known: bronchospasm

Skin and subcutaneous disorders:

Very rare: erythema, urticaria, rash

Not known: Toxic epidermal necrolysis (TEN), Stevens-Johnson syndrome (SJS), acute generalized exanthematous pustulosis, fixed drug eruption.

Hepatobiliary disorders

Not known: cytolytic hepatitis, which may lead to acute hepatic failure

Ibuprofen:

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| Infections and Infestations | Very rare | <p>Exacerbation of infection-related inflammations (e.g. development of necrotising fasciitis) coinciding with the use of nonsteroidal antiinflammatory drugs has been described. This is possibly associated with the mechanism of action of the nonsteroidal antiinflammatory drugs.</p> <p>The symptoms of aseptic meningitis with neck stiffness, headache, nausea, vomiting, fever or consciousness clouding have been observed under ibuprofen. Patients with autoimmune disorders (SLE, mixed connective-tissue disease) appear to be predisposed.</p> |
| Blood and Lymphatic System Disorders | Very rare | Disturbances to blood formation (anaemia, leukopenia, thrombocytopenia, pancytopenia, agranulocytosis). The first signs may be fever, sore throat, superficial wounds in the mouth, influenza-like complaints, severe lassitude, nosebleeds and skin bleeding. The blood count should be checked regularly in long-term therapy. |
| Immune System Disorders | Uncommon | Hypersensitivity reactions with skin rashes and itching, as well as asthma attacks (possibly with drop in blood pressure). |
| | Very rare | Severe general hypersensitivity reactions. They |

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| | | may present as face oedema, swelling of the tongue, swelling of the internal larynx with constriction of the airways, respiratory distress, racing heart, drop in blood pressure up to life-threatening shock. If one of these symptoms occurs, which can happen even on first use, the immediate assistance of a physician is required. |
| Psychiatric Disorders | Very rare | Psychotic reactions, depression |
| Nervous System Disorders | Uncommon | Central nervous disturbances such as headache, dizziness, sleeplessness, agitation, irritability or tiredness |
| Eye Disorders | Uncommon | Visual disturbances |
| Ear and Labyrinth Disorders | Rare | Tinnitus |
| Cardiac Disorders | Very rare | Palpitations, heart failure, myocardial infarction |
| Vascular Disorders | Very rare | Arterial hypertension, vasculitis |
| Gastrointestinal Disorders | Common | Gastro-intestinal complaints such as pyrosis, abdominal pain, nausea, dyspepsia 17, vomiting, flatulence, diarrhoea, constipation and slight gastro-intestinal blood losses that may cause anaemia in exceptional cases |
| | Uncommon | Gastrointestinal ulcers, potentially with bleeding and perforation. Ulcerative stomatitis, exacerbation of colitis and Crohn's disease , gastritis |
| | Very rare | Oesophagitis, pancreatitis, formation of intestinal diaphragm-like strictures. The patient is to be instructed to withdraw the medicinal product and to go to a physician immediately if severe pain in the upper abdomen or melaena or haematemesis occurs. |
| Hepatobiliary Disorders | Very rare | Hepatic dysfunction, hepatic damage, particularly in long-term therapy, hepatic failure, acute hepatitis |
| Skin and Subcutaneous Tissue Disorders | Uncommon | Skin rashes |
| | Very rare | Bullous reactions including Stevens-Johnson syndrome and toxic epidermal necrolysis (Lyell's syndrome 17), alopecia. In exceptional cases, severe skin infections and soft-tissue complications may occur during a varicella infection (see also "Infections and infestations"). |
| | Not known | photosensitivity reaction |
| Renal and Urinary Disorders | Rare | Kidney-tissue damage (papillary necrosis) and elevated uric acid concentrations in the blood may also occur rarely. |
| | Very rare | Formation of oedemas, particularly in patients with arterial hypertension or renal insufficiency, nephrotic syndrome, interstitial nephritis that may be accompanied by acute renal insufficiency. Renal function should therefore be checked |

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| | | regularly. |
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If appropriate, patients should be adequately informed that they should stop taking **Combiflam**[®] tablet immediately and consult a physician if they experience one of the following conditions:

- Severe gastro-intestinal complaints, pyrosis or abdominal pain
- Hematemesis
- Meleana or blood in the urine
- Cutaneous reactions, such as itching eruptions
- Respiratory distress and/or facial or laryngeal edema
- Fatigue combined with loss of appetite
- Sore throat, combined with aphthous ulcers, fatigue and fever
- Heavy epistaxis and cutaneous bleeding
- Abnormal fatigue combined with reduced urine excretion
- Edema of feet or legs
- Breast pain
- Visual disturbances

OVERDOSE

Paracetamol

Elderly persons, small children, patients with liver disorders, chronic alcohol consumption or chronic malnutrition, as well as patients concomitantly treated with enzyme-inducing drugs are at an increased risk of intoxication, including fatal outcome.

Signs and Symptoms:

Nausea, vomiting, anorexia, pallor, abdominal pain, generally appear during the first 24 hours of overdose with paracetamol. Overdosage with paracetamol may cause hepatic cytolysis which can lead to hepatocellular insufficiency, gastrointestinal bleeding, metabolic acidosis, encephalopathy, coma and death. Increased levels of hepatic transaminases, lactate dehydrogenase and bilirubin with a reduction in prothrombin level can appear 12 to 48 hours after acute overdose. It can also lead to pancreatitis, acute renal failure and pancytopenia.

Management:

Despite a lack of significant early symptoms, patients should be referred to hospital urgently for immediate medical attention.

Treatment involves gastric aspiration and lavage, preferably within 4 hours of ingestion.

Determinations of the plasma concentration of paracetamol are recommended.

Plasma concentration of paracetamol should be measured at 4 hours or later after ingestion (earlier concentrations are unreliable).

Where paracetamol intoxication is suspected, intravenous administration of SH group donors such as N-acetylcysteine within the first 10 hours after ingestion is indicated. Although N-acetylcysteine is most effective if initiated within this period, it can still offer

some degree of protection if given as late as 48 hours after ingestion; in this case, it is taken for longer.

Further measures will depend on the severity, nature and course of clinical symptoms of paracetamol intoxication and should follow standard intensive care protocols.

Ibuprofen:

Ibuprofen overdose may cause metabolic acidosis.

Signs and Symptoms:

The symptoms of overdose can include CNS-related symptoms such as headache, dizziness, light-headedness and unconsciousness (also myoclonic convulsions in children), abdominal pain, nausea, vomiting, gastrointestinal bleeding and hepatic and renal dysfunction, hypotension, respiratory depression and cyanosis.

Ibuprofen overdose may cause metabolic acidosis

Management:

A specific antidote does not exist.

Oral administration of activated charcoal is to be considered, if the patient presents within 1 hour of ingestion of a potentially toxic amount.

INTERFERENCES WITH LABORATORY AND DIAGNOSTIC TEST

Effects on laboratory values

Intake of paracetamol may affect the laboratory determination of uric acid by phosphotungstic acid and of blood glucose by glucose oxidase-peroxidase.

Manufactured in India by:

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- CCDS V1.0 for Ibuprofen dated Oct 2018