1.3 PRODUCT INFORMATION

1.3.1 Summary of product Characterstics (SmPC)

The Summary of Product Characteristics of Aceclofenac Tablets 100 mg are enclosed in the following pages.

SMPC

SUMMARY OF PRODUCT CHARACTERISTICS

1. Name of the medicinal product

Aceclofenac Tablets 100 mg.

2. Quality and Quantitative composition :

Each film coated tablet contains

Aceclofenac BP 100 mg

Color: Titanium Dioxide

For list of Excipients see section 6.1.

3. Pharmaceutical form

White colored biconvex, smooth film coated tablets.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Aceclofenac 100 mg Tablets are indicated for the relief of pain and inflammation in osteoarthritis, rheumatoid arthritis and ankylosing spondylitis.

4.2 Posology and method of administration

Aceclofenac tablets are supplied for oral administration and should be swallowed whole with a sufficient quantity of liquid. Aceclofenac should be taken preferably with or after food.

Undesirable effects may be minimised by using the lowest effective dose for the shortest duration necessary to control symptoms.

Adults

The recommended dose is 200 mg daily, taken as two separate 100 mg doses, one tablet in the morning and one in the evening.

Children

There are no clinical data on the use of Aceclofenac in children and therefore it is not recommended for use in children.

Elderly

The pharmacokinetics of Aceclofenac are not altered in elderly patients, therefore it is not considered necessary to modify the dose or dose frequency.

As with other non-steroidal anti-inflammatory drugs (NSAIDs), caution should be exercised in the treatment of elderly patients, who are at increased risk of the serious consequences of adverse reactions, and who are more likely to be suffering from impaired renal, cardiovascular or hepatic function and receiving concomitant medication. The elderly should be monitored regularly for GI bleeding during NSAID therapy.

Renal insufficiency

There is no evidence that the dosage of Aceclofenac needs to be modified in patients with mild renal impairment, but as with other NSAIDs caution should be exercised (See also Precautions).

Hepatic insufficiency

There is some evidence that the dose of Aceclofenac should be reduced in patients with hepatic impairment and it is suggested that an initial daily dose of 100 mg be used.

4.3 Contraindications

Hypersensitivity to any of the constituents.

NSAIDs are contraindicated in patients who have previously shown hypersensitivity reactions (e.g. asthma, rhinitis, angioedema or urticaria) in response to ibuprofen, aspirin, or other non-steroidal anti-inflammatory drugs.

Severe hepatic and cardiac failure (See section 4.4 - Special warnings and precautions for use).

Moderate to severe renal failure.

During the last trimester of pregnancy (See section 4.6 - Pregnancy and lactation)

Active or previous peptic ulcer.

History of upper gastrointestinal bleeding or perforation, related to previous NSAIDs therapy.

Use with concomitant NSAIDs including cyclooxygenase 2 specific inhibitors.

4.4 Special warnings and precautions for use

Undesirable effects may be minimised by using the lowest effective dose for the shortest duration necessary to control symptoms (see section 4.2, and GI and cardiovascular risks below).

Elderly:

The elderly have an increased frequency of adverse reactions to NSAIDs especially gastrointestinal bleeding and perforation which may be fatal (See section 4.2 - Posology and administration).

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 (See also section 4.3 – Contraindications). Effects on renal function are usually reversible on withdrawal of Aceclofenac.

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. Hepatitis may occur without prodromal symptoms.

Use of Aceclofenac in patients with hepatic porphyria may trigger an attack.

Gastrointestinal bleeding, ulceration and perforation:

GI bleeding, ulceration or 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.

The risk of GI bleeding, ulceration or performation is higher with increasing NSAID doses, in patients with a history of ulcers, particularly if complicated with haemorrhage or perforation (see section 4.3), and in the elderly. These patients shouls 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 conconminant low dose asprin, or other drugs likely to increase gastrointestinal risk (see below and section 4.5).

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.

Cardiovascular and cerebrovascular effects:

Appropriate monitoring and advice are required for patients with a history of hypertension and/or mild to moderate congestive heart failure as fluid retention and oedema have been reported in association with NSAID therapy.

Clinical trial and epidemiological data suggest that use of some NSAIDs (particularly at high doses and in long term treatment) may be associated with a small increased risk of arterial thrombotic events (for example myocardial infarction or stroke). There are insufficient data to exclude such a risk for Aceclofenac.

Patients with uncontrolled hypertension, congestive heart failure, established ischaemic heart disease, peripheral arterial disease, and/or cerebrovascular disease should only be treated with Aceclofenac after careful consideration. Similar consideration should be made before initiating longer-term treatment of patients with risk factors for cardiovascular disease (e.g. hypertension, hyperlipidaemia, diabetes mellitus, smoking).

Caution should be advised in patients receiving concomitant medications which could increase the risk of gastrotoxicity or bleeding, such as corticosteroids, or anticoagulants such as warfarin, selective serotonin-reuptake inhibitors or anti-platelet agents such as aspirin (See section 4.5).

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 gastrointestinal disease (ulcerative colitis, Crohn's disease) as these conditions may be exacerbated (See section 4.8 – Undesirable effects).

Close medical surveillance is imperative in patients with bleeding diathesis or haematological abnormalities.

SLE and mixed connective tissue disease:

In patients with systemic lupus erythematosus (SLE) and mixed connective tissue disorders there may be an increased risk of aseptic meningitis (See section 4.8 – Undesirable effects).

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 (see section 4.8). Patients appear to be at highest risk for 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. Aceclofenac should be discontinued at the first appearance of skin rash, mucosal lesions, or any other sign of hypersensitivity.

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 (See anticoagulants under 'Interactions').

Long-term treatment:

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

4.5 Interaction with other medicinal products and other forms of interaction

Lithium: Aceclofenac, like many NSAIDs, may increase plasma concentrations of lithium.

Cardiac Glycosides: Through their renal effects, NSAIDs may increase plasma glycoside (including digoxin) levels, exacerbate cardiac failure and reduce the glomerular filtration rate in patients receiving glycosides.

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

Anticoagulants: Like other NSAIDs, Aceclofenac may enhance the activity of anticoagulants such

as warfarin (See section 4.4 - Special warnings and precautions for use). Close monitoring of patients on combined anticoagulant and Aceclofenac therapy should be undertaken.

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.

Methotrexate: Caution should be exercised if NSAIDs and methotrexate are administered within 24 hours of each other, since NSAIDs may increase methotrexate plasma levels, resulting in increased toxicity.

Mifepristone: NSAIDs should not be used for 8-12 days after mifepristone administration as NSAIDs can reduce the effect of mifepristone.

Ciclosporin: Ciclosporin nephrotoxicity may be increased by the effect of NSAIDs on renal prostaglandins.

Quinolone antimicrobials: Convulsions may occur due to an interaction between quinolones and NSAIDs. This may occur in patients with or without a previous history of epilepsy or convulsions. Therefore, caution should be exercised when considering the use of a quinolone in patients who are already receiving a NSAID.

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 (See section 4.3).

Anti-hypertensives*:* Reduced anti-hypertensive effect.

Corticosteroids: Increased risk of gastrointestinal ulceration or GI bleeding (See section 4.4).

Tacrolimus*:* Possible increased risk of nephrotoxicity when NSAIDs are given with tacrolimus.

Anti-platelet agents and selective serotonin reuptake inhibitors (SSRIs): Increased risk of gastrointestinal bleeding (see section 4.4)

Zidovudine: Increased risk of haematological toxicity 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.

Ritonavir: plasma concentration of Aceclofenac possibly increased by ritonavir.

4.6 Pregnancy and lactation

Pregnancy:

Congenital abnormalities have been reported in association with NSAID administration in man; however, these are low in frequency and do not appear to follow any discernible pattern. In view of the known effects of NSAIDs on the foetal cardiovascular system (risk of closure of the ductus arteriosus), use in the last trimester of pregnancy is contraindicated. The onset of labour may be delayed and the duration increased with an increased bleeding tendency in both mother and child

(See section 4.3 Contraindications). NSAIDs should not be used during the first two trimesters of pregnancy or labour unless the potential benefit to the patient outweighs the potential risk to the foetus.

Animal studies indicate that there was no evidence of teratogenesis in rats although the systemic exposure was low and in rabbits, treatment with aceclofenac (10 mg/kg/day) resulted in a series of morphological changes in some foetuses.

Lactation:

There is no information on the secretion of Aceclofenac to breast milk; there was however no notable transfer of radio-labelled (^{14}C) aceclofenac to the milk of lactating rats.

In limited studies so far available, NSAIDs can appear in breast milk in very low concentrations. NSAIDs should, if possible, be avoided when breast-feeding.

4.7 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.

4.8 Undesirable effects

The majority of adverse reactions reported have been reversible and of a minor nature. The most frequent are gastro-intestinal disorders, in particular dyspepsia, abdominal pain, nausea and diarrhoea, and occasional occurrence of dizziness. Dermatological complaints including pruritus and rash and abnormal hepatic enzyme and serum creatinine levels have also been reported with the frequencies indicated in the following table.

If serious side effects occur, Aceclofenac should be withdrawn.

The following is a table of adverse reactions reported during clinical studies and after authorisation, grouped by System-Organ Class and estimated frequencies.

WHO System Organ Class	**Common 1 to 10%**	**Uncommon 0.1 to 1%**	**Rare or very rare <0.1%**
Gastrointestinal System disorders	Dyspepsia, Abdominal pain, Nausea, Diarrhoea.	Flatulence, Gastritis, Constipation, Vomiting, Ulcerative stomatitis.	Melaena, Stomatitis, Haematemesis, Gastrointestinal haemorrhage,Gastric ulcer Pancreatitis.
Urinary system disorders	-	-	Renal failure, Nephrotic syndrome
Central and peripheral nervous system disorders	Dizziness	Vertigo	Paraesthesia, Tremor.
Psychiatric disorders	-	-	Depression, Abnormal dreamimg, Somnolence, Insomnia.

Disorders of the skin and appendages	-	Pruritus, Rash, Eczema, Dermatitis Urticaria.	Bullous dermatoses.
Liver and Biliary Disorders	Hepatic enzymes increased	-	Hepatitis, jaundice.
Metabolic disorders	-	BUN increased Blood creatinine increased	Alkaline phosphatase increased, Hyperkalaemia.
Cardiovascular disorders	-	-	Oedema in lower limbs, Palpitation, Cramps in legs, Flushing, Purpura.
Respiratory disorders	-	-	Dyspnoea,Stridor, Bronchospasm.
Haematological disorders	-	-	Anaemia, Granulocytopenia, Thrombocytopenia, Neutropenia, Haemolytic anaemia.
Body as a whole – General disorders	-	-	Allergic reaction, Anaphylactic reactions, (including shock)Headache, Fatigue, Face oedema, Hot flushes,Weight increase.
Others	-	-	Abnormal vision,Abnormal taste

Other rare or very rare class-effects reported with NSAIDs in general are:

Gastrointestinal System – Duodenal ulcer, Gastrointestinal perforation

Urinary System – Interstitial nephritis

Central and Peripheral Nervous System – Optic neuritis

Psychiatric – Hallucination, Drowsiness, Confusion

Skin and Appendages – Epidermal necrolysis, Erythema multiforme, Exfoliative dermatitis

Respiratory – Aggravated asthma

Haematological – Aplastic anaemia

Others – Tinnitus, Photosensitivity, Malaise

Oedema, hypertension and cardiac failure have been reported in association with NSAID treatment.

Clinical trial and epidemiological data suggest that use of some NSAIDs (particularly at high doses and in long term treatment) may be associated with a small increased risk of arterial thrombic events (for example myocardial infarction or stroke (see section 4.4 Special warnings and precautions for use).

Other undesirable effects that have been reported are exacerbation of colitis and Crohn's disease, angioedema, aseptic meningitis (especially in patients with existing auto-immune disorders, such as

systemic lupus erythematosus, mixed connective tissue disease), with symptoms such as stiff neck, headache, nausea, vomiting, fever or disorientation and also asthma (See section 4.4 Special warnings and precautions for use).

4.9 Overdose

There are no human data available on the consequences of Aceclofenac overdose.

a) Symptoms

Symptoms include headache, nausea, vomiting, epigastric pain, gastrointestinal bleeding, rarely diarrhoea, disorientation, excitation, coma, drowsiness, dizziness, tinnitus, fainting, occasionally convulsions. In cases of significant poisoning acute renal failure and liver damage are possible.

b) Therapeutic measure

Patients should be treated symptomatically as required.

Within one hour of ingestion of a potentially toxic amount activated charcoal should be considered.

Alternatively, in adults, gastric lavage should be considered within one hour of ingestion of a potentially life-threatening overdose.

Good urine output should be ensured.

Renal and liver function should be closely monitored.

Patients should be observed for at least four hours after ingestion of potentially toxic amounts.

Frequent or prolonged convulsions should be treated with intravenous diazepam.

Other measures may be indicated by the patient's clinical condition.

Specific therapies such as forced diuresis, dialysis or haemoperfusion are probably of no help in eliminating NSAIDs due to their high rate of protein binding and extensive metabolism.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

ATC code: M01A B16.

Aceclofenac is a non-steroidal agent 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 cyclo-oxygenase, which is involved in the production of prostaglandins.

5.2 Pharmacokinetic properties

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 into the synovial fluid, where the concentrations reach approximately 57% of those in plasma. The volume of distribution is approximately 25 L.

The mean (geometrical) plasma elimination half-life is 2.30 hours. Aceclofenac is highly protein-

bound (> 99%). Aceclofenac circulates mainly as unchanged drug. 4'-Hydroxyaceclofenac is the main metabolite detected in plasma. Approximately two-thirds of the administered dose is excreted via the urine, mainly as hydroxymetabolites.

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

5.3 Preclinical safety data

The results from preclinical studies conducted with aceclofenac are consistent with those expected for NSAIDs. The principal target organ was the gastro-intestinal tract. No unexpected findings were recorded.

Aceclofenac was not considered to have any mutagenic activity in three *in vitro* studies and an *in vivo* study in the mouse.

Aceclofenac was not found to be carcinogenic in either the mouse or rat.

6.0 Pharmaceutical particulars

6.1 List of excipients:

Tablet Core: Microcrystalline Cellulose PH 101, Sodium Starch glycolate Type-A (Glycolys), Maize starch, Povidone (Plasdone K- 29/32), Sodium Lauryl Sulphate (TEXAPON k12P PH), Microcrystalline Cellulose PH 102, Colloidal Silicon Dioxide, Magnesium Stearate, Instacoat Universal white ICU-1308, Purified water.

6.2 Incompatibilities: Not applicable.

6.3 Shelf life : 2 years.

6.4 Special precautions for storage:

Store below 30°C, Protect from light and moisture.

6.5 Nature and contents of container :

Blister pack of 3 X 10's in a unit carton.

7. Marketing Authorization Holder :

MSN LABORATORIES PRIVATE LIMITED

MSN House, Plot No. : C-24, Industrial Estate,

Sanath Nagar, Hyderabad – 500 018

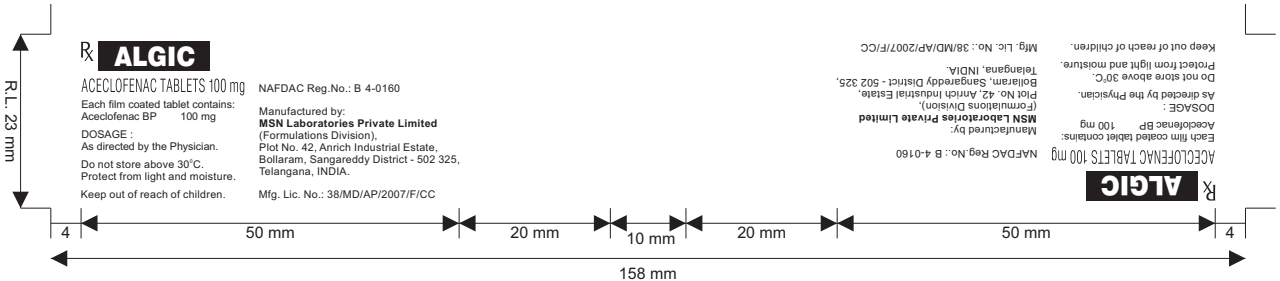
Andhra Pradesh, India.

8. Date of revision of the text : December, 2013.

1.3.2 Labelling (outer & inner labels)

The artworks of container label, carton & Pack Insert for Aceclofenac Tablets 100 mg are enclosed in the following pages..

Art Works



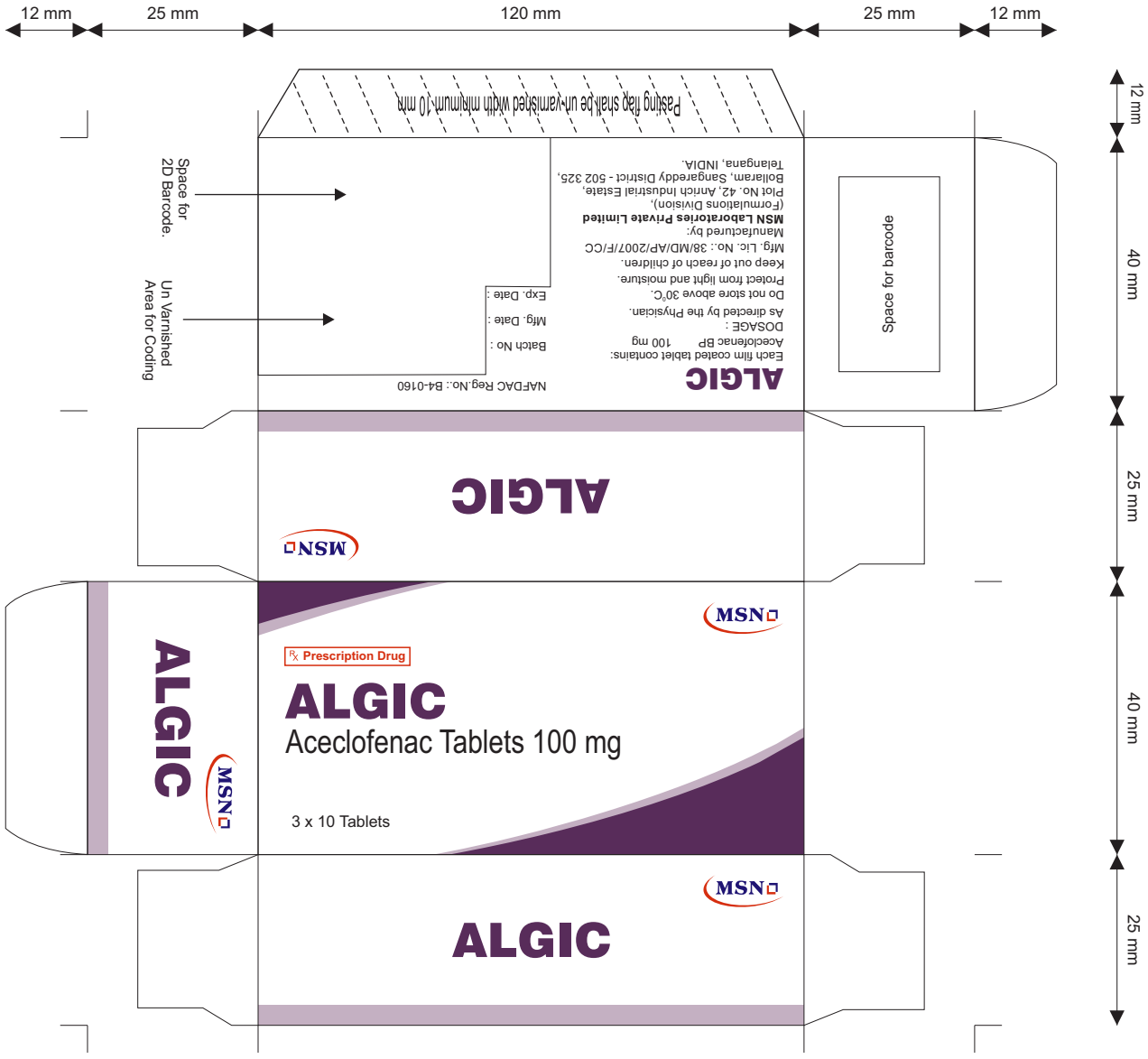
BLACK

Version: 00

Foil Width 158 mm
Blister Size 75 x 35mm (Repeat 1.25)
Blister : 4+50+20+10+20+50+4

Blister Foil

Test	Specification
1. Description	Printed hard tampered aluminium foil with VMCH coating on the sealing side.
2. Thickness of Aluminium	0.018 to 0.022 mm
3. Width	158 ± 1.0 mm (157 – 159 mm)
4. Aluminium foil GSM VMCH Coating GSM	49.86 to 58.54 GSM 4 to 6 GSM
5. Pin Holes	Nil
6. Ink Adhesion Test	No Ink Lifting
7. Inner Core Diameter	76 ± 1 mm



PANTONE 519 C PANTONE 273 C PANTONE 485 C Black

Dimension: 80 x 25 x 40 mm

Version: 00

Module-1.3,Pg.no-15

150 mm

400 mm

ALGIC

For the use of registered medical practitioner or a hospital or a laboratory only

ALGIC

ACECLOFENAC TABLETS 100 MG

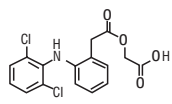
COMPOSITION

Each film coated tablet contains:

Aceclofenac BP 100 mg

DRUG DESCRIPTION

The chemical name for Aceclofenac is 2-[2-[2-(2,6 Dichlorophenyl)aminophenyl]acetyl] oxyacetic acid with the following structural formula:



The empirical formula for Aceclofenac is C16H13Cl2NO4 and molecular weight is 354.19.

PHARMACEUTICAL FORM

Aceclofenac film-coated tablets 100 mg are presented as white round film-coated tablets with plain surface on both side.

DOSAGE AND ADMINISTRATION

The recommended dose is 200 mg daily for adults, taken as two separate 100 mg doses, one tablet in the morning and one in the evening.

INDICATIONS

Aceclofenac belongs to a group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs). It is indicated for the relief of pain and inflammation in osteoarthritis, rheumatoid arthritis and ankylosing spondylitis.

CLINICAL PARTICULARS

Posology and method of administration

Aceclofenac film-coated tablets are supplied for oral administration and should be swallowed whole with a sufficient quantity of liquid. To be taken preferably with or after food. When Aceclofenac was administered to fasting and fed healthy volunteers only the rate and not the extent of aceclofenac absorption was affected.

Undesirable effects may be minimized by using the lowest effective dose for the shortest duration necessary to control symptoms

Adults

The recommended dose is 200 mg daily, taken as two separate 100 mg doses, one tablet in the morning and one in the evening.

Children

There are no clinical data on the use of Aceclofenac in children and therefore it is not recommended for use in children.

Elderly

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.

The pharmacokinetics of Aceclofenac are not altered in elderly patients, therefore it is not considered necessary to modify the dose or dose frequency.

Renal insufficiency

There is no evidence that the dosage of Aceclofenac need to be modified in patients with mild renal impairment, but as with other NSAIDs caution should be exercised (see also Precautions).

Hepatic insufficiency

There is some evidence that the dose of Aceclofenac should be reduced in patients with hepatic impairment and it is suggested that an initial daily dose of 100 mg be used.

Contraindications

Hypersensitivity to aceclofenac or to any of the excipients: Active, or 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, angioedema or urticaria) in response to ibuprofen, aspirin, or other non-steroidal anti-inflammatory drugs. Severe heart failure, hepatic failure and renal failure.

History of gastrointestinal bleeding or perforation, related to previous NSAIDs therapy.

Aceclofenac should not be prescribed during pregnancy, especially during the last trimester of pregnancy, unless there are compelling reasons for doing so. The lowest effective dosage should be used.

Special warnings and precautions for use

Undesirable effects may be minimised by using the lowest effective dose for the shortest duration necessary to control symptoms, and GI and cardiovascular risks below).

The use of Aceclofenac with concomitant NSAIDs including cyclooxygenase- 2 selective inhibitors should be avoided

Elderly:

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

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.

Renal:

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:

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.

Cardiovascular and cerebrovascular effects:

Appropriate monitoring and advice are required for patients with a history of hypertension and/or mild to moderate congestive heart failure as fluid retention and oedema have been reported in association with NSAID therapy.

Clinical trial and epidemiological data suggest that use of some NSAIDs (particularly at high doses and in long term treatment) may be associated with a small increased risk of arterial thrombotic events (for example myocardial infarction or stroke). There are insufficient data to exclude such a risk for aceclofenac.

Patients with uncontrolled hypertension, congestive heart failure, established ischaemic heart disease, peripheral arterial disease, and/or cerebrovascular disease should only be treated with aceclofenac after careful consideration. Similar consideration should be made before initiating longer-term treatment of patients with risk factors for cardiovascular disease (e.g. hypertension, hyperlipidaemia, diabetes mellitus, smoking).

Gastrointestinal 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 gastro-intestinal disorders, with a history suggestive of gastro-intestinal 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 gastrointestinal 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.

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 gastrointestinal disease (ulcerative colitis, Crohn's disease) as these conditions may be exacerbated.

SLE and mixed connective tissue disease:

In patients with systemic lupus erythematosus (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: 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.

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 (see anticoagulants under 'Interactions').

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.

Interaction with other medicinal products and other forms of interaction

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.

Anti-hypertensives: Reduced anti-hypertensive effect.

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: NSAIDs may exacerbate cardiac failure, reduce GFR (glomerular filtration rate) and increase plasma glycoside levels.

Lithium: Decreased elimination of lithium

Methotrexate: Decreased elimination of methotrexate. 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.

Ciclosporin: Increased risk of nephrotoxicity.

Mifepristone: NSAIDs should not be used for 8-12 days after mifepristone administration as NSAIDs can reduce the effect of mifepristone.

Corticosteroids: Increased risk of gastrointestinal ulceration or bleeding.

Anti-coagulants: NSAIDs may enhance the effects of anti-coagulants, such as warfarin. Close monitoring of patients on combined anti-coagulants 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.

Anti-platelet agents and selective serotonin reuptake inhibitors (SSRIs): Increased risk of gastrointestinal bleeding.

Tacrolimus: Possible increased risk of nephrotoxicity when NSAIDs are given with tacrolimus.

Single Colour Black

Dimensions (Front - 400 x 150 mm - Back - 400 x 150 mm)

Bible Paper 40 GSM

Version: 00

Module-1.3,Pg.no-16

150 mm

400 mm

Zidovudine: Increased risk of haematological toxicity 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 with 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.

Pregnancy and lactation

Pregnancy:

Congenital abnormalities have been reported in association with NSAID administration in man; however, these are low in frequency and do not appear to follow any discernible pattern. In view of the known effects of NSAIDs on the foetal cardiovascular system (risk of closure of the ductus arteriosus) and on the possible risk of persistent pulmonary hypertension of the new born, use in the last trimester of pregnancy is contraindicated. The regular use of NSAIDs during the last trimester of pregnancy may decrease uterine tone and contraction. The onset of labour may be delayed and the duration increased with an increased bleeding tendency in both mother and child. NSAIDs should not be used during the first two trimesters of pregnancy or labour unless the potential benefit to the patient outweighs the potential risk to the foetus.

Animal studies indicate that there was no evidence of teratogenesis in rats although the systemic exposure was low and in rabbits, treatment with aceclofenac (10 mg/kg/day) resulted in a series of morphological changes in some foetuses.

Lactation:

In limited studies so far available, NSAIDs can appear in breast milk in very low concentrations. NSAIDs should, if possible, be avoided when breastfeeding. Special warnings and precautions for use, regarding female fertility.

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.

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.

Undesirable effects

Gastrointestinal: The most commonly-observed adverse events are gastrointestinal in nature. 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, angioedema 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.

Clinical trial and epidemiological data suggest that use of some NSAIDs (particularly at high doses and in long term treatment) may be associated with an increased risk of arterial thrombotic events (for example myocardial infarction or stroke).

The majority of adverse reactions reported have been reversible and of a minor nature. The most frequent are gastro-intestinal disorders, in particular dyspepsia, abdominal pain, nausea and diarrhoea, and occasional occurrence of dizziness. Oedema, hypertension, and cardiac failure, have been reported in association with NSAID treatment. Dermatological complaints including pruritus and rash.

Investigations: Abnormal hepatic enzyme and serum creatinine levels have also been reported.

Other adverse reactions reported less commonly include:

Renal: Nephrotoxicity in various forms, including interstitial nephritis, nephrotic syndrome and renal failure.

Hepatic: abnormal liver function, hepatitis and jaundice.

Neurological and special senses: Visual disturbances, optic neuritis, headaches, paraesthesia, reports of aseptic meningitis (especially in patients with existing auto immune disorders, such as systemic lupus erythematosus, mixed connective tissue disease), with symptoms such as stiff neck, headache, nausea, vomiting, fever or disorientation, depression, confusion, hallucinations, tinnitus, vertigo, dizziness, malaise, fatigue and drowsiness.

Haematological: Thrombocytopenia, neutropenia, agranulocytosis, aplastic anaemia and haemolytic anaemia.

Dermatological: Bullous reactions including Stevens Johnson Syndrome and Toxic Epidermal Necrolysis (very rare). Photosensitivity.

If serious adverse reactions occur, Aceclofenac should be withdrawn.

The following is a table of adverse reactions reported during clinical studies and after authorization, grouped by System-Organ Class and estimated frequencies.

MedDRa SOC	Common <10%->1%	Uncommon <1%->0.1%	Rare <G.1% - >0.01%	Very rare/ isolated reports < 0.01%
Blood and lymphatic system disorders			Anaemia	Granulocytopenia Thrombocytopenia Neutropenia Haemolytic anaemia
Immune system disorders			Anaphylactic reaction(including shock) Hypersensitivity	
Metabolism and nutrition disorders				Hyperkalemia
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
Cardiac disorders				Palpitations
Vascular disorders				Flushing Hot flush
Respiratory, thoracic and mediastinal disorders			Dyspnoea	Bronchospasm Stridor
Gastrointestinal disorders	Dyspepsia Abdominal pain Nausea Diarrhoea	Flatulence Gastritis Constipation Vomiting Mouth ulceration	Melaena	Stomatitis Haematemesis Gastrointestinal haemorrhage Gastric ulcer Pancreatitis
Hepatobiliary disorders				Hepatitis Jaundice
Skin and subcutaneous tissue disorders		Pruritus Rash Dermatitis Urticaria	Face oedema	Purpura Dermatitis bullous
Renal and urinary disorders				Renal insufficiency Nephrotic syndrome
General disorders and administration site conditions				Oedema Fatigue Cramps in legs
Investigations	Hepatic enzyme increased	Blood urea increased Blood creatinine increased		Blood alkanine phosphatase increased Weight increase

PHARMACOLOGICAL PROPERTIES:

Pharmacodynamic properties

Aceclofenac is a non-steroidal agent with marked anti-inflammatory and analgesic properties.

The mode of action of aceclofenac is largely based on the inhibition to prostaglandin synthesis. Aceclofenac is a potent inhibitor of the enzyme cyclo-oxygenase, which is involved in the production of prostaglandins

PHARMACOKINETIC PROPERTIES

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 into the synovial fluid, where the concentrations reach approximately 57% of those in plasma. The volume of distribution is approximately 25 L.

The mean plasma elimination half-life is around 4 hours. Aceclofenac is highly protein- bound >99%). Aceclofenac circulates mainly as unchanged drug. 4'- Hydroxyaceclofenac is the main metabolite detected in plasma. Approximately two- thirds of the administered dose is excreted via the urine, mainly as hydroxymetabolites.

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

Preclinical safety data

The results from preclinical studies conducted with aceclofenac are consistent with those expected for NSAIDs. The principal target organ was the gastro-intestinal tract. No unexpected findings were recorded.

Aceclofenac was not considered to have any mutagenic activity in three in vitro studies and an in vivo study in the mouse.

Aceclofenac was not found to be carcinogenic in either the mouse or rat.

OVERDOSE

There are no human data available on the consequences of Aceclofenac overdose.

a) Symptoms

Symptoms include headache, nausea, vomiting, epigastric pain, gastrointestinal bleeding, rarely diarrhoea, disorientation, excitation, coma, drowsiness, dizziness, tinnitus, fainting, occasionally convulsions. In cases of significant poisoning acute renal failure and liver damage are possible.

b) Therapeutic measure

Patients should be treated symptomatically as required.

Within one hour of ingestion of a potentially toxic amount activated charcoal should be considered. Alternatively, in adults, gastric lavage should be considered within one hour of ingestion of a potentially life-threatening overdose.

Good urine output should be ensured.

Renal and liver function should be closely monitored.

Patients should be observed for at least four hours after ingestion of potentially toxic amounts.

Frequent or prolonged convulsions should be treated with intravenous diazepam.

Other measures may be indicated by the patient's clinical condition.

Specific therapies such as forced diuresis, dialysis or haemoperfusion are probably of no help in eliminating NSAIDs due to their high rate of protein binding and extensive metabolism.

STORAGE

Do not store above 30°C.

Protect from light and moisture.

Keep out of reach of children.

PACKING INFORMATIONA

Aceclofenac tablets in Alu-Alu Blister pack of 10 Tablets.

Manufactured by:
MSN Laboratories Private Limited
(Formulations Division),
Plot No. 42, Anrich Industrial Estate,
Bollaram, Sangareddy District - 502 325,
Telangana, INDIA.

NAFDAC Reg.No.: B4-0160

1.3.3 Package Insert (also known as patient information PIL)

Patient Information leaflet for Aceclofenac Tablets 100 mg has been enclosed in the following pages.

PIL

PACKAGE LEAFLET: INFORMATION FOR THE USER
ALGIC Film Coated Tablets 100 mg
Aceclofenac

Read all of this leaflet carefully before you start taking this medicine.

• Keep this leaflet. You may need to read it again.

• If you have any further questions, ask your doctor or pharmacist.

• This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.

• If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. WHAT ALGIC IS AND WHAT IT IS USED FOR

Algic belongs to a group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs). These drugs have anti-inflammatory and painkiller properties. The active ingredient of Algic is aceclofenac.

Algic works by blocking the production of hormone-like substances called prostaglandins. Prostaglandins are released at the sites of injury, tissue damage and immune reactions. Prostaglandins play an important role in both the inflammatory response of the body and stimulating the re-absorption of bone in diseases.

Algic is used to relieve pain and inflammation in patients suffering from:

• arthritis of the joints (osteoarthritis). This commonly occurs in patients over the age of 50 and causes the loss of the cartilage and bone tissue next to the joint.

• autoimmune disease that causes chronic inflammation of the joints (rheumatoid arthritis).

• arthritis of the spine which can lead to the fusion of the vertebrae (ankylosing spondylitis).

2. BEFORE YOU TAKE ALGIC

Do not take Algic

• if you are allergic (hypersensitive) to aceclofenac or any of the other ingredients of Algic.

• if you are allergic (hypersensitive) to aspirin or any other NSAIDs (such as ibuprofen, naproxen or diclofenac).

• if you have taken aspirin or any other NSAIDs and experienced one of the following:

- asthma attack
- runny nose, itching and/or sneezing (irritation of the nose)
- raised red circular patchy rash on the skin which may have been itchy, stung or had a burning sensation
- severe allergic reaction (anaphylactic shock). Symptoms include difficulty breathing, wheezing, abnormal pain and vomiting

• if you have a history of, suffer from, or suspect that you have a stomach ulcer or intestinal bleeding.

• if you have moderate to severe kidney disease.

• if you have or have ever had a severe heart failure (heart attack).

• if you suffer from, or suspect that you have liver failure.

• if you are pregnant (unless considered essential by your doctor). Algic is not recommended for use in children

Take special care with Algic

Before you start taking Algic, tell your doctor:

• if you suffer from any other form of liver disease.

• if you have any of the following gastro-intestinal disorders:

- inflammatory bowel disease (ulcerative colitis)
- chronic inflammatory bowel disease (Crohn's disease)
- bleeding
- vomiting of blood

• if you have, or have ever had problems with the circulation of the blood to your brain.

• if you suffer from asthma or any other breathing problems.

• if you suffer from a blood disorder known as porphyria.

• if you have heart problems, previous stroke or think that you might be at risk of these conditions (for example, if you have high blood pressure, diabetes, high cholesterol or are a smoker) you

should discuss your treatment with your doctor or pharmacist.

• If you are elderly (your doctor will prescribe you the lowest effective dose over the shortest duration).

Medicines such as Algic may be associated with a small increased risk of heart attack ("myocardial infarction") or stroke. Any risk is more likely with high doses and prolonged treatment.

Do not exceed the recommended dose or duration of treatment.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Please tell your doctor if you are taking:

• medicines used to treat depression or manic depression (lithium)

• medicines used to treat heart failure and irregular heart beats (cardiac glycosides)

• medicines used to treat high blood pressure (antihypertensives)

• quinolone antibiotics

• drugs used to increase the rate of urine excretion (diuretics)

• medicines that stop blood clotting (anticoagulants) such as warfarin, heparin

• methotrexate which is used to treat cancer and autoimmune disorders

• mifepristone which is used as an emergency contraceptive or to induce abortions

• any steroids (oestrogens, androgens, or glucocorticoids)

• medicines used to supress the immune system (cyclosporin or tacrolimus)

• medicines used to treat HIV (zidovudine)

• medicines used to lower blood sugar levels (antidiabetics)

• any other NSAID drugs (aspirin, ibuprofen, naproxen)

Taking Algic with food and drink

Algic must be taken preferably with or after food.

Pregnancy and breast-feeding

You should inform your doctor if you are planning to become pregnant or if you have problems becoming pregnant. NSAIDs may make it more difficult to become pregnant.

Do not take Algic if you are pregnant or think you are pregnant. The safety of this medicine for use during pregnancy has not been established. It is not recommended for use in pregnancy unless considered essential by your doctor.

Algic should not be used if you are breast-feeding. It is not known if this medicine passes into breast milk. It is not recommended for use during breast-feeding unless considered essential by your doctor.Consult your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

If you are taking Algic and you experience dizziness, drowsiness, tiredness or any visual disturbances, you must not drive or use machinery.

3. HOW TO TAKE ALGIC

Always take Algic exactly as your doctor has told you. You will be prescribed the lowest effective dose over the shortest duration to reduce side effects. You should check with your doctor or pharmacist if you are not sure.

The recommended dose in adults is 200mg (two Algic tablets). One 100mg tablet should be taken in the morning and one in the evening.

Tablets should be swallowed whole with plenty of water and should be taken with or after food.

Do not crush or chew the tablets.

Do not exceed the stated daily dose.

Elderly

If you are elderly, you are more likely to experience serious side-effects.

If your doctor prescribes Algic for you, you will be given the lowest effective dose over the shortest duration.

If you take more Algic than you should

If you accidentally take too many Algic tablets, contact your doctor immediately or go to your nearest hospital casualty department. Please take this leaflet or the box the Algic tablets came in, with you to the hospital so that they will know what you have taken.

If you forget to take Algic

If you miss a dose, do not worry, just take the next dose at the usual time.

Do not take a double dose to make up for a forgotten tablet dose.

If you stop taking Algic

Do not stop taking Algic unless your doctor advises you.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Algic can cause side effects, although not everybody gets them.

If you experience any of the following side effects, tell your doctor **IMMEDIATELY**:

• medicines such as Algic may be associated with a small increased risk of heart attack ("myocardial infarction") or stroke
• severe allergic reaction (anaphylactic shock). Symptoms may include difficulty breathing, wheezing, abnormal pain and vomiting
• swelling of the face
• kidney failure

If you suffer from any of the following at any time during your treatment **STOP TAKING** the medicine and seek immediate medical help:

• Pass blood in your faeces (stools/motions)
• Pass black tarry stools
• Vomit any blood or dark particles that look like coffee grounds.

STOP TAKING the medicine and tell your doctor if you experience:

• Indigestion or heartburn
• Abdominal pain (pains in your stomach) or other abnormalstomach symptoms.

If any of the **below** side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Common (occur in more than 1 in 100 patients but in less than 1 in 10 patients):

• dizziness
• nausea (feeling sick)
• diarrhoea
• increased liver enzymes in the blood

Uncommon (occur in more than 1 in 1,000 patients but in less than 1 in 100 patients):

• wind (flatulence)
• inflammation or irritation of the lining of the stomach (gastritis)
• constipation
• vomiting
• mouth ulcers
• itching
• rash
• inflammation of the skin (dermatitis)

• raised circular red itchy, stinging or burning patches on the skin (hives)
• increase in blood urea levels
• increase in blood creatinine levels

Rare (occur in more than 1 in 10,000 patients but in less than 1 in 1,000 patients):

• low levels of iron in the blood
• hypersensitivity (allergic reaction)
• visual disturbance
• shortness of breath

Very Rare (occur in less than 1 in 10,000 patients):

• low white blood cells levels
• low platelets levels in the blood
• abnormal breakdown of red blood cells (anemia)
• high potassium levels in the blood
• depression
• strange dreams
• inability to sleep
• tingling, pricking or numbness of skin
• uncontrollable shaking (tremor)
• drowsiness
• headaches
• abnormal taste in the mouth
• sensation of spinning when standing still
• heart pounding or racing (palpitations)
• hot flushes
• difficulty breathing
• high pitched noise when breathing
• inflammation of the mouth
• stomach ulcer
• inflammation of the pancreas (pancreatitis)
• inflammation of the liver (hepatitis)
• yellowing of the skin (jaundice)

• spontaneous bleeding into the skin (appears as a rash)
• blisters
• water retention and swelling
• tiredness
• leg cramps
• increased blood alkaline phosphatase levels
• weight gain

If any of the **below** side effects get serious, please tell your doctor or pharmacist.

Other side effects that have been reported with this type of drug (NSAIDs) are:

• hallucinations
• confusion
• blurred, partial or complete loss of vision
• painful movement of the eye
• ringing in the ears
• aggravated asthma
• ulcers
• perforation of either the stomach, large intestine or bowel wall
• blistering and peeling of the top layer of skin
• mild, itchy pink/redness of the skin
• reddening or scaling of skin
• skin irritation (eczema)
• skin reaction to sunlight
• inflammation of the kidneys
• generally feeling unwell
• aseptic meningitis
• exacerbation of colitis and Crohn's disease
• hypertension (high blood pressure)
• cardiac failure
• bone marrow depression

5. HOW TO STORE ALGIC

Keep out of the reach and sight of children.

Do not store above 25ºC.

Do not use Algic after the expiry date which is stated on the outer carton. The expiry date refers to the last day of that month. It is recommended that you store Algic in the original box.
Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Algic contains

The active substance is aceclofenac 100mg.

The other ingredients are:

Tablet core - microcrystalline cellulose, sodium starch glycolate, maize starch, povidone and sodium lauryl sulphate, colloidal silicon dioxide, magnesium stearate.

Coating Material - partially substituted hydroxypropyl methylcellulose, macrogol, talc and titanium dioxide.

What Algic looks like and contents of the pack

Algic 100 mg film-coated tablets are white, round tablets.

Algic tablets are available in boxes of 30 tablets.

Manufacturer:

MSN Laboratories Pvt. Limited
Plot No 42.Anrich Industrial Estate,
Bollaram, Medak Dist. 502 325, A.P ,INDIA.