Summary of Product Characteristics

(Product Data Sheet)

1. Name of the Medical Product

1.1 Product Name : ACTINAC 100 (Aceclofenac Tablets 100 mg)

1.2 Strength:

Each film coated tablet contains:
Aceclofenac BP ..... 100 mg
Colour: Brilliant Blue FCF

1.2 Pharmaceutical Dosage Form: Film coated tablet

2. Qualitative & Quantitative Composition

Sr.No.	Ingredients	Specification	Quantity per unit (in mg)
Active Ingredient			
01.	Aceclofenac	BP	100.00
Excipients			
02.	Microcrystalline Cellulose	USPNF	67.00
03.	Hydrophobic Colloidal Silica	USPNF	3.00
04.	Croscarmellose Sodium	USPNF	4.00
05.	Magnesium Stearate	BP	6.00
Film coating materials			
06.	Insta moistshield A21D01238 Blue [§]	IH	4.50
07.	Instaglow IG-001 White [£]	IH	0.50
08.	Isopropyl alcohol [$]	BP	q.s
09.	Dichloromethane [$]	BP	q.s

BP : British Pharmacopoeia
USPNF : United States Pharmacopoeia- National Formulary
IH : In-house Specification
[§] Insta moistshield A21D01238 Blue IH consists Hydroxy Propyl Methyl Cellulose, Triacetin, Ethyl cellulose, Talc, Titanium Dioxide, Lake Brilliant blue.
[£] Instaglow IG-001 White consists Hydroxy Propyl Methyl Cellulose, Polyethylene Glycol, Glycerin, Talc.
[$] Used as vehicle and does not remain in final product.

3. Pharmaceutical Form:

Film coated tablet for oral administration

4. Clinical Particulars

4.1 Therapeutic Indications:

	Aceclofenac is indicated for the relief of pain and inflammation in osteoarthritis, rheumatoid arthritis and ankylosing spondylitis.
	4.2 Posology and Method of administration *Aceclofenac film-coated tablets are supplied for oral administration.* **Posology** 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 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. ***Paediatric population*** 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 needs to be modified in patients with mild renal impairment, but as with other NSAIDs caution should be exercised. ***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. **Method of administration**

	To be taken preferably with or after food. The tablets should be swallowed whole with a sufficient quantity of liquid.
	4.3 Contraindication Active, or history of recurrent peptic ulcer/hemorrhage (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. Hepatic failure and renal failure. Patients with established congestive heart failure (NYHA II-IV), ischemic heart disease, peripheral arterial disease and/or cerebrovascular disease. History of gastrointestinal bleeding or perforation, related to previous NSAIDs therapy. Active bleedings or bleeding disorders. 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.
	4.4 Special warning and precautions for use 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. ***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 or recovering from major surgery, and the elderly. The importance of prostaglandins in maintaining renal blood flow should be taken into account in these patients.

Renal function should be monitored in these patients.

Renal:

Patients with mild to moderate renal impairment should be kept under surveillance, since the use of NSAIDs may result in deterioration of renal function. The lowest effective dose should be used and renal function monitored regularly. Effects on renal function are usually reversible on withdrawal of Aceclofenach.

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.

Patients with congestive heart failure (NYHA-I) and patients with significant risk factors for cardiovascular events (e.g. hypertension, hyperlipidemia, diabetes mellitus, smoking) should only be treated with aceclofenac after careful consideration. 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.

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 involving either the upper or lower gastrointestinal tract, with a history suggestive of gastro-intestinal ulceration, bleeding or perforation, with ulcerative colitis or with Crohn's disease, or haematological abnormalities, as these conditions may be exacerbated.

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 hemorrhage 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.

Caution should be advised in patients receiving concomitant medications which could increase the risk of ulceration or bleeding, such as systemic corticosteroids, anticoagulants such as warfarin, selective serotonin-reuptake inhibitors or antiplatelet agents such as aspirin.

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

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. Exceptionally, varicella can trigger serious cutaneous and soft tissues infections 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. ***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. ***Long-term treatment:*** All patients who are receiving NSAIDs should be monitored as a precautionary measure e.g. renal, hepatic function (elevation of liver enzymes may occur) and blood counts. ***Sodium:*** This medicine contains less than 1mmol sodium (23 mg) per tablet that is to say essentially 'sodium free'.
	4.5 DRUG INTERACTIONS / 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,

including GI bleeding.

Anti-hypertensives: NSAID's may reduce the effect of antihypertensives. 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: Aceclofenac, like other NSAIDs, may inhibit the activity of diuretics. 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, like digoxin: NSAIDs may exacerbate cardiac failure, reduce GFR (glomerular filtration rate) and inhibit the renal clearance of glycosides, resulting in increased plasma glycoside levels. The combination should be avoided unless frequent monitoring of glycoside levels can be performed.

Lithium: Several NSAID drugs inhibit the renal clearance of lithium, resulting in increased serum concentrations 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 born in mind also 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 both an NSAID and methotrexate are administered within 24 hours of each other, since NSAIDs may increase plasma levels of methotrexate, 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.

	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. ***Ciclosporin, tacrolimus:*** Administration of NSAID drugs together with cyclosporin or tacrolimus is thought to increase the risk of nephrotoxicity due to decreased synthesis of prostacyclin in the kidney. During combination therapy it is therefore important to carefully monitor renal function. Zidovudine: Increased risk of haematological toxicity when NSAIDs are given with zidovudine. There are indications 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.
	4.6 Fertility, pregnancy and lactation ***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/fetal 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. From the 20th week of pregnancy onward, aceclofenac use may cause oligohydramnios resulting from foetal renal dysfunction. This may occur shortly after treatment initiation and is usually reversible upon discontinuation. In addition, there have been reports of ductus arteriosus constriction following treatment in the second trimester, most of which resolved after treatment cessation. Therefore, 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. Antenatal monitoring for oligohydramnios and ductus arteriosus constriction should be considered after exposure to aceclofenac for several days from gestational week 20 onward. Aceclofenac should be discontinued if oligohydramnios or ductus arteriosus constriction are found. During the third trimester of pregnancy, all prostaglandin synthesis inhibitors may expose the foetus to: - Cardiopulmonary toxicity (premature constriction /closure of the ductus arteriosus and pulmonary hypertension); - Renal dysfunction, 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 labour. Consequently, aceclofenac is contraindicated during the third trimester of pregnancy ***Breastfeeding:*** There is no information on the secretion of aceclofenac to breast milk; there was however no notable transfer of radio labelled (14C) 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. ***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.
	4.7 Effects on ability to drive and use machines Undesirable effects such as dizziness, drowsiness, vertigo, fatigue, visual disturbances or other central nervous system disorders are possible after taking NSAIDs. If affected, patients should not drive or operate machinery.
	4.8 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, angiodema and, more rarely exfoliative and bullous dermatoses (including epidermal necrolysis and erythema multiform). ***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 (for example myocardial infarction or stroke, particularly at high doses or in long 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:

***Renal*:** interstitial nephritis.

Neurological and special senses: optic neuritis, 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 confusion, hallucinations, malaise and drowsiness.

Haematological: agranulocytosis, aplastic 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. 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).

MedDRa SOC	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
Blood and lymphatic system disorders			Anaemia	Bone Marrow depression 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
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
Gastrointestinal disorders	Dyspepsia Abdominal pain Nausea Diarrhoea	Flatulence Gastritis Constipation Vomiting Mouth ulceration		Melaena Gastrointestinal haemorrhage Gastrointestinal ulceration	Stomatitis Intestinal perforation Exacerbation of Crohn's dis 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		Angioedema	Purpura Severe mucocutaneous skin reaction (including Stevens Johnson Syndrome and Tox 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

4.9 Overdose

a) Symptoms

Symptoms include headache, nausea, vomiting, epigastric pain, gastrointestinal irritation,

	gastrointestinal bleeding, rarely diarrhoea, disorientation, excitation, coma, drowsiness, dizziness, tinnitus, hypotension, respiratory depression, fainting, occasionally and 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. Specific therapies such as dialysis or haemoperfusion are probable 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 four 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, gastro-intestinal irritation, and respiratory depression
5.	**Pharmacological properties**
	5.1 ATC CODE M02AA25 **5.2 Pharmacodynamics 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 prostaglandin
	5.3 Pharmacokinetics 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.
	5.4 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. 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 fetuses.
6.	**Pharmaceutical particulars**
	6.1 List of Excipients: Microcrystalline Cellulose USPNF Hydrophobic Colloidal Silica USPNF Croscarmellose Sodium USPNF Magnesium Stearate BP Insta moistshield A21D01238 Blue IH Instaglow IG-001 White IH

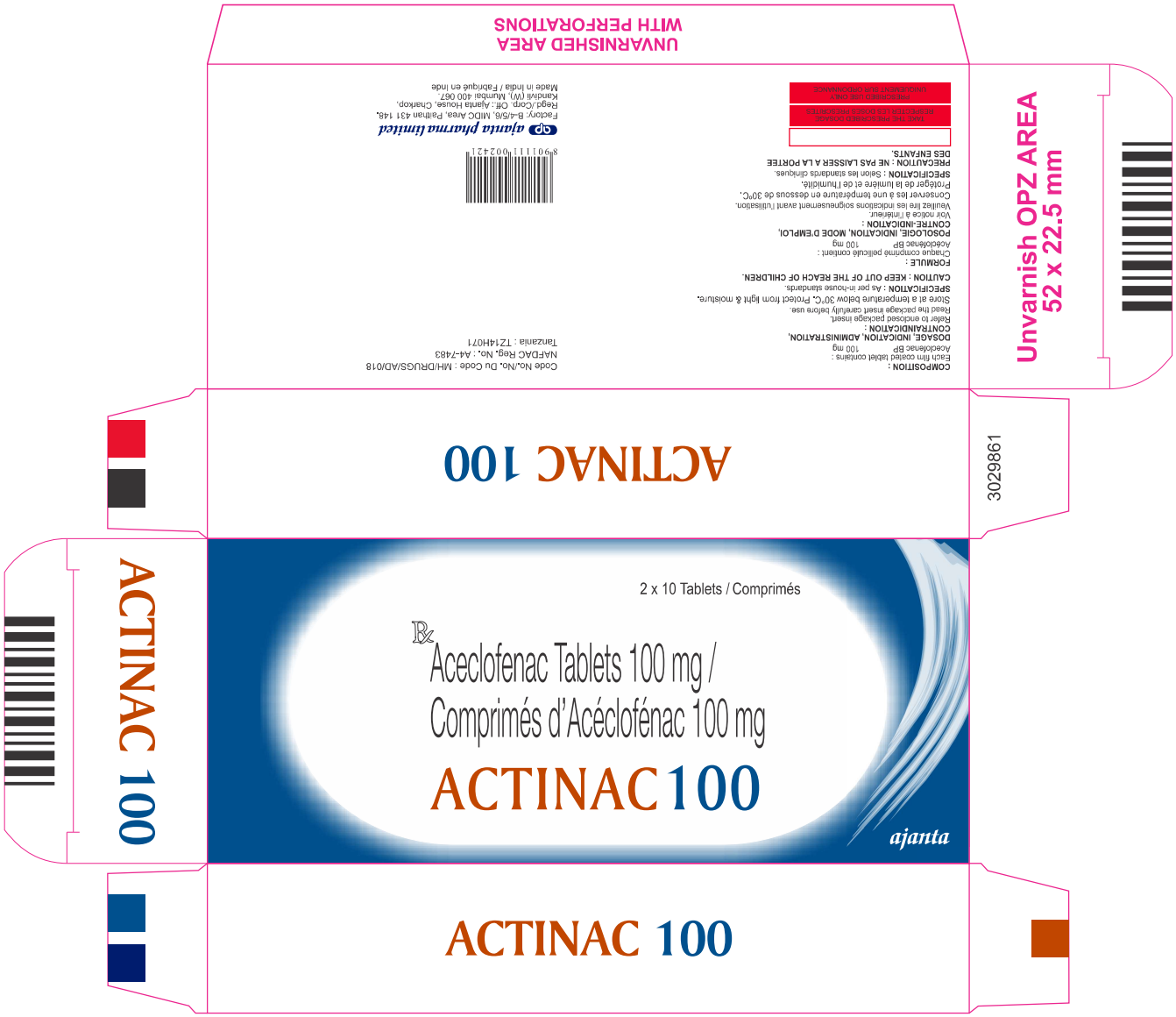
	Isopropyl alcohol BP Dichloromethane BP IH : In House Specification BP : British Pharmacopoeia USP-NF: United States Pharmacopoeia- National Formulary
	6.2 Incompatibilities: Not applicable
	6.3 Shelf life: 36 months
	6.4 Special Precautions for storage: Store at a temperature below 30°C. Protect from light & moisture.
	6.5 Nature and contents of container: Available in blister of 10 Tablets, 2 such blisters are packed in a carton along with pack insert.
	6.6 Special precautions for disposal and other handling: Not applicable
7.	**Marketing authorization holder and manufacturing site addresses:** Ajanta House, Charkop, Kandivli (West), Mumbai- 400 067, India Manufacturing site address: Ajanta Pharma Limited Plot No. B-4/5/6, MIDC, Paithan, Aurangabad 431148, Maharashtra State, India.
8.	**Marketing authorization number:** A4-7483
9.	**Date of first registration/ renewal of the registration:** Feb 28, 2019
10.	**Date of revision of text:** Jun, 2023

ACTINAC 100
Aceclofenac Tablets 100 mg

1.13 Artworks

Please find enclosed herewith Artworks (Carton, Foil, and Pack Insert).

Actual Size : 122 x 24 x 52 mm



Pharma Code : 29861 Standard

Direction for Travel

ajanta pharma limited

Name & Signature

Checked By :

Verified By :

Approved By :

Date :

Packaging Department

For : Anglo Africa | Co-ordinator Name : Anand | Software : Corel Draw | Date : 08/11/2021

New Item Code : 3029861 | Item Type: Carton (Cartonetor) | Artist Name : Kiran

Product Name : Actinac 100 Tablets, 2x10's | Earlier Item Code: TN3678C

Material : 300 gsm ITC FBB Board

Actual Size : 122 x 24 x 52 mm | Folding Size : NA | Varnish : Aqua

Print Repeat : NA | Drawing No. : C-100-1609-1200

CMYK / Pantone : Pantone 7686 C | Pantone 1525 C | Pantone 2748 C | Pantone 185 C | Black

Reason for Change : New Dev. for Anglo Africa.

Front Panel:

℞ generic Name
BRAND NAME Strength
Pack Size / Volume
Pneumonic
ajanta

Back Panel / Side Panel

Composition	☐	Barcode	☐
Colour	☐	Warnings / Schedule H	☐
Dosage	☐	Caution / Schedule G	☐
Storage	☐	Statutory Contents	☐
Made in India	☐	Directions for use	☐
Company's Name	☐	Neutral code	☐
H.O.Address	☐	Factory + H.O.Address	☐
Factory Address	☐	Red line	☐
Toll Free No. / Email ID	☐	Other	☐

Side Panels

BRAND NAME ☐

PTN ☐ CKL ☐ CTGN ☐ LL ☐ TP ☐ DHJ ☐ GHT ☐ PMR ☐

Others:

Item Code	☐	Pharma Code	☐
LIF	☐	Colour Code	☐
Printed License No.	☐	Reference Sample	☐
O.P.Zone / DGFT	☐	Back-side Printing	☐
MOH approved a/w	☐	Change Parts	☐
		Buyer/IBM approval	☐

NOTE TO PRINTERS: THE CD OUTPUT MAY / MAY NOT BE MATCHING WITH THE OUTPUT. FOR THIS COLOUR MATCH AS PER ATTACHED SAMPLE WITH A/W IF IT IS NOT MATCHING WITH THE GIVEN REFERENCE SAMPLE THE PM/PROOF REJECTION WILL BE SUPPLIERS RESPONSIBILITY. FOR CARTON GRAIN DIRECTION PERPENDICULAR TO MAIN CREASE. / REMARK: BLOCK PROOF REQUIRE BEFORE PRINTING.

Actual Blister Size : 115 x 48 mm

Note : Pharma Code will be repeat after every 200 mm for reading feasibility on machine.

Pharma Code : 100000 Standard

Direction for Travel

Date	: 11.02.2021
Artist	: Ganesh
Product	: Actinac 100 mg Tablets
Actual Blister Size	: 115 x 48 mm
Ref artwork	: P29755
Colour	: Pantone 7686 C Black Pantone 185 C
Country	: Anglo Africa

FRONT

3020589

℞ Aceclofenac Tablets 100 mg

ACTINAC 100

COMPOSITION :
Each film-coated tablet contains
Aceclofenac BP ..... 100 mg

CLINICAL PHARMACOLOGY
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 theproduction 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.

INDICATIONS
Actinac is indicated for the relief of pain and inflammation in osteoarthritis, rheumatoid arthritis and ankylosing spondylitis.

CONTRAINDICATIONS
NSAIDs should not be administered to patients with a history of or active or suspected peptic ulcer or gastro-intestinal bleeding.
Actinac should not be given to patients with moderate to severe renal impairment.
Actinac should not be prescribed during pregnancy, unless there are compelling reasons for doing so. The lowest effective dosage should be used.
Actinac should not be administered to patients previously sensitive to aceclofenac or in whom aspirin or NSAIDs precipitate attacks of asthma, acute rhinitis or urticaria or who are hypersensitive to these drugs.
Actinac is contraindicated in cases where there is hypersensitivity to any of its constituents.

WARNINGS AND PRECAUTIONS
General
- Close medical surveillance is imperative in patients with symptoms indicative of gastrointestinal disorders, with a history suggestive of gastrointestinal ulceration, with ulcerative colitis or with Crohn's disease, bleeding diathesis or haematological abnormalities.
- Gastrointestinal bleeding or ulcerative perforation, haematemesis and melaena have in general more serious consequences in the elderly. They can occur at any time during treatment, with or without warning symptoms or previous history. In the rare instances, where gastrointestinal bleeding or ulceration occurs in patients receiving aceclofenac, the drug should be withdrawn. Close medical surveillance is also imperative in patients suffering from severe impairment of hepatic function.
- Aceclofenac should be given with caution to elderly patients with renal, hepatic or cardiovascular impairment and to those receiving other medication. The lowest effective dose should be used and renal function monitored regularly.
- As with other NSAIDs, allergic reactions, including anaphylactic/ anaphylactoid reactions, can also occur without earlier exposure to the drug.
- 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.
- Caution should also be exercised in patients with history of coagulation defects and history of liver dysfunction.
- Renal and hepatic function and blood counts should be monitored during long-term treatment. Persistently elevated hepatic enzyme levels necessitate withdrawal of aceclofenac.

Pregnancy
The drug is not recommended in pregnant women

Lactation
The drug is not recommended in breast-feeding women.

Paediatric use
There are no clinical data on the use of aceclofenac in children.

Drug Interactions
Drug interactions associated with aceclofenac are similar to those observed with other NSAIDs.
Aceclofenac may increase plasma concentrations of lithium, digoxin and methotrexate, increase the activity of anticoagulants, inhibit the activity of diuretics, enhance cyclosporin nephrotoxicity and precipitate convulsions when coadministered with quinolone antibiotics.
When concomitant administration with potassium sparing diuretics is employed, serum potassium should be monitored.
Furthermore, hypo or hyperglycaemia may result from the concomitant administration of aceclofenac and antidiabeticdrugs, although this is rare. The coadministration of aceclofenac with other NSAIDs or corticosteroids may result in increased frequency of side effects.
Caution should be exercised if NSAIDs and methotrexate are administered within 2-4 hours of each other, since NSAIDs may increase methotrexate plasma levels, resulting in increased toxicity.

Effects on ability to drive and use machines
Patients suffering from dizziness, vertigo, or other central nervous system disorders whilst taking NSAIDs should refrain from driving or handling dangerous machinery.

ADVERSE EFFECTS
Aceclofenac is well tolerated, with most adverse events being minor and reversible and affecting mainly the GI system.
Most common events include dyspepsia, and abdominal pain (> 5% incidence). Dizziness, vertigo, pruritus, rash and dermatitis have been reported with aceclofenac, but the incidence of these events is low (< 5%).

DOSAGE AND ADMINISTRATION
The usual dose of aceclofenac is 100 mg given twice daily by mouth. One tablet in the morning and one in the evening.
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. 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.
Aceclofenac tablets should be swallowed whole with a sufficient quantity of liquid. When aceclofenac was administered to fasting and fed healthy volunteers only the rate and not the extent of aceclofenac absorption was affected and as such aceclofenac can be taken with food.

SPECIFICATION : As per in-house standards.

PRESENTATION
Available in Blister pack of 10 tablets

Store at a temperature below 30°C.
Protect from light & moisture.

CAUTION : KEEP OUT OF THE REACH OF CHILDREN.

A Product of :

ajanta pharma limited
Ajanta House, Charkop,
Kandivli (W), Mumbai 400 067.
Made In India

BACK

℞ Comprimés d'Acéclofénac 100 mg

ACTINAC 100

COMPOSITION :
Chaque comprimé pelliculé contient
Acéclofénac BP ..... 100 mg

PHARMACOLOGIE CLINIQUE
L'Acéclofénac est un agent non stéroïdien ayant des propriétés anti-inflammatoires et analgésiques marquées.
Le mode d'action de l'Acéclofénac est en grande partie basé sur l'inhibition de la synthèse de prostaglandine. L'Acéclofénac est un puissant inhibiteur de l'enzyme cyclo-oxygénase, qui est impliqué dans la production de prostaglandines.
Propriétés pharmacocinétiques
Après administration orale, l'Acéclofénac est rapidement et complètement absorbé sous forme inchangée. L'Acéclofénac pénètre dans le fluide synovial, où les concentrations atteignent approximativement 57% de celles dans le plasma. Le volume de distribution est d'environ 25 l.
La demi-vie moyenne d'élimination plasmatique est d'environ 4 heures. L'Acéclofénac est hautement lié aux protéines (>99%). L'Acéclofénac circule principalement sous forme inchangée. Le 4-hydroxyacéclofénac est le principal métabolite détecté dans le plasma. Environ deux tiers de la dose administrée sont excrétés par voie urinaire, principalement sous forme d'hydroxymétabolites.
Aucun changement dans la pharmacocinétique de l'Acéclofénac n'a été détecté chez les personnes âgées.

INDICATIONS
L'Actinac est indiqué dans le traitement symptomatique de la douleur et de l'inflammation liée à l'ostéoarthrite, l'arthrite rhumatoïde et à la spondylite ankylosante.

CONTRE INDICATIONS
Les AINS ne doivent pas être prescrits aux patients ayant déjà été traités pour un ulcère peptique actif ou suspecté ou pour un saignement gastro-intestinal.
L'Actinac ne doit pas être prescrit aux patients souffrant d'insuffisance rénale modérée ou sévère.
L'Actinac ne doit pas être prescrit pendant la grossesse sauf s'il y a des raisons majeures pour le faire. Le dosage efficace le plus bas doit être pris.
L'Actinac ne doit pas être administré à des patients ayant manifesté précédemment une hypersensibilité à l'Acéclofénac ou chez qui l'aspirine ou les AINS peuvent déclencher des crises d'asthme, de rhinite aiguë ou d'urticaire ou qui sont hypersensibles à ces médicaments.
L'Actinac est contre-indiqué en cas d'hypersensibilité à l'un de ses composants.

MISE EN GARDE ET PRÉCAUTIONS
Généralités
- Une surveillance médicale étroite est impérative chez lespatients ayant des symptômes gastro-intestinaux, des antécédents d'ulcération gastro-intestinale, une colite ulcéreuse ou une maladie de Crohn, une diathèse hémorragique ou des anormalités hématologiques.
- L'hémorragie gastro-intestinale ou la perforation ulcéreuse, l'hématémèse et le melaena ont en général des conséquences plus graves chez les personnes âgées. Ils peuvent survenir à n'importe quel moment pendant le traitement, avec ou sans symptômes d'avertissement ou d'antécédents. Dans les rares cas, où une hémorragie gastro-intestinale ou une ulcération se produirait chez les patients prenant de l'Acéclofénac, le médicament doit être discontinué. Une étroite surveillance médicale est également impérative chez les patients souffrant d'une insuffisance hépatique aiguë.
- L'Acéclofénac doit être prescrit avec précaution chez les patients âgés souffrant d'insuffisance rénale, hépatique ou cardiovasculaire et chez ceux prenant d'autres médicaments. La dose efficace la plus basse doit être utilisée et la fonction rénale régulièrement surveillée.
- Tout comme pour les autres AINS, des réactions allergiques comme les réactions anaphylactiques/anaphylactoïdes, peuvent également apparaître sans que l'on ait été précédemment exposé au médicament.
- L'importance des prostaglandines pour maintenir le flux sanguin rénal doit être prise en compte chez les patients souffrant d'insuffisance cardiaque ou rénale, chez ceux traités avec des diurétiques ou en convalescence après une opération capitale. Les effets sur la fonction rénale sont en général réversibles après arrêt de l'Acéclofénac.
- Des précautions sont également à prendre chez les patients ayant des antécédents des défauts de coagulation et un antécédent de dysfonctionnement hépatique.
- La fonction rénale et hépatique et la numération globulaire doivent être surveillées pendant un traitement à long terme. Des niveaux d'enzyme hépatique élevés persistants nécessitent le retrait de l'acéclofénac.

Grossesse
Le médicament est déconseillé pour les femmes enceintes

Allaitement
Le médicament est déconseillé aux femmes allaitant.

Utilisation Pédiatrique
Il n'existe aucune donnée clinique concernant l'utilisation de l'Acéclofénac chez les enfants.

Interactions médicamenteuses
Les interactions liées à l'Acéclofénac sont semblables à celles observées pour les AINS.
L'Acéclofénac peut augmenter les concentrations plasmatiques de lithium, de digoxine et de méthotrexate, augmenter l'activité des anticoagulants, inhiber l'activité des diurétiques, augmenter la néphrotoxicité de la cyclosporine et provoquer les convulsions lorsqu'il est co-administré avec des quinolones.
Lorsqu'il est administré de façon concomitante avec un diurétique épargnant le potassium, le potassium dans le sérum doit être surveillé.
De plus, une hypo ou hyperglycémie peut se produire à partir d'une administration concomitante d'Acéclofénac et de médicaments antidiabétiques, bien que cela soit rare. La co-administration d'Acéclofénac avec d'autres AINS ou des corticostéroïdes peut accroître la fréquence d'effets secondaires.
Des précautions sont à prendre si des AINS et le méthotrexate sont administrés à moins de 2-4 heures l'un de l'autre, car les AINS peuvent accroître les niveaux plasmatiques de méthotrexate, conduisant à une augmentation de la toxicité.

Effets sur la capacité de conduire et utiliser des machines
Les patients souffrant de vertiges, d'éblouissements ou autres troubles du système central nerveux en prenant des AINS doivent éviter de conduire ou utiliser des machines dangereuses.

Effets indésirables
L'Acéclofénac est bien toléré, la plupart des effets indésirables étant mineurs et réversibles et affectant principalement le système GI.
Les effets les plus courants sont la dyspepsie et des douleurs abdominales (>5% d'incidence). Vertiges, éblouissement, prurit, démangeaisons et dermatite ont été rapportées avec l'Acéclofénac, mais l'incidence de ces événements est faible (< 5%).

POSOLOGIE ET ADMINISTRATION
La dose habituelle d'Acéclofénac est de 100 mg administrée par voie orale deux fois par jour. Un comprimé matin et soir.
Rien ne prouve que le dosage d'Acéclofénac doive être modifié chez les patients souffrant d'une légère insuffisance rénale, mais comme pour les autres AINS il faut être prudent. Il est prouvé que la dose d'Acéclofénac doit être réduite chez les patients souffrant d'insuffisance hépatique et la dose quotidienne initiale recommandée est de 100 mg.
Les comprimés d'Acéclofénac sont à avaler entiers avec une quantité liquide suffisante. Lorsque l'Acéclofénac a été administré à des volontaires en bonne santé à jeun et nourris, seulement le taux mais non pas l'étendue de l'absorption d'Acéclofénac a été affecté. Par conséquent l'Acéclofénac peut être pris avec de la nourriture.

SPECIFICATIONS : Selon les standards cliniques.

PRESENTATION
Disponible en plaquette alvéolaire de 10 comprimés

Conserver les à une température en dessous de 30°C.
Protéger de la lumière et de l'humidité.

PRECAUTION : NE PAS LAISSER A LA PORTEE DES ENFANTS.

Un Produit de :
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Ajanta House, Charkop,
Kandivli (W), Mumbai 400 067.
Fabriqué en Inde

140 X 210 mm