1.3 Product information

1.3.1 Summary of product characteristics (SMPC)

1. NAME OF THE MEDICINAL PRODUCT

1.1 Product Name: CHIFENAC

1.2 Generic Name: Aceclofenac Softgel Capsules 100 mg

1.3 Strength: Aceclofenac 100 mg

1.4 Pharmaceutical Form: Softgel Capsule

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Composition

Each Softgel Capsule Contains:

Aceclofenac BP 100 mg.

Excipients q.s.

Approved colour used in softgel capsules shell.

Brand Name: CHIFENAC
Generic Name: Aceclofenac Softgel Capsules 100 mg

Dr. Smiths Biotech Pvt. Ltd.

Batch size: 1,00,000 softgel capsules

Sr. No.	Ingredients	Label Claim	Overages (%)	Spec	Quantitative for / Capsules (mg)	Quantitative for 1.0 Lac Capsules (kg)	Uses
FOR MEDICAMENT							
1	Aceclofenac	100 mg	10	BP	110.000	11.000	Anti-inflammatory and Analgesic
2	White Beeswax			BP	5.000	0.500	Thickener
3	Hydrogenated Vegetable Oil			BP	15.000	1.500	Excipient
4	Soya Lecithin			IH	25.000	2.500	Emulsifier
5	Butylated Hydroxyanisole			BP	0.300	0.030	Preservative
6	Butylated Hydroxytoluene			BP	0.300	0.030	Preservative
7	Soyabean Oil			BP	94.400	9.440	Excipient
				Total	**250.00**	**25.00**	
FOR GELATIN MASS							
1	Gelatin			BP	294.00	29.400	Excipient
2	Glycerol			BP	84.00	8.400	Plasticizer
3	Sorbitol Solution (70%) (Non Crystallising)			BP	56.00	5.600	Sweetener
4	Methyl Hydroxybenzoate			BP	1.40	0.140	Preservative
5	Propyl Hydroxybenzoate			BP	0.70	0.070	Preservative
6	Colour Ponceau 4R Supra			IH	1.55	0.155	Colouring Agent
7	Titanium Dioxide			BP	2.80	0.280	Colouring Agent
8	Purified Water			BP	259.55	25.955	Excipient
				Total	**700.00**	**70.000**	

Average fill weight = 250 mg./Capsule

Average weight of Capsules = 425 mg/Capsule (After Drying)

Legend

BP: British Pharmacopeia

IH: In house

3. PHARMACEUTICAL FORM VISUAL DESCRIPTION:

Red colour, opaque, oval shaped, soft gelatin capsule containing white oily semi solid mass.

4. CLINICAL PARTICULARS

4.1 THERAPEUTIC INDICATIONS:

-Toothache, inflammation caused by external wound, lumbago, sciatic pain, post-episiotomy, post-parturition, pains due to nonarticular rheumatism

-Rheumatoid arthritis, ankylosing spondylitis, osteoarthritis, scapulohumeral periarthritis

4.2 POSOLOGY AND METHOD OF ADMINISTRATION

Adults: The recommended dose is one capsule twice daily (every 12 hours). Or as prescribed by the physician.

4.3 CONTRAINDICATIONS

1. Patients with active peptic ulcer
2. Patients with hypersensitivity to these drugs or other analogues (diclofenac)
3. 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 (containing COX-2 inhibitor). (Rarely as with other NSAIDs, allergic reactions, including anaphylactic/anaphylactoid reactions, can also occur in these patients.)
4. Patients with asthma, like NSAIDs, acetylsalicylic acid and other drugs (like aspirin) which inhibit prostagladin-synthesis may precipitate attacks of asthma, acute rhinitis or urticaria.
5. For treatment of pain which is caused before and after Coronary Artery Bypass Graft (CABG)

4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE

1. Undesirable effects may be minimized by using the minimum effective dose for the shortest possible duration.
2. Renal: Patients with mild renal or cardiac impairment and the elderly 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.
3. 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.
4. Hepatic: If abnormal liver function test persists 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.
5. Use of aceclofenac in patients with hepatic porphyria may trigger an attack.
6. Haematological: Aceclofenac may reversibly inhibit platelet aggregation.
7. Cardiovascular: NSAIDs should be given with care to patients with a history of heart failure or hypertension since edema has been reported in association with NSAIDs administration.
8. 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.
9. Fertility: NSAIDs may impair fertility and is not recommended in women trying to conceive. The temporary discontinuation of aceclofenac should be considered on women having difficulties to conceiver or undergoing investigations for infertility.
10. Use with caution in patients suffering from or with a history of bronchial asthma since NSAIDs have been known to cause bronchospasm in such patients.

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 bendrofluazide, 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. 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 hypoglycemic agents.

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.

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

Other NSAIDs and steroids: Concomitant therapy with aspirin, other NSAIDs and steroids may increase the frequency of adverse reactions, including the risk of GI bleeding

Cyclosporin: Cyclosporin nephrotoxity may be increased by the effect of NSAIDs on renal prostagladins

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 NSAIDs.

4.6 FERTILITY, 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. 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 (14C) 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 breastfeeding

4.7 EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

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

4.8 ADVERSE REACTION:

The majority of adverse reactions reported have been reversible and of a minor nature. The most frequent are gastro-intestinal disorders particularly dyspepsia, abdominal pain, nausea and diarrhea, rash, ruber, urticaria, symptoms of enuresis, headache, and drowsiness and occasional occurrence of dizziness.

4.9 OVERDOSE

There are no human data available on the consequences of aceclofenac over dosage.

If over dosage is observed, therapeutic measures should be taken according to symptoms, supportive and symptomatic treatment should be given for complications such as hypotension, gastro-intestinal irritation, respiratory depression, and convulsions.

5. PHARMACOLOGICAL PROPERTIES

5.1 PHARMACODYNAMIC PROPERTIES

Mechanism of Action

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.

5.2 PHARMACOKINETIC PROPERTIES

Aceclofenac is well-absorbed from the gastro-intestinal tract; peak plasma concentrations are reached 1 to 3 hours after an oral dose. Aceclofenac is more than 99% bound to plasma proteins. The plasma-elimination half-life is approximately 4 hours. About two-thirds of a dose is excreted in the urine, mainly as hydroxymetabolites.

6. PHARMACEUTICAL PARTICULARS

6.1 LIST OF EXCIPIENTS

Sr. No.	Ingredients	Specification
1.	White Beeswax	BP
2.	Hydrogenated Vegetable Oil	BP
3.	Soya Lecithin	IH
4.	Butylated Hydroxyanisole	BP
5.	Butylated Hydroxytoluene	BP
6.	Soyabean Oil	BP
7.	Gelatin	BP
8.	Glycerol	BP
9.	Sorbitol Solution (70%) (Non Crystallising)	BP
10.	Methyl Hydroxybenzoate (Methylparaben)	BP
11.	Propyl Hydroxybenzoate (Propylparaben)	BP
12.	Colour Ponceau 4R Supra	IH
13.	Titanium Dioxide	BP
14.	Purified Water	BP

6.2 INCOMPATIBILITIES

Not applicable.

6.3 SHELF LIFE

36 Months

6.4 SPECIAL PRECAUTIONS FOR STORAGE

Preserve in tight containers. Store at room temperature not exceeding 30°C.

6.5 NATURE AND CONTENTS OF CONTAINER

10 Softgels are packed in Alu-PVC Blister, such 5 Blisters are packed in one pouch and such two pouch are packed in printed carton along with pack insert.

7. MANUFACTURER

DR. SMITHS BIOTECH PVT. LTD.

(An ISO 9001:2015 & WHO GMP Certified Co.)

B-5, Khasra No. 9 & 10, Dev Bhoomi Industrial Estate,

Bantakhedi, Roorkee, Distt. Haridwar (Uttarakhand)-247667

8. DISTRIBUCARETED BY:

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9. DATE OF REVISION OF THE TEXT

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10. DOSIMETRY (IF APPLICABLE)

Not Applicable