# Summary of Product Characteristics (SPC)

## 1. Name of medicinal product

### 1.1. Product name

CHIFENAC SOFT CAPSULE

### 1.2 Strength

100 mg

### 1.3. Pharmaceutical dosage form

Soft Capsule

## 2. Quality & Quantitative Composition

### 2.1. Qualitative declaration

Aceclofenac 100 mg

### 2.2. Quantitative declaration

Each soft capsule contains Aceclofenac 100 mg

## 3. Pharmaceutical form

Each red, oval soft capsule is filled with mucous liquid, “CLS” is printed.

## 4. Clinical Particulars

### 4.1. Therapeutic indications

Aceclofenac is indicated for the relief of pain and inflammation in toothache, trauma, lumbago, osteoarthritis, rheumatoid arthritis and ankylosing spondylitis.

### 4.2. Posology and method of a administration

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

*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*: Swallow the tablet whole with a glass of water. Do not crush or chew the tablets.

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

## 4.3. Contraindications

1) Active, or history of recurrent peptic ulcer/haemorrhage (two or more distinct episodes of proven ulceration or bleeding).

2) Hypersensitivity to Aceclofenac or to any of the excipients.

3) 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.

4) Patients with asthma. Non-steroidal anti-inflammatory drugs, acetylsalicylic acid and other drugs which inhibit prostaglandin-synthesis may precipitate attacks of asthma, acute rhinitis or urticaria.

5) Treatment of pain due to Coronary artery bypass grafting (CABG).

6) Severe heart failure, hepatic failure and renal failure

7) History of gastrointestinal bleeding or perforation, related to previous NSAIDS therapy.

8) Women during the last stages of pregnancy, and during lactation.

9) Disorders in the intestine, such as Crohn's disease or ulcerative colitis.

10) History of active bleedings or bleeding disorders

11) Patients hypersensitive or allergic to soy beans, beans, or peanuts

## 4.4. Special warning and precaution for use

1) Close medical surveillance is imperative when the person who drinks alcohol regularly should take this drug or other antipyretics and analgesics. This drug may cause gastric-bleeding to this person.

2) 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. 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.

3) 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, and in the elderly. These patients shouls commence

treatment on the lowest dose available. 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.

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

5) GI events : 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. Combination therapy with protective agents (e.g. misoprostol or proton pump inhibitors) should be considered for these patients, and also for patients requiring 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.

6) Hypersensitivity reactions : As with other NSAIDs, allergic reactions, including anaphylactic/anaphylactoid reactions, can also occur without earlier exposure to the drug.

7) 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.

8) 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. Effects on renal function are usually reversible on withdrawal of Aceclofenac.

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11) 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.

12) 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.

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

**4.5. Interaction with other medicinal products and other forms of interactions**

1) Consult with the physician before use if concurrently taking lithium and digoxin, oral antidiabetic agents, anticoagulants, diuretics, and other analgesics.

2) ACE inhibitor: NSAIDs may reduce the effect of anti-hypertensives. Therefore, the combination should be administered with caution

3) Aspirin: There is no evidence that concomitant use of NSAIDs with aspirin may decrease the risk of severe cardiovascular reactions. As with other NSAIDs, concomitant use of CLANZA S with aspirin may increase the risk of severe gastrointestinal adverse reactions, and thus concomitant use is not recommended.

4) Furosemide: CLANZA S causes inhibition of prostaglandin synthesis in the kidney, which decreases the natriuresis excretion effect of furosemide and thiazide diuretics. Signs of renal failure must be monitored during the combined treatment of these drugs with NSAIDs.

5) 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.

6) Methotrexate: Combination therapy of methotrexate with NSAIDs decreases excretion of methotrexate in the renal tubules, which leads to lethal hematological toxicity. Thus, high doses of methotrexate should not be coadministered; low doses of methotrexate should be administered with caution.

7) Warfarin: Warfarin and NSAIDs cause a synergistic effect of gastrointestinal bleeding. Combined treatment may increase the risk of severe gastrointestinal bleeding.

8) Other NSAIDs: Concomitant therapy with aspirin or other NSAIDs may increase the frequency of adverse reactions.

**4.6. Pregnancy and lactation**

*Pregnancy:*

1) There is no information on the use of aceclofenac during pregnancy. As with other NSAIDs, administration of aceclofenac during the last trimester of pregnancy

may cause closure of the ductus arteriosus of the fetus, and thus use in the last trimester of pregnancy is contraindicated.

2) Since there is no information on the safe use of aceclofenac during pregnancy. As with other prostaglandin synthesis inhibitors, administration of NSAIDs in rats has been shown to result in dystocia and delayed or prolonged labour, and embryo-fetal lethality.

*Lactation:*

1) There is no information on the safety of administration during lactation or if Aceclofenac is secreted through breast milk. However, many medicines are secreted through human milk, increasing the risk of severe adverse reactions in infants, and thus the use of CLANZA S should be avoided in lactation unless the potential benefits to the other outweigh the possible risks to the fetus.

### 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. Undesirable effects

The majority of adverse-effects observed have been reversible and of a minor nature and include gastro-intestinal disorders (dyspepsia, abdominal pain, nausea), rash, urticaria, symptoms of enuresis, headache, dizziness and drowsiness.

### 4.9. Overdose

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

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. Incompatibilities

Not applicable

### 6.2. Shelf life

36 months

### 6.3. Special precautions for storage

Store at temperatures not exceeding 30°C.

### 6.4. Nature and contents of container

10 Caps./ Blister x 5 Blisters/ Alu. Bag x 2 Alu. Bags/ Box.

### 6.5. Special precautions for disposal and other handling

Any unused product or waste material should be disposed of in accordance with local requirements.

## 7. Marketing Authorization Holder

Korea United Pharm. Inc.
25-23, Nojanggongdan-gil, Jeondong-myeon, Sejong-si, Korea

## 8. Marketing Authorization Numbers

590 (Korea Registration Number)

## 9. Date of First Authorization/Renewal of The Authorization

May 29, 2002

## 10. Date of Revision of The Text

April 07, 2017