# SUMMARY OF PRODUCT CHARACTERISTICS (SmPC) OF CETAHAB EXTRA

## 1. NAME OF THE MEDICINAL PRODUCT

CETAHAB EXTRA
(Paracetamol 325 mg + Diclofenac sodium 50 mg + Caffeine 30 mg Tablets)

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each uncoated tablet contains:
Paracetamol BP…….325 mg
Diclofenac sodium BP……..50 mg
Caffeine (Anhydrous) BP…..30 mg
Excipients……q.s.
Approved colour used

| Sr. No. | Ingredients | Specification | Label Qty/ Tablet (mg) |
|---|---|---|---|
| | **Dry Mixing** | -- | -- |
| 1. | Paracetamol | BP | 325 |
| 2. | Diclofenac Sodium | BP | 50 |
| 3. | Caffeine | BP | 30 |
| 4. | Sodium starch glycollate | BP | 16.38 |
| 5. | *Maize Starch | BP | 489 |
| | **Binder** | | |
| 6. | *Maize Starch | BP | 16.32 |
| 7. | Methyl Paraben | BP | 0.99 |
| 8. | Sodium Propyl Paraben | BP | 0.099 |
| 9. | Povidone | BP | 0.849 |
| 10. | Gelatin | BP | 1.23 |
| 11. | Colour Tartrazine Supra | IH | 0.43 |
| 12. | **Purified Water | -- | 42.6 |
| | **Lubrication** | | |
| 13. | Purified talc | BP | 14.77 |
| 14. | Magnesium stearate | BP | 4.98 |
| 15. | Sodium Starch glycollate | BP | 19.99 |
| | **Average Weight** | | **970.0 mg** |

*10% added extra to compensate loss on drying
**Does not appear in final product.

For a full list of excipients, see Section 6.1.

## 3. PHARMACEUTICAL FORM

Uncoated Tablet for Oral Use.
A yellow coloured uncoated caplet shaped standard concave tablet having embossing "CETAHAB" on one side & break line on other side

## 4. Clinical particulars

### 4.1 Therapeutic indications

For the relief of pains of minor and middle intensity such as headaches, neuralgia, myalgia, arthralgia, toothache, dysmenorrhoea.
As antipyretic, it is used for relief from signs and symptoms of rheumatoid arthritis and osteo-arthritis.

### 4.2 Posology and method of administration

**Adults :** 2-3 Tablets per day.
**Children over 12 years:** 1 to 2 Tablets daily or as directed by the Physician.

**Mode of Administration :** Oral

### 4.3. Contraindications:

**CETAHAB EXTRA** should not be used in patients who have previously exhibited hypersensitivity to Diclofenac Sodium, Paracetamol and Caffeine, or in individuals with the syndrome of nasal polyps, angio-oedema and bronchospastic reactivity to other non-steroidal anti-inflammatory agents

### 4.4. Warning & Special Precautions for administration:

**CETAHAB EXTRA** is to be advocated with caution in liver & kidney damage, elderly, patients requiring surgery, anemia, bronchial asthma, stomatitis, compromised cardiac function, heart failure, pre-existing edema, systemic lupus erythematosus.

**CETAHAB EXTRA** should not be preferably co-administered with other NSAIDs, corticosteroids, hypoglycemics, digoxin, lithium, methotrexate, cyclosporine, coagulants & anticoagulants, bone marrow suppressants as well as probenecid.
Abrupt stoppage of caffeine-containing products is not advisable since it could cause withdrawal symptoms such as headache, anxiety, or muscle tension within 12 to 18 hours.

### 4.5. Drug Interactions:

**Diclofenac Sodium**

The products that may interact with Diclofenac Sodium include: aliskiren, ACE Inhibitors (such as lisinopril), angiotensin II receptor blockers (such as valsartan, losartan), corticosteroids (such as prednisone), cidofovir, cyclosporine, lithium, methotrexate, pemetrexed. This medication may increase the risk of bleeding when taken with other drugs that also may cause bleeding. Examples include anti-platelet drugs such as clopidogrel, "blood thinners" such as dabigatran/enoxaparin/warfari.

Many medications contain pain relievers/fever reducers (aspirin, NSAIDs such as celecoxib, ibuprofen, or ketorolac). These drugs are similar to diclofenac and may increase your risk of side effects if taken together.

**Paracetamol :**
Absorption rate of paracetamol may increase when using metoclopramide and domperidone, and may decrease when using cholestyramine. Anticoagulant effect of warfarin and other coumarins may increase in concomitant regular daily use of paracetamol, with an increased risk of bleeding. When administered periodically, it has no significant effect.

Barbiturates reduce the antipyretic effect of paracetamol.
Anticonvulsants (including phenytoin, barbiturates, carbamazepine) which stimulate the activity of microsomal liver enzymes may increase the toxic effects of paracetamol on the liver due to increased metabolism of the drug into hepatotoxic metabolites. In concomitant use of paracetamol with hepatotoxic agents, their toxic effect on the liver increases.
Concomitant use of high doses of paracetamol and isoniazid, rifampicin increases the risk of hepatotoxic syndrome. Paracetamol reduces the efficacy of diuretics.
Do not use with alcohol.

**Caffeine:**
Aspirin, clozapine, theophylline
Plasma levels of these agents may be elevated by caffeine, increasing their pharmacologic effects and adverse reactions.
Cimetidine, disulfiram, fluoroquinolones, mexiletine, oral contraceptives
May increase caffeine levels, enhancing the effects.
Lithium
Plasma levels may be reduced by caffeine, decreasing the pharmacologic effect.
Phenytoin, smoking
May decrease caffeine levels.

## 4.6 Pregnancy and lactation
It is risk to use this drug during pregnancy & Breastfeeding.

## 4.7 Effects on ability to drive and use machines
There is no specific effect on driving or Operating machinery while using this medicine

## 4.8 Undesirable effects
Abdominal pain or cramps, constipation, diarrhea, flatulence, GI bleeding, GI perforation, peptic ulcer, vomiting, dyspepsia, nausea, dizziness, headache liver function test abnormalities, renal function abnormalities, anemia, prolonged bleeding time, pruritus, rash, tinnitus, edema, rash, allergic reaction.

## 4.9 Overdose
Symptoms of overdose may include: severe drowsiness, seizures, widened pupils. In children, mental/mood changes (such as restlessness, irritability, hallucinations) may occur before drowsiness.

# 5. PHARMACOLOGICAL PROPERTIES

## 5.1 Pharmacodynamic properties

Pharmacotherapeutic group: {group}, ATC code: {code}

**CETAHAB EXTRA** is a combined drug with a pronounced anti-inflammatory, analgesic and antipyretic effect. Pharmacological activity of the drug is due to the properties of Diclofenac, caffeine and paracetamol, which are the components of the drug. Diclofenac sodium has a pronounced anti-inflammatory and analgesic, and a moderate antipyretic effect. Paracetamol has a pronounced analgesic, slight antipyretic and anti-inflammatory effect. Caffeine has analeptic effect. The mechanism of action is associated with inhibition of prostaglandin synthesis

## 5.2 Pharmacokinetic properties

After the intake, the drug is rapidly and completely absorbed. Food has no effect on absorption of the drug. Plasma concentrations of active substances are linearly dependent on the dose; the maximum levels are reached in 60-90 minutes after ingestion.

Binding of diclofenac to plasma proteins (mainly albumin) reaches 99.7%. The expected volume of distribution is 0.12-0.17 L/kg. Diclofenac penetrates into synovial liquid, where its maximum concentration is reached 2-4 hours later than in blood plasma. The half-life for elimination from the synovial fluid is 3-6 hours.

Diclofenac is metabolized by glucuronidation of unchanged molecule and methoxylation, which forms several phenolic metabolites, the biological activity of which is considerably inferior to the activity of the parent substance.

General plasmatic clearance of diclofenac is approximately 300 mL/min. Terminal half-life is 1-2 hours. 60% of the administered dose is excreted in the urine as glucuronic conjugates of unchanged diclofenac; the rest is excreted in the bile and feces.

Paracetamol is metabolized in the liver and is mainly excreted in the urine..
Caffeine is 99% absorbed orally, Rapidly distributed throughout tissues; crosses the blood-brain barrier and placenta; excreted in breast milk. 17% to 36% protein bound, Rapidly metabolized in the liver to 1-methyluric acid, 1-methylxanthine, and 7-methylxanthine; CYP1A2 is involved in the biotransformation, The $t_{½}$ is 3 to 5 h. Approximately 1% is excreted in the urine as unchanged drug.
After repeated administration of the drug, pharmacokinetic parameters of active substances remain unchanged. No accumulation occurs provided the recommended dosage intervals are observed

### 5.3 Preclinical safety data

Not Applicable

## 6. PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

| Excipients | specification |
|---|---|
| Maize Starch | BP |
| Methyl Paraben | BP |
| Sodium Propyl Paraben | BP |
| Povidone | BP |
| Gelatin | BP |
| Colour Tartrazine Supra | IH |
| **Purified Water | BP |
| Purified talc | BP |
| Magnesium stearate | BP |
| Sodium Starch glycollate | BP |

### 6.2 Incompatibilities

Not applicable.

### 6.3 Shelf life : 36 Months (3 years)

### 6.4 Special precautions for storage

Store in a cool & dry place below $30^0$C.

Keep all medicines away from reach of children.

### 6.5 Nature and contents of container

One Alu- Pvc blister of 10 tablets packed in a carton along with insert. Such a 10 cartons packed in one outer carton.

### 6.6 Special precautions for disposal <and other handling>

No special requirements.

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

**7.** **<APPLICANT**
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