Product Name: CAPEX CAPSULE (Paracetamol, Diclofenac Sodium & Caffeine Capsules)
Module 1: Administrative Information & Prescribing Information.

SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)
TEMPLATE

1. NAME OF THE MEDICINAL PRODUCT

CAPEX CAPSULES (Paracetamol, Diclofenac Sodium & Caffeine capsules)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each Hard gelatin capsule contains
Paracetamol BP 500 mg
Diclofenac Sodium BP 50 mg
Caffeine (anhydrous) BP 30 mg

For a full list of excipients, see Section 6.1.

Sr. No.	Ingredients	Specification	Label claim/Tab (in mg)	Per dosage unit (mg)	Reason for Inclusion
1	Paracetamol	BP	325	325	Medicament
2	Ibuprofen	BP	400	400	Medicament
3	Microcrystalline Cellulose	BP		10	Diluent
4	Maize Starch*	BP		20	Diluent / lubricant
5	Colour Tartrazine Yellow	IH		1	Colouring
6	Povidone K-30	BP		4	Binder
7	Maize Starch	BP		5	Binder
8	Methyl Hydroxybenzoate	BP		1	Preservative
9	Propyl Hydroxybenzoate			0.2	Preservative
10	Gelatin	BP		5	Binder
11	Sodium Starch Glycolate	BP		5	Disintegrant
12	Colloidal Anhydrous Silica	BP		6	Lubricant
13	Magnesium Stearate	BP		6	Lubricant
14	Purified Talc	BP		3	Lubricant
15	Maize Starch	BP		3.55	Lubricant
16	Purified Water	BP		0.25 ml	Vehicle

BP = British Pharmacopeia
IH = In House.

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3. PHARMACEUTICAL form

Capsule

Description: Hard gelatin capsule of size "O" printed with CPAEX on green coloured caps & yellow coloured body containing white powder.

4. Clinical particulars

4.1 Therapeutic indications

Capex Capsule is indicated for the following:
Relieving headache, migraine headache, toothaches, muscle aches, premenstrual, migraine headache or other minor aches and pains.

4.2 Posology and method of administration

1 capsule three times daily or as directed by the physician.

Method of administration: Capsule

4.3 Contraindications

Contraindicated for use in patients known to be hypersensitive to any of its ingredients conta-indicated in respiratory depression especially in the presence of cyanosis and excessive bronchial secretion after operation on the biliary tract, acute alcoholism, head injuries and conditions in which intracranial pressure is raised. It should not be given an attack of bronchial asthma or in heart failure secondary to chronic lung disease.

4.4 Special warnings and precautions for use.

The safety of continous administration of CAPEX CAPSULES has not been established for a greater than four weeks. Exceeding the prescribed dose, together with prolonged and continous use of this medication may lead to dependency and addiction. Dosage in excess of those recommended may cause severe liver damage. Hence it is advisable to follow the Doctor's or physicians dosage regimen carefully.

4.5 Interaction with other medicinal products and other forms of interaction

Capex capsule should not be given in persons already on therapy with the following drugs:
Carbonic anhydrous inhibitors (e.g acetazolamide) because they may decrease effectiveness of CAPEX CAPSULES.
Anticoagulants, clopidogrel, corticosteroids, heparin, ketorolac, NSAIS's, Ibuprofen or serotonin reuptake inhibitors (e.g fluoxetine) because the risk of bleeding may be increased.
Insulin , isoniazid, oral hypoglycemic (e.g glyburide, repaglinide) or quinolone antibiotics (e.g ciprofloxacin) because the risk of their side effects may be increased by taking Capex capsules.
Methotrexate, theophylline or vaiproic acid because their actions and the risk of their side effects may be increased by taking.

4.6 Pregnancy and lactation

Capex capsule are not recommended for use by pregnant or breast feeding women. Regular use of NSAIDs during the third trimester of pregnancy may result in premature closure of the foteal ductus arteriosus in utero and possibly in persistent pulmonary hypertension of the newborn. The onset of labour may be delayed and its duration increased. Do not breast feed while taking Capex Capsules.

4.7 Effects on ability to drive and use machines

Not known.

4.8 Undesirable effects

Common adverse effects include Heartburn, nausea, upset stomach constipation, drowsiness. Some rare allergic reactions may include (rash, hives., itching, difficulty in breathing, tightness in the chest, swelling of the mouth, face, lips or tongue) fainting, symptoms of liver problems.

4.9 Overdose

Overdosage may cause nausea, vomiting, pain in the abdomen, dizziness, headache, sweating, pancreatitis, hepatic failure and acute renal failure.
In the event of overdosage consult a doctor or take the patient to the nearest hospital immediately. Specialised treatment is essential as soon as possible. Prompt treatment is essential. Any patient who has ingested an overdosage of capex capsule in the preceding 4 hours should undergo gastric lavage. Specific therapy with an antidote such as acetylcysteine or methionine may be necessary.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group:

Paracetamol:
ATC code: N02BE01
Other Analgesic & antipyretic

Ibuprofen:
ATC code: M01AE51
Antiinflammatory & Antirheumatic products

5.2 Pharmacokinetic properties

The pharmacokinetic of this combination of capex capsule is well matched and synergistic. All the drugs are well absorbed orally.

5.3 Preclinical safety data

Not Applicable.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients:

The excipients used in the formulation of Capex Capsules are mentioned as follows:

- Paracetamol
- Ibuprofen
- Microcrystalline cellulose
- Maize starch
- Colour Tartrazine yellow
- Povidone K-30
- Maize starch
- Methyl Hydroxybenzoate
- Propyl Hydroxybenzoate
- Gelatin
- Sodium starch glycolate
- Magnesium Stearate
- Purified Talc
- Maize Starch
- Purified Water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

36 Months from Date of Manufacturing.

6.4 Special precautions for storage

Do not store above 30^0 C. Protect from Light.

6.5 Nature and contents of container <and special equipment for use, administration or implantation>

A blister of 10 capsules are packed in carton along with pack insert.

6.6 Special precautions for disposal <and other handling>

Any unused medicinal products and waste materials should be disposed of in accordance with local requirements.

7. <APPLICANT/SUPPLIER>

Applicant:

Name	**:**	Habmay Pharmacy Ltd.
Address	**:**	P.O.Box No. AS81, Asawasi - Kumasi, Ghana.
Telephone Number	**:**	03220-38998.
E-mail	**:**	habmay1010@yahoo.com
Web	**:**	

Supplier:

Name	**:**	MERCURY HEALTHCARE PVT LTD
Address	**:**	12-B, Gr. Floor, Girichhaya, Loyalka Estate, Chowpatty Band Stand, Mumbai, 400 002.
Telephone Number	**:**	++91-22-66172224/5
E-mail	**:**	info@mercuryhealthcare,net
Web	**:**	www.mercuryhealthcare.net

8. FDA APPLICATION NUMBER

FDA/DRID/DER/FLR/17/0496

9. DATE OF <REGISTRATION> / <RENEWAL OF REGISTRATION>

Date of Registration **:** 04/06/2017.

10. DATE OF REVISION OF THE TEXT

02/07/2020.