For the use of a Registered Medical Practitioner only

Cardiovascular Risk

- NSAIDs may cause an increased risk of serious cardiovascular thrombotic events, myocardial infarction, and stroke, which can be fatal. This risk may increase with duration of use. Patients with cardiovascular disease or risk factors for cardiovascular disease may be at greater risk
- Mefenamic acid is contraindicated for the treatment of peri-operative pain in the setting of coronary artery bypass graft (CABG) surgery.

Gastrointestinal Risk

- NSAIDs cause an increased risk of serious gastrointestinal adverse events including bleeding, ulceration, and perforation of the stomach or intestines, which can be fatal. These events can occur at any time during use and without warning symptoms. Elderly patients are at greater risk for serious gastrointestinal events.

1. GENERIC NAME & BRAND NAME

Camylofin Dihydrochloride & Mefenamic Acid Tablets

ANAFORTAN®-MF

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film coated tablet contains:

Camylofin Dihydrochloride 50 mg

Mefenamic Acid I.P. 250 mg

Colour: Lake of Erythrosine & Lake of Brilliant Blue FCF & Titanium dioxide I.P.

3. DOSAGE FORM AND STRENGTH

Kindly refer section 1 and 2

4. CLINICAL PARTICULARS

4.1 THERAPEUTIC INDICATION

Moderate to severe dysmennorhoea and pain associated with menorrhagia.

4.2 POSOLOGY AND METHOD OF ADMINISTRATION

The recommended dosage is one tablet thrice daily

4.3 CONTRAINDICATIONS

It is contraindicated in patients with:

- Narrow-angle glaucoma
- Prostatic hypertrophy
- Mechanical stenoses.
- Hypersensitivity to any of ingredients
- Pregnancy and lactation

- Children below 12 years
- Urinary retention
- Mega colon
- GI hemorrhage
- Tachyarrythmia
- Porphyria.
- Bleeding peptic ulcers

4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE

Camylofin must be used with caution in patients with thyrotoxicosis, obstructive lung disease, during cardiac surgery or those with fever.
It should be used with caution in elderly, in patients with urinary retention, prostatic enlargement, tachycardia, cardiac insufficiency, paralytic ileus, ulcerative colitis and pyloric stenosis, pregnancy and in breast feeding, May aggravate gastroesophageal reflux.

Pregnancy/Teratogenicity
Inadequate data with Camylofin safety in pregnancy requires that ANAFORTAN is avoided during pregnancy

4.5 DRUG INTERACTIONS
The important drug interactions are listed below

Camylofin

- Antacids interfere with absorption of camylofin.
- Antihistaminics, tricyclic antidepressants, phenothiazines, disopyramide, pethidine have anticholinergic property-additive effects occur with camylofin

Mefenamic acid drug interactions

	Drug	Interaction	Remarks
1.	ACE-inhibitors	NSAIDs may reduce the antihypertensive effect of ACE inhibitors.	This interaction must be considered in patients taking

			NSAIDs concomitantly with ACE-inhibitors.
2.	Aspirin	When mefenamic acid is administered with aspirin, its protein binding is reduced, but the clearance of free mefenamic acid is not altered.	Concomitant administration of mefenamic acid and aspirin is not recommended due to the potential of increased adverse effects.
3.	Diuretics	Mefenamic acid can reduce the natriuretic effect-of furosemide and thiazides secondary to inhibition of renal prostaglandin synthesis.	During concomitant therapy of NSAIDs, the patient should be observed closely for signs of renal failure
4.	Lithium	NSAIDs cause an elevation of plasma lithium levels and a reduction in renal lithium clearance. The mean minimum lithium concentration increased by 15% and the renal clearance decreased by 20%. These effects may be due to inhibition of renal prostaglandin synthesis by the NSAID.	When NSAIDs and lithium are administered concurrently, patients should be monitored carefully for signs of lithium toxicity.
5.	Methotrexate	NSAIDs competitively inhibit methotrexate accumulation in rabbit kidney slices. They could enhance the toxicity of methotrexate.	Caution should be used when NSAIDs are administered concomitantly with methotrexate.
6.	Warfarin	The effects of warfarin and NSAIDs on GI bleeding are synergistic	There is an increased risk of serious GI bleeding higher
7.	Antacids	Intake of an antacid containing 1.7-gram of magnesium hydroxide with 500-mg of mefenamic acid increased the Cmax and AUC of mefenamic	

		acid by 125% and 36%, respectively.	

Mefenamic acid may prolong prothrombin time. Therefore, when the drug is administered to patients receiving oral anticoagulant drugs, frequent monitoring of prothrombin time is necessary.

4.6 USE IN SPECIAL POPULATIONS (SUCH AS PREGNANT WOMEN, LACTATING WOMEN, PAEDIATRIC PATIENTS, GERIATRIC PATIENTS ETC.)

Pregnancy

There is no data on the safety and efficacy of camylofin in pregnant women. Hence, it is not recommended for use in pregnancy.

In late pregnancy, as with other NSAIDs, mefenamic acid should be avoided because it may cause premature closure of the ductus arteriosus.

Lactation

There is no data on the safety and efficacy of camylofin in lactating women. Hence, it is not recommended for use in lactating mother.

Pediatric

There is no specific contraindication for use of camylofin in children, however, there is no data establishing the safety and efficacy of camylofin in children less than 12 years.
Safety and effectiveness of mefenamic acid in pediatric patients below the age of 14 have not been established.

Geriatric

It should be used with caution in elderly, in patients with urinary retention, prostatic enlargement, tachycardia, cardiac insufficiency, paralytic ileus, ulcerative colitis and pylonic stenosis, pregnancy and in breast feeding, May aggravate gastroesophageal reflux.

Clinical studies of mefenamic acid did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. As with any NSAIDs, caution should be exercised in treating the elderly (65 years and older). This drug is known to be substantially excreted by the kidney, and the risk of toxic reactions to this drug may be greater in patients with impaired renal function. Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection, and it may be useful to monitor renal function

4.7 EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

Not known

4.8 UNDESIRABLE EFFECTS

Adverse experiences reported occasionally are:

Body as a whole - fever, infection, sepsis

Nervous system – headache, anxiety, asthenia, confusion, depression, dream abnormalities, drowsiness; insomnia, malaise, nervousness, paresthesia, somnolence, tremors, vertigo

Cardiovascular system- congestive heart failure, hypertension, tachycardia, syncope

Digestive system - dry mouth, esophagitis, gastric/peptic ulcers, gastritis, gastrointestinal bleeding, glossitis, hematemesis, hepatitis, jaundice, abdominal pain, constipation, diarrhea, dyspepsia, flatulence, elevated liver enzymes

Hemic and lymphatic system - ecchymosis, eosinophilia, leukopenia, melena, purpura, rectal bleeding, stomatitis, thrombocytopenia, increased bleeding time

Metabolic and nutritional - weight changes

Respiratory system- asthma, dyspnea

Skin and appendages - alopecia, photosensitivity, pruritus, sweat,rash

Special senses - blurred vision, tinnitus

Urogenital system - interstitial nephritis, oliguria/polyuria, cystitis, dysuria, hematuria, proteinuria, renal failure

Other adverse reactions, which occur rarely are:

Body as a whole - anaphylactoid reactions, appetite changes, death

Digestive system – pancreatitis, eructation, liver failure

Hemic and lymphatic system - aplastic anemia, lymph- adenopathy, pancytopenia, agranulocytosis, hemolytic anemia,

Cardiovascular system - hypotension, myocardial infarction, palpitations, vasculitis, arrhythmia

Metabolic and nutritional - hyperglycemia

Nervous system - hallucinations, meningitis, convulsions, coma,

Respiratory- respiratory depression, pneumonia

Skin and appendages - urticaria ,angioedema, toxic epidermal necrosis, erythema multiforme, exfoliative dermatitis, Stevens-Johnson syndrome

Special senses - conjunctivitis, hearing impairment

4.9 OVERDOSE

In case of overdosage, discontinue medication, treat symptomatically, and institute supportive measures as required

Following symptoms have been documented with overdose

Dry mouth, difficulty in swallowing and talking, flushed and hot skin (especially over face and neck), fever, difficulty in micturition, decreased bowel sounds, dilated pupil, photophobia, blurring of near vision, palpitation, a scarlet rash may appear occurring within a period of 8 hours or less.

5. PHARMACOLOGICAL PROPERTIES

5.1 MECHANISM OF ACTION

Camylofin is a spasmolytic agent with a potent dual mode of action, i.e. it possesses both musculotropic and neurotropic effects.
Camylofin has a direct papaverine like spasmolytic action on smooth muscles, where it inhibits the enzyme phosphodiesterase IV, which in turn causes an increase in intracellular concentration of cyclic AMP and smooth muscle relaxation by depletion of intracellular calcium levels. This is the more predominant action of camylofin.
Camylofin also possesses a neurotropic action i.e. a mild atropine like anti-cholinergic effect, where by it causes smooth muscle relaxation, by inhibiting the binding of acetylcholine with the muscarinic receptors.
Mefenamic acid is a non-steroidal anti-inflammatory drug (NSAID) that exhibits anti-inflammatory, analgesic, and antipyretic activities in animal models. The mechanism of action of mefenamic acid , like that of other NSAIDs, is not completely understood but may be related to prostaglandin synthetase inhibition.

5.2 PHARMACODYNAMIC PROPERTIES

Camylofin is a smooth muscle relaxant with both anticholinergic action as well as direct smooth muscle action. Anticholinergic action is produced by inhibiting the binding of acetylcholine to muscarinic receptors, but the action is less pronounced. Direct smooth muscle relaxation is achieved by inhibiting phosphodiesterase type IV, which leads to increased cyclic AMP and eventually reduced cytosolic calcium. Thus, Camylofin has a comprehensive action to relieve smooth muscle spasm.

Antacids interfere with absorption of camylofin. Antihistaminics, tricyclic antidepressants, phenothiazines, disopyramide, pethidine have anticholinergic property-additive effects occur with camylofin. It is metabolized in liver and rest is excreted unchanged in urine

Mefenamic acid is a non-steroidal anti-inflammatory drug (NSAID) that exhibits anti-inflammatory, analgesic, and antipyretic activities in animal models. The mechanism of action of mefenamic acid , like that of other NSAIDs, is not completely understood but may be related to prostaglandin synthetase inhibition.

5.3 PHARMACOKINETIC PROPERTIES

Parameters	**Mefenamic acid**
Absorption	Mefenamic acid is rapidly absorbed after oral administration. Peak plasma levels are attained in 2 to 4 hours and the elimination half-life approximates 2 hours.
Distribution	About 90% of Mefenamic acid is bound to albumin. The apparent volume of distribution is 1.06 L/kg.[2] It is expected to be excreted in human breast milk.
Metabolism	Mefenamic acid is metabolized by cytochrome P450 enzyme CYP2C9 to 3-hydroxymethyl mefenamic acid (Metabolite I). Further oxidation to a 3-carboxymefenamic acid (Metabolite II) may occur. The activity of these metabolites has not been studied. The metabolites may undergo glucuronidation and mefenamic acid is also glucuronidated directly
Excretion	Fifty-two percent of a mefenamic acid dose is excreted into the urine primarily as glucuronides of mefenamic acid (6%), 3-hydroxymefenamic acid (25%) and 3- carboxymefenamic acid (21%). The faecal route of elimination accounts for up to 20% of the dose, mainly in the form of unconjugated 3-carboxymefenamic acid

Half life	The elimination half-life of mefenamic acid is approximately two hours.

6. NONCLINICAL PROPERTIES

6.1 ANIMAL TOXICOLOGY OR PHARMACOLOGY

The dual mode of action of camylofin has been demonstrated in animal experiments, where in camylofin abolished the spasm inducing effects of both carbachol (cholinergic spasms) and barium chloride (muscular spasms.)

Reproductive studies with mefenamic acid conducted in rats and rabbits have not demonstrated evidence of developmental abnormalities.

7. DESCRIPTION

ANAFORTAN-MF is supplied for oral administration, as a film-coated tablet. Each film coated tablet of ANAFORTAN-MF contains Camylofin Dihydrochloride 50 mg and Mefenamic Acid 250 mg.

8. PHARMACEUTICAL PARTICULARS

8.1 INCOMPATIBILITIES

Not applicable

8.2 SHELF-LIFE

Refer pack

8.3 PACKAGING INFORMATION

Refer pack

8.4 STORAGE CONDITION AND HANDLING INSTRUCTIONS

Refer pack

9. PATIENT COUNSELLING INFORMATION

- Advise patients to inform the doctor if they are allergic to camylofin or mefenamic acid or any other ingredient in this formulation.

- Patients should be advised that they must avoid taking this medicine if they have narrow-angle glaucoma (optic nerve damage due to sudden high eye pressure), prostatic hypertrophy (enlargement of prostate gland causing difficulty with urination) or urinary retention or constipation, heart problems.
- Patients should be advised that they must inform their doctor if they have tachycardia, ulcerative colitis and gastroesophageal reflux disease.
- Patients must be advised to take Anafortan MF in the dose prescribed by the doctor
- Anafortan MF has mefenamic acid which is an NSAID. **Advise patients to avoid taking NSAIDs:**

- if they have had an asthma attack, hives, or other allergic reaction with aspirin or any other NSAIDs.
- right before or after heart bypass surgery.

Before taking NSAIDs, patients must tell their healthcare provider about all of their medical conditions, including if they :

- have liver or kidney problems
- have high blood pressure
- have asthma
- peptic ulcer disease

Patients must be informed that NSAID medicines can cause ulcers and bleeding in the stomach and intestines at any time during treatment.

Ulcers and bleeding:

•can happen without warning symptoms

•may cause death

The chance of a person getting an ulcer or bleeding increases with:

- taking medicines called "corticosteroids" and "anticoagulants"
- longer use

- smoking
- drinking alcohol
- older age
- having poor health

Patients must be advised to talk to the doctor if they are considering taking NSAIDs during pregnancy.

Patients must be advised **not take NSAIDs**

- after 29 weeks of pregnancy.
- If they are breastfeeding or plan to breast feed.

Patients must be advised to tell their healthcare provider about all of the medicines they take, including prescription or over-the-counter medicines, vitamins, or herbal supplements. NSAIDs and some other medicines can interact with each other and cause serious side effects. They must not start taking any new medicine without talking to the doctor first.

10. DETAILS OF MANUFACTURER
Refer Pack for manufacturer details

MARKETED BY
Abbott Healthcare Private Limited
Angel Space, Bldg. D-4, Gala No. 1 to 3 & 11 to 13 Ground Floor,
101 to 106 & 111 to 116 First Floor, 201 to 206 & 211 to 216
2nd Floor, Pimplas, Dist. Thane, Bhiwandi - 421 302,
Maharashtra, India.

11. DETAILS OF PERMISSION OR LICENCE NUMBER
Refer Pack for Permission/Licence details

12. DATE OF REVISION
Version 5.0 dated 4-May-26

For Product Complaints/Adverse events or Queries please write to
webmasterindia@abbott.com