For the use of a Registered Medical Practitioner only

1. Generic Name and Brand Name

Camylofin Dihydrochloride Drops

ANAFORTAN® DROPS

2. Qualitative and Quantitative Composition

Each ml contains:
Camylofin Dihydrochloride 20 mg
Flavoured syrup base q.s
Colour: Carmoisine

3. Dosage Form and Strength

Kindly refer section 1 and 2

4. Clinical Particulars

4.1 Therapeutic Indication

Treatment of abdominal colic of various origin and other conditions associated with smooth muscle spasm.

4.2 Posology and Method of Administration

The recommended dosage in babies is 0.9 mg/kg body weight of Camylofin up to thrice daily.

Up to 6 months age	0.25 mL	Maximum three times in a day
6 months to 12 months age	0.50 mL	Maximum three times in a day

4.3 Contraindications

It is contraindicated in patients with:

- Narrow-angle glaucoma
- Prostatic hypertrophy
- Mechanical stenoses.
- Hypersensitivity to any of ingredients
- Pregnancy and lactation
- Urinary retention
- Mega colon
- GI hemorrhage
- Tachyarrhythmia
- Porphyria.

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. , May aggravate gastroesophageal reflux.

4.5 Drug Interactions

Camylofin

- Antacids interfere with absorption of camylofin.
- Anti-histaminic, tricyclic antidepressants, phenothiazines, disopyramide, pethidine have anticholinergic property-additive effects occur with camylofin.
- Use with caution in patients being treated with Amantadine, Quinidine & Tricyclic anti-depressants.

4.6 Use in Special Populations.

It is contraindicated in pregnant and lactating women.

Pregnancy

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

Lactation

There is no data on the safety and efficacy of Camylofin (injection) 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.

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.

4.7 Effects on Ability to Drive and Use Machines

Not known

4.8 Undesirable Effects

Skin rashes, other allergic reactions and infrequently atropine-like side effects

4.9 Overdose

In case of overdosage, discontinue medication, treat symptomatically, and institute supportive measures as required. There is evidence, although limited, to suggest management of a case of overdose of camylofin in neonates with naloxone i.v (0.02mg / Kg body weight), leading to a prompt improvement in clinical picture.

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.

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.

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.
For Paediatric Use

5.3 Pharmacokinetic Properties
Not available

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).

7. Description
Anafortan Drops is supplied for oral administration, as drops of Camylofin Dihydrochloride. Each ml of Anafortan Drops contains Camylofin Dihydrochloride 20 mg.

8. Pharmaceutical Particulars
8.1 Incompatibilities
Not applicable

8.2 Shelf-Life
Refer pack

8.3 Packaging Information
Refer pack

8.4 Storage and Handling Instructions
Refer pack

9. Patient Counselling Information
Patients must be advised to take Anafortan in the dose prescribed by the doctor. Advise patient's guardian to:

- Follow the instructions on the label of the medicine or as directed by the doctor
- Avoid exceeding the maximum dose recommended
- Contact the doctor or seek urgent help if overdose occurs

10. Details of Manufacturer
Refer pack for manufacturer details.

Marketed By:
Abbott Healthcare Pvt. Ltd.
Angel Space, Bldg. D-4, Gala No. 1 to 6 &
11 to 16 Ground Floor, 101 to 106 &
111 to 116 First Floor, 201 to 206 & 211 to 216
2nd Floor, Pimplas, Dist. Thane, Bhiwandi - 421 302, India.

11. Details of Permission or Licence Number
Refer pack for Permission/License details.

12. Date of Revision
Version 4.0, dated 15/05/2024

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