For the use of a Registered Medical Practitioner only

1.0 GENERIC NAME AND BRAND NAME

Micronized Purified Flavonoid Fraction of Rutaceae 1000 mg Tablets
DEZOFLAV™

2.0 QUALITATIVE AND QUANTITATIVE COMPOSITION:

Each film coated tablet contains:
Micronized Purified Flavonoid Fraction of Rutaceae composed of:

Diosmin	900 mg
Flavonoids Expressed as Hesperidin	100 mg
Excipients	q.s.

Colours: Titanium Dioxide I.P., Ferric Oxide (Yellow) USP-NF, Ferric Oxide (Red) USP-NF & Lake of Sunset yellow FCF.

3.0 DOSAGE FORM AND STRENGTH

Refer section 1 & 2

4.0 CLINICA PARTICULARS

4.1 THERAPEUTIC INDICATIONS

Acute hemorrhoid (piles)

4.2 POSOLOGY AND METHOD OF ADMINISTRATION

For the treatment of acute haemorrhoidal attacks; MPFF 1000 mg 3 tablets daily for 4 days followed by 2 tablets daily for 3 days. For the treatment of haemorrhoids; the maintenance dose is 1 tablet daily for a duration according to the physician's discretion.

4.3 CONTRAINDICATIONS

Hypersenstivity to the micronized purified flavonoid fraction or to any of the excipients.

4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE

Hemorrhoidal attack:
The administration of this product does not preclude treatment for other anal conditions.
The treatment must be short-term. If symtoms do not subside prompity; a proctological examination should be performed and the treatment should be reviewed.

4.5 DRUG INTERACTIONS

No interaction studies have been performed. However taking into consideration the huge post marketing experience on the product, no drug interaction has been reported to date.

4.6 USE IN SPECIAL POPULATION

Pregnancy
Experimental studies performed in animals have not revealed any teratogenic effect. Moreover, no harmful effects have been reported to date in humans.

Breast-Feeding
In the absence of data concerning excretion into breast milk, breastfeeding is not recommended during treatment.

Fertility
Reproductive toxicity studies showed no effect on fertility in male and female rats (see section pre-clinical safety data)

4.7 EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

No studies on the effects of MPFF on the ability to drive and use machines have been performed. However, on the basis of the overall safety profile of flavonoid fraction, MPFF has no or negligible influence on these abilities.

4.8 UNDESIRABLE EFFECTS

Summary of the safety profile
Side effects reported with MPFF in clinical trials are of mild intensity. They consist mainly in gasto-intestinal events (diarrhea, dyspepsia, nausea, vomiting).

Tabulated List of adverse reactions
The following adverse effects or events have been reported and are ranked, using the following frequency:
Very common (≥1/10): common (≥1/100, <1/10): uncommon (≥1/1000, <1/100): rare ((≥1/10000, <1/1000); very rare (<1/10000): not known (can not be estimated from the available data).

System Organ Class	Frequency	Preferred Term
Nervous system disorders	Rare	Dizziness
		Headache
		Malaise
Gastrointestinal Disorders	Common	Diarrhoea
		Dyspepsia
		Nausea
		Vomiting
	Uncommon	Colitis
	Not Known*	Abdominal Pain
Skin and subcutaneous tissue disorders	Rare	Pruritus
		Rash
		Urticaria
	Not Known*	Isolated face, lip, eyelid oedema. Exceptionally Quincke's oedema

*Post marketing experience

4.9 OVERDOSE

No case of overdose with MPFF has been reported.

5.0 PHARMACOLOGICAL PROPERTIES

5.1 Mechanism of action

MPFF has a variety of significant anti-inflammatory, antioxidant, and venoprotective actions, which form the basis of its beneficial clinical effects. In a number of experimental models, it reduced venous inflammation by inhibiting leukocyte rolling, adhesion, and migration, and inhibited the synthesis of inflammatory mediators. It improves venous tone and lymphatic drainage by modulating noradrenergic signalling and reducing norepinephrine metabolism. MPFF significantly reduces capillary hyperpermeability and improves the capillary resistance in patients with abnormal capillary fragility leading to further improvement of microcirculation.

5.2 Pharmacodynamic Properties

MPFF is a phlebotonic drug and a vascular protecting agent. The efficacy of MPFF is accounted for by its specific action on the principal elements of venous disease.

MPFF is phlebotonic: MPFF decreases venous capacitance, venous distensibility and venous emptying time. MPFF protects the microcirculafion by fighting the microcirculation-damaging process; it combats venous inflammation by decreasing leukocyte activation, and as a consequence, by inhibiting the release of inflammatory mediators, principally free radicals and prostaglandins. Thus, MPFF normalizes capillary permeability and strengthens capillary resistance.

MPFF acts on the lymphatic system: It improves lymphatic drainage by increasing lymph flow and decreasing lymph oncotic pressure. This action on the lymphatic system, associated with a phlebotonic and vasculoprotective effect, explains the activity of MPI on Chronic Venous insufficiency associated edema.

Clinical Pharmacology: MPFF is highly effective in the treatment of chronic hemorrhoidai disease. It significantly improves subjective symptoms and objective signs, eg,anal discomfort, pain, redness, anal discharge, proctitis, tenesmus, pruritus, erythema and bleeding. MPFF also significantly reduces the frequency, severity and duration of acute hemorrhoidal attacks.

Dose/effect relationship: Statistically-significant dose-effect relationship have been demonstrated for the following venous plethysmography parameters: capacitance, disintesibility and emptying time. The best dose/effect ratio is obtained with 1 tablet.

Venotonic Activity: It increases venous tone: venous occlusion plethysmography with a mercury strain gauge, revealed a reduction in venous emptying time.

Microcirculatory Activity: Controlled, double-blind studies have demonstrated a statistically-significant difference between MPFF and placebo. In patients with signs of capillary fragility, it increases capillary resistance as measured by angiosterrometry.

5.3 Pharmacokinetic properties

Absorption: Not detectable in plasma. Present in the aglycone form diosmetin reaches a peak plasma level of 400 ng/ml 1 hour after an oral dose of 10 mg/kg .
Distribution: Volume of distribution = 60 liters, indicating an affinity for tissue
Half-life: The plasma elimination half-life of diosmetin is 26--43 hours.
Metabolism: Quickly metabolized in the lumen of the esophagus or at the hepatic level.
Elimination: Renal route: eliminated as conjugated metabolites. After intravenous administration, elimination is in the urine. Fecal route: after oral administration, elimination is in the urine and feces.

6.0 NON-CLINICAL PROPERTIES

6.1 ANIMAL TOXICOLOGY OR PHARMACOLOGY

Repeated oral administration in rats and monkeys of doses 35 times the therapeutic dose used in humans in the chronic indication showed no toxic or lethal effects and led to no behavioural changes and no biological, anatomical or histological abnormalities. Studies carried out in rats and rabbits showed no embryo-toxic or teratogenic effects. There was no impairment of fertility. In vitro and in-Vivo testing demonstrated the absence of mutagenic potential.

7.0 DESCRIPTION

DEZOFLAV is supplied for oral administration, as a film coatd tablet of Micronized Purified Flavonoid Fraction of Rutaceae. Each film coated tablet of DEZOFLAV contains Micronized Purified Flavonoid Fraction of Rutaceae composed of : Diosmin 900 mg & Flavonoids Expressed as Hesperidin 100 mg.

8.0 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

9.0 PATIENT COUNSELING

a. Appropriate treatment:

Each film coated tablet contains: Micronized Purified Flavonoid Fraction of Rutaceae (Diosmin 900 mg) & Flavonoids (Hesperidin 100 mg) and is indicated for treatment of acute haemorrhoidal attacks.

Haemorrhoidal disease leads to symptoms such as bleeding, prolapse and thrombosis. There are two types of haemorrhoids: external and internal. Thrombosis usually occurs in external haemorrhoids. Internal haemorrhoids, usually painless, can bleed and prolapse but rarely thrombose. The posology should be adjusted according to the individual needs of the patient.

Experimental studies have not revealed any teratogenic effect & no harmful effects have been reported to date in humans but due to absence of data, breastfeeding is not recommended during treatment.

Advise the patient to reach out to the doctor if these symptoms do not improve after a while, if you develop new symptoms or you are concerned about your symptoms.

b. Interactions

No drug interaction has been reported to date.

c. Warning and precautions

Advise the patient that the administration of this product does not preclude treatment for other anal conditions and the treatment must be short-term. Advise the patient to visit a doctor for proctological examination if symtoms do not subside promptly.

10.0 DETAILS OF MANUFACTURER
Refer Pack for manufacturer details.

MARKETED BY:
Abbott India Limited
Angel Space, Lifestyle Bldg. No. D-4,
Gala No. 4 to 10 & 14 to 20 Ground Floor,
107 to 110 & 117 to 120 1st Floor, 207 to 210
& 217 to 220 2nd Floor, Pimplas, Dist. Thane,
Bhiwandi - 421 302, Maharashtra, India.

11.0 DETAILS OF REVISION OR LICENSE NUMBER
Refer Pack for Permission/License details.

12.0 DATE OF REVSION
Version 4.0 dated 13-Jul-26

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

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References:

- Daflon Prescribing Information. http://www.meppo.com/pdf/drugs/469-DAFLON-1439985296.pdf
- Daflon 500. Official monograph. Summary of product characteristics. Available from: https://www.servier.com.ve/sites/default/files/spc-pil/spc-daflon500.pdf