SUMMARY OF PRODUCT CHARACTERISTICS

FOR

FENAMEX DT

(MEFENAMIC ACID DISPERSIBLE TABLETS)

1. NAME OF THE MEDICINAL PRODUCT

Fenamex DT

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dispersible tablet contains:

Mefenamic Acid BP 100 mg

Excipients q.s.

For a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Light yellow circular uncoated dispersible tablets having BG embossed on one side & breakline on other side of each tablet having pleasant mango flavour.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Fenamex DT is used in cases of pyrexia in children; as an anti-inflammatory analgesic for the symptomatic relief of juvenile rheumatoid arthritis (including Still's Disease); pain including muscular, traumatic and dental pain; headaches of most etiology; post-operative pain.

4.2 Posology and method of administration

For oral administration

Children under 12 years of age: Recommended usual dose of Fenamex DT is 25 mg / kg of bodyweight daily, in divided doses. Table below gives dosage recommendations for various age groups:

Age of the Child	Recommended dose
6 months to under 2 years	½ tablet
2 years to under 5 years	One tablet
5 years to under 9 years	1 ½ tablet
9 years to 12 years	Two tablets

4.3 Contraindications

Fenamex DT is contraindicated in patients with hypersensitivity to Mefenamic acid or any of the other ingredients of the products, inflammatory bowel disease, gastrointestinal bleeding or perforation, active or history of recurrent peptic ulcer, severe heart failure, hepatic failure and renal failure and in treatment of pain after coronary artery bypass graft (CABG) surgery.

4.4 Special warnings and precautions for use

Using lowest effective dose for the shortest duration may control symptoms. Patients on prolonged therapy should be kept under regular surveillance.

Appropriate monitoring and caution should be taken while administering to patients suffering from dehydration and renal disease, respiratory disorders, cardiovascular or hepatic impairment, intracranial haemorrhage, bleeding diathesis, gastrointestinal bleeding, ulceration, perforation, SLE, mixed connective tissue disease, skin reactions, epilepsy, elderly patients

Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption, known or suspected poor CYP2C9 metabolisers based on previous history/experience with other CYP2C9 substrates, should not take Mefenamic acid medicine.

4.5 Interaction with other medicinal products and other forms of interaction

Concurrent therapy with other plasma protein binding drugs may necessitate a modification in dosage.

Mefenamic acid should be cautiously administered with anti-coagulants such as warfarin, lithium, two or more NSAIDs (including aspirin), antidepressents, antihypertensives, diuretics, anti-platelet agents, ciclosporin, corticosteroids, probenecid, quinolone antibiotics, tacrolimus, zidovudine since it may lead to increased side effects or toxicity levels

Administration of Mefenamic acid with aminoglycosides, cardiac glycosides, oral hypoglycaemic agents, methotrexate may lead to increased plasma concentrations of the latter. Use of Mefenamic acid with mifepristone may lead to decreased effects of the latter drugs.

4.6 Pregnancy and lactation

Not applicable

4.7 Effects on ability to drive and use machines

Undesirable effects such as dizziness, drowsiness, fatigue and visual disturbances are possible after taking NSAIDs. If affected, patients should not drive or operate machinery.

4.8 Undesirable effects

The most frequently reported side effects are gastrointestinal disturbances such as diarrhoea, peptic ulcers, perforation or GI bleeding, nausea, vomiting, flatulence, constipation, dyspepsia, abdominal pain, less frequently, gastritis has been observed.

Frequencies are not known for the following adverse reactions:

Blood and the lymphatic system disorders such as anemia, thrombocytopenic purpura, leukopenia, agranulocytosis, immune system disorders like asthma, bronchospasm, dyspnoea, skin disorders including rashes of various types, pruritus, urticaria, angioedema, Metabolism and nutritional disorders such as glucose intolerance in diabetic patients, hyponatraemia, pyschiatric disorders inclusive of confusion, depression, hallucinations, nervousness, nervous system disorders including optic neuritis, headaches, paraesthesia, dizziness, drowsiness, reports of aseptic meningitis, blurred vision, convulsions, insomnia, eye disorders, ear and labyrinth disorders, palpitations, hypotension, asthma, dyspnoea, mild hepatotoxicity, hepatitis, hepatorenal syndrome, oedema, erythema multiforme, perspiration, rash, photosensitivity reaction, dysuria, haematuria, nephrotic syndrome, non-oliguric renal failure, fatigue, malaise, multi-organ failure, pyrexia.

4.9 Overdose

Symptoms: Possible symptoms include headache, nausea, vomiting epigastric pain, rarely diarrhoea, disorientation, excitation, drowsiness, tinnitus and fainting

Therapeutic measure: Patients should be treated symptomatically within one hour of ingestion of a potentially toxic amount activated charcoal. Alternatively, in adults gastric lavage should be considered within one hour of ingestion of a potentially life-threatening overdose. Good urine output, renal and liver function should be closely monitored. Patients should be observed for at least four hours after ingestion of potentially toxic amounts

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Mefenamic acid is non-steroidal anti-inflammatory drug (NSAID) with anti-inflammatory, analgesic and antipyretic properties.

Its anti-inflammatory effect was first established in the UV erythema model of inflammation. Further studies included inhibition of granulation tissue growth into subcutaneous cotton pellets in rats and carrageenin induced rat paw oedema tests. Antipyretic activity was demonstrated in yeast-induced pyresis in rats. In this model its antipyretic activity was roughly equal to that of phenylbutazone and flufenamic acid, but less than that of indomethacin. Analgesic activity was demonstrated in tests involving pain sensitivity of rats paws inflamed by brewers yeast. Mefenamic acid was less potent than flufenamic acid in this model.

Prostaglandins are implicated in a number of disease processes including inflammation, modulation of the pain response, dysmenorrhoea, menorrhagia and pyrexia.

In common with most NSAIDs Mefenamic acid inhibits the action of prostaglandin synthetase (cyclo oxygenase). This results in a reduction in the rate of prostaglandin synthesis and reduced prostaglandin levels, which contributes to the pharmacological activity and clinical efficacy of Mefenamic acid.

5.2 Pharmacokinetic properties

The linear calibration curve of Mefenamic acid in serum was obtained over the range of 0.13 to 8.28 mg·L-1(r=0.999 3). The average recovery was (97.30±4.54)%. The inter-day and intra-day validation did not exceed 15%. The main pharmacokinetic parameters of Mefenamic acid dispersible tables were: tmax, ρmax, t1/2(Ke), AUC(0 ～ 14h) were (1.04±0.50) h, (5.94±2.51) mg·L-1, (2.12±0.69) h, (18.19±4.05) mag·h·L-1, respectively.

5.3 Preclinical safety data

Preclinical safety data does not add anything of further significance to the prescriber.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Microcystalline Cellulose, Crospovidone, Colloidal Anhydrous Silica, Saccharine Sodium, Colour tartarazine supra, Maize Starch, Purified Talc, Magnesium Stearate, Croscarmellose, Mango flavour, Polysorbate 80.

6.2 Incompatibilities

None Known

6.3 Shelf life

36 months from the date of manufacture.

6.4 Special precautions for storage

Store in a dry place, below 30°C. Protect from light.

6.5 Nature and contents of container

The product is available in Aluminum /PVC foil unit dose blisters. Each mono carton contains 10 blisters of 10 Tablets along with insert.

6.6 Special precautions for disposal and other handling

Not applicable

7. MARKETING AUTHORISATION HOLDER

BLISS GVS PHARMA LIMITED,
102, Hyde Park, Saki-Vihar road,
Andheri (East) Mumbai 400 072,
INDIA

8. NUMBER(S) IN THE NATIONAL REGISTER OF FINISHED PHARMACEUTICAL PRODUCTS

Not Applicable

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Not Applicable

10. DATE OF REVISION OF THE TEXT

Not Applicable