MAY AND BAKER NIGERIA PLC

SUMMARY OF PRODUCTS CHARACTERISTICS

BROMATAN 3MG

1. NAME OF THE MEDICINAL PRODUCT

Bromatan 3 mg

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

Bromazepam 3 mg

3. PHARMACEUTICAL FORM

Tablet

4. Clinical particulars

4.1 Therapeutic indications

Emotional disturbance: anxiety and tension states, as adjuvant therapy for anxiety in depressed patients, nervous tension, restlessness, and anxiety and tension-related insomnia. As an adjuvant to treatment of an underlying disease responsible for functional or psychosomatic impairments of various organs caused or exacerbated by anxiety and tension:

Cardiovascular and respiratory systems: (e.g. pseudoangina pectoris, precordial anxiety, tachycardia, emotiogenic hypertension, dyspnea and hyperventilation); Gastrointestinal tract: (e.g. irritable bowel syndrome), ulcerative colitis, epigastric pain, spasm, meteorism and diarrhea); Urogenital tract: (e.g. irritable bladder, urinary frequency, dysmenorrhea); other psychomatic disturbances: (e.g. psychogenic headache, psychogenic dermatoses).

Bromatan is also suitable for treatment of anxiety and tension states due to chronic organic disease and as adjuvant to psychotherapy and to psychoneuroses.

4.2 Posology and method of administration

Posology and administration

One tablet (3mg) can be taken up to three times daily. In severe cases, especially in hospitalized patients, the dosage may be increased. These amounts are general recommendations, and dosage should be individually

determined. Treatment of outpatients should begin with low doses, gradually increased to the optimum level. After several weeks, but not later than three months, according to progress in therapy, an attempt should be made to withdraw treatment. Should it be necessary to continue therapy beyond this point, withdraw should be gradual.

4.3 Contraindications

BROMATAN must not be administered to patients with known hypersensitivity to benzodiazepines. Patients with known or presumed dependence on alcohol, medicines or drugs should not take BROMATAN, except in rare situations under medical supervision. In patients with myasthenia gravis who are prescribed BROMATAN, care should be taken on account of pre-existing muscle weakness. The established principle of not prescribing drugs of any kind in early pregnancy should be borne in mind. As the active ingredient of BROMATAN can pass into the breast milk, nursing mothers must not take BROMATAN. In the first four to six hours after taking high doses, patients should avoid driving a car or operating dangerous machinery because BROMATAN may, depending on the dosage and individual sensitivity, modify the patients' reactions.

4.4 Special warnings and precautions for use

Chronic pulmonary insufficiency, chronic renal or hepatic disease. In the elderly, judgement and dexterity may be impaired; patients should be warned of these effects. Do not use alone to treat depression or anxiety associated with depression. In case of bereavement, psychological adjustment may be impaired. Avoid long term use; withdraw gradually.

4.5 Interaction with other medicinal products and other forms of interaction

As with all psychoactive substances, the effect of BROMATAN may be intensified by alcohol. If BROMATAN is combined with other centrally active drugs such as neuroleptics, tranquilizers, antidepressants, hypnotics, analgesics and anaesthetics, its central sedative effect may be enhanced.

4.6 Pregnancy and Lactation

Pregnancy: The established principle of not prescribing drugs of any kind in early pregnancy should be borne in mind. Benzodiazepines should not be used during pregnancy, especially during the first and last trimesters as it may cause foetal damage when administered to pregnant women

If the drug is prescribed to a woman of childbearing potential, she should be warned to contact her physician about stopping the drug if she intends to become, or suspects that she is, pregnant.

Lactation: As the active ingredient of BROMATAN can pass into the breast milk, nursing mothers must not take BROMATAN

4.7 Effects on ability to drive and use machines

In the first four to six hours after taking high doses, patients should avoid driving a car or operating dangerous machinery because BROMATAN may, depending on the dosage and individual sensitivity, modify the patients' reactions.

4.8 Preclinical safety data

If use of the drugs in indicated in children, the dosage should be adjusted to their lower body weight. Elderly and debilitated patients and patients with disturbances of hepatic and /or renal function require lower doses because of individual variations in sensitivity and pharmacokinetics.

Most frequently reported adverse reactions associated with benzodiazepines include daytime drowsiness, dizziness, muscle weakness, and ataxia.

4.9 OVER DOSAGE:

Over dosage of benzodiazepines is usually manifested by degrees of central nervous system depression ranging from drowsiness to coma. In mild cases, symptoms include drowsiness, mental confusion and lethargy. In more serious cases, symptoms may include ataxia, hypotonia, hypotension, respiratory depression, coma and very rarely death. Coma may be more protracted and cyclical, particularly in elderly patients. Benzodiazepine respiratory depressants, effects are more serious in patients with respiratory disease.

Benzodiazepines increase the effects of other central nervous system depressants, including alcohol. When combined with other CNS depressants, the effects of over dosage are likely to be severe and may prove fatal.

5.0 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamics properties

Pharmacotherapeutic group: Anxiolytic, ATC code: N05BA08

5.2 Pharmacokinetic properties

Bromazepam is almost completely absorbed from the gastrointestinal tract and peak serum levels are reached in 2 hours. It is metabolised by a simple one-step process to a pharmacologically inert glucuronide. There are no major active metabolites. The elimination half-life is about 12 hours and there is minimal risk of excessive accumulation.

5.3 Preclinical safety data

Conventional studies using the currently accepted standards for the evaluation of toxicity to reproduction and development are not available.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Maize Starch BP (Internal)

Microcrystalline Cellulose 101 (Avicel)

Lactose Monohydrate

Erythrosine 85%

Purified water BP

Maize Starch BP (Paste)

Sodium Starch Glycolate (Type A)

Magnesium Stearate BP

Purified Talc BP

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years

6.4 Special precautions for storage

Protect from light. Store in a cool dry place.

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

Bromatan 3 mg are packed in a pack of 30's.

6.6 Special precautions for disposal <and other handling>

To be destroyed by NAFDAC enforcement unit.

7. Applicant/Manufacturer

May & Baker Nigeria, PLC
1, May & Baker Avenue,
Off Idiroko Road,
(Opposite Covenant University),
Ota, Ogun State, Nigeria