1. NAME OF THE MEDICINAL PRODUCT

M & B Albendazole 200mg & 400mg Tablet

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Albendazole 200 mg.
Albendazole 400mg

Excipients:
For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Tablet.
200mg: Light pink coloured capsule shaped tablet with "MBN" engraved on one side and plain on the other side.
400mg: An orange colored capsule shaped tablet embossed "MBN" on one side and plain on the other side.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Intestinal and skin infections

- Threadworms (*Enterobius vermicularis*),
- Roundworms (*Ascaris lumbricoïdes*),
- Hookworms (*Ankylostoma duodenale*, *Necator americanus*),
- Whipworms (*Trichuris trichuria*),
- Anguillulosis (*Strongyloides stercoralis*),
- Taeniasis (*Taenia saginata*, *Taenia solium*),
- Giardiasis (*Gardia intestinalis* or *duodenalis*) in children,

Systemic infections

- Trichinosis (*Trichinella spiralis*).

4.2 Posology and method of administration

Posology

Indications	Daily dose	Treatment duration
Intestinal and skin infections (short-term treatment with lower dose)		
Oxyurosis	Children from 1 to 2 years: 5 ml suspension (200 mg) in one single dose Adults and children older than 2 years*: 400 mg, 1 single tablet or 10 ml of suspension in single dose Strict hygiene measures should be taken and family environment should also be treated.	Single dose to be repeated 7 days after.

Roundworms Hookworms Whipworms	Children from 1 to 2 years: 5 ml of suspension (200 mg) Adults and children older than 2 years*: 400 mg, 1 single tablet or 10 ml of suspension in single dose.	Single dose. **
Anguillulosis Taeniasis (associated with others parasitosis)	Adults and children older than 2 years *: 400 mg, 1 tablet or 10 ml of suspension daily	1 daily dose during 3 days. **
Giardiasis	Children older than 2 years*: 1 tablet or 10 ml of suspension daily.	1 daily dose during 5 days.
Systemic infections (long-term treatment with higher doses)		
Trichinosis	Children*: 15 mg/kg/day divided into two daily doses Adults: 1 tablet or 10 ml of suspension twice daily	2 daily doses (morning & evening) during 10 to 15 days depending on the severity of the symptoms and on the onset of treatment.

* For children under 6 years, tablet form of 400 mg is inappropriate due to wrong route risk, and only suspension form should be used.
**If the worm control performed 3 weeks after the treatment is positive, a second treatment should be administered.

Special populations
Elderly people:
Data concerning patients from 65 years old are limited. Reports suggest that no adaptation of the posology is required in elderly people. However, Albendazole should be used with care in patients with a liver dysfunction.

Liver failure:
Albendazole is rapidly metabolized by the liver, the main metabolite, albendazole sulfoxide, is pharmacologically active. Hence, liver failure might result in significant effect on the pharmacokinetics of albendazole sulfoxide.
Patients with abnormal liver function tests (transaminases) prior to treatment with albendazole should be closely monitored. The treatment should be stopped in case of significant increase in liver enzymes or in case of clinically significant decrease in blood formula numeration (see section 4.4).

Renal failure:

As the elimination of albendazole and its main metabolite, albendazole sulfoxide are negligible, it is unlikely that the clearance of these compounds are modified in patients with renal failure. No dose adaptation of posology is required, however, patients with renal failure should be closely monitored.

Method of administration
Oral route.
Neither purge, nor fast prior treatment is necessary

4.3 Contraindications

- Hypersensitivity to albendazole or to any of the components
- Pregnancy and women of childbearing age who do not use an efficient contraceptive method (see section 4.6)
- Breastfeeding

4.4 Special warnings and precautions for use

Neurologic symptoms

A treatment with albendazole might reveal a pre-existing neurocysticercosis, in particular in regions of strong infestation with taeniasis. Patients might feel neurological symptoms such as convulsions, increase in intracranial pressure and focal signs resulting from the inflammatory reactions following the death of the parasite in the brain. Symptoms might appear shortly after the treatment; an adapted treatment with corticoids and anticonvulsants should be immediately started.

Precaution for use when using albendazole for systemic infections (long-term treatment with higher doses):

- **Liver disorders**

Albendazole might result in a slight to moderate increase in liver transaminases, normalising generally when stopping the treatment. Serious cases of hepatitis have also been reported when treating systemic helminth infections (long-term treatment with higher doses) (see section 4.8). Tests of the liver function should be carried out prior to starting the treatment and at least every second week during the treatment. Albendazole shall be stopped in case of increase in hepatic enzymes (more than twice normal). If reintroducing the treatment is indispensable, this should be done after normalisation of liver enzymes. Moreover, a close monitoring should be carried out, keeping in mind that potential relapses might appear because an allergic mechanism cannot be discarded.

- **Medullar depression**

Cases of medullar depression have been reported during treatment of systemic helminth infections (long-term treatment with higher doses) (see section 4.8). Numerations of blood formula should be performed when starting the treatment and then after two weeks of treatment with albendazole.
Patients with a liver disease, including liver echinococcosis, seem more likely to develop a medullar depression, leading to pancytopenia, medullar aplasia, agranulocytosis and leucopoenia. Then, an increase monitoring of the blood formula is recommended in patients showing a liver disease.
Albendazole shall be stopped in case of significant decrease in the number of blood cells (see section 4.2 and 4.8).
In the treatment of trichinosis, few data are available with albendazole in children under 6 years of age.
In the treatment of trichinosis, because of the activity, in particular on the intestinal forms and of the larvae in the early phase of the tissue migration, it is recommended to administer albendazole as early as possible at the start of the infestation in order to decrease the symptoms and the complications. This treatment remains inactive on the encysted larvae in chronic forms and when it is initiated belatedly.

- Contraception

Before initiating the treatment with albendazole, the doctor should inform the patient of the embryotoxic, teratogenic and aneugenic risks of albendazole, of the necessity of an efficient contraception and of the

potential consequences on pregnancy if it occurs during the course of the treatment with albendazole (see section 4.6).

Verzol tablet contains lactose and should not be used by patients with rare hereditary problems of galactose intolerance, lactase deficiency or glucose-galactose malabsorption
Verzol suspension contains sucrose and sorbitol. Patients with rare hereditary problems of fructose intolerance, glucose/galactose malabsorption and sucrase-isomaltase insufficiency should not take this medicine.
The tablets and suspension contain an azo colouring agent (E110) that may cause allergic reactions.

4.5 Interaction with other medicinal products and other forms of interaction

Enzymes inducers anticonvulsivants, ritonavir and rifampicine may have the potential to reduce plasma concentrations of albendazole and of its active metabolite, albendazole sulfoxide with a risk of decrease in its efficacity. Clinical monitoring of the therapeutic efficacy and the potential adaptation of the posology of albendazole during the course of the treatment with an enzymatic inducer and after stopping.

4.6 Fertility, pregnancy and lactation

Female patients
Given the aneugenic, embryotoxic and teratogenic potential of albendazol, all the precautions should be taken in order to avoid pregnancy in these female patients. Treatment with albendazole should not be initiated before a negative result to a pregnancy test performed risht before the treatment initiation. Women of childbearing age should use an efficient contraceptive method during the treatment and 6 months after stopping the treatment.

Male patients and their female partners
All precaution should be taken in order to avoid pregnancy in the partners of male patients treated with albendazole. It is not known if the presence of albendazole in sperm can cause teratogenic or genotoxic effects on human embryo/foetus. Men or their female partners of childbearing age must be informed of the obligation to use an efficient contraceptive method during all the course of the treatment with albendazole and during 3 months after stopping the treatment. Men whose partners are pregnant should be informed of the obligation to use a condom in order to reduce the exposition of their partner to albendazole.
Pregnancy
Studies in animal showed teratogenic embryotoxic effects in rat and rabbit at doses close to those used in men (see section 5.3). In clinical trials, the data on the use of albendazole during the first term of pregnancy are limited. Albendazole is contraindicated during pregnancy (see section 4.3 and 4.4), espacially because there are therapeutical alternatives that are better assessed in terms of safety in pregnant woman. Female patients should be informed of the necessity to consult their doctor immediately in case of pregnancy. This is based on prenatal monitoring targeted on malformations described in animal (skeletic, cranofacial, limbs).

Fertility
In rat or mouse, studies have showed testicular toxicity of albendazole (see section 5.3). Albendazole has an aneugic activity, which is a risk factor for alteration of fertility in man.

Breasfeeding
Albendazole is present in human breast milk after a single dose of 400 mg. Because of its aneugenic activity, a risk for the new born child cannot be excluded. In case of a single dose, breastfeeding should be stopped at the time of intake and for at least 5.5 half-lives (about 48 hours) after stopping the treatment. Before initiatiing breastfeeding, pump all the available breast milk and dispose of it; in case of repeated intakes, breastfeeding is contraindicated.

4.7 Effects on ability to drive and use machines

When driving or using machines, it should be kept in mind that dizziness have been reported after usingalbendazole (see section 4.8).

4.8 Undesirable effects

The frequency of side effects very common to rare have been determined based on the data from the clinical trials. The frequencies of the other side effects are mainly based on the post-marketing data and are referred to the reported observations rather than the real frequencies.
The side effects listed below are classified by organ system and frequency, according to the following convention:
Very common ≥ 1/10
Common ≥ 1/100 to < 1/10
Uncommon ≥ 1/1,000 to < 1/100
Rare ≥ 1/10,000 to < 1/1,000
Very rare < 1/10,000
Unknown frequency (cannot be estimated based on the available data).

Intestinal and skin infections (short-term treatment with low doses)

Systemic class organs	**Uncommon**	**Unknown frequency**
Immune system disorders		Hypersensitivity reaction, including skin rash, itching and hives
Nervous system disorders	Headaches Dizziness (see section 4.7)	
Gastro-intestinal disorders	Gastro-intestinal symptoms (epigastric or abdominal pains, nausea, vomiting) and diarrhoea	
Hepatobiliary disorders		Increase in liver enzymes (see section 4.4)
Skin and subcutaneous tissue disorders		Polymorphic erythema Stevens-Johnson syndrome

Systemic infections (long-term treatment with higher doses)

Systemic class organs	**Very common**	**Common**	**Uncommon**	**Unknown frequency**
Haematological and lymph system disorders				*Medullar aplasia* *Leucopoenia* *Pancytopenia* *Agranulocytosis (see section 4.4)*
Immune system disorders			*Hypersensitivity reactions including skin rash, itching, hives*	
Nervous system disorders	*Headaches*	*Dizziness (see section 4.7)*		
Gastro-intestinal disorders		*Gastro-intestinal disorders (abdominal pains, nausea and vomiting)*		
Hepatobiliary disorders	*Slight to moderate increase in liver enzymes (see section 4.4)*		*Hepatitis (see section 4.4)*	

Skin and subcutaneous tissue disorders		*Reversible alopecia (decrease in thickness of the hair, moderate hair loss)*		*Polymorphic erythema, Stevens-Johnson syndrome*
General disorders and administration site conditions		*Fever*		

Risk of allergic reactions due to the presence of yellow sunset colouring agent.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the national reporting system.

4.9 Overdose

In case of overdose, symptomatic treatment and medical monitoring are recommended.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Antiparasitics - antihelmintics, ATC code: P02CA03.

Albendazole is a benzimidazole carbamate. Albendazole is broad-spectrum antihelmintics, which is effective against a wide range of intestinal helminths.
Albendazole acts on helminths'cytoskeleton by the inhibition of tubulin polymerisation and thus, their introduction in the microtubules, blocking glucose absorption of parasites and resulting in their death.
Albendazole is also active on *Giardia intestinalis* (or *duodenalis*). It has an irreversible action that is targeted on the ventral disc of the trophozoites by acting on the polymerisation of tubulin and giardine, leading to a disorganisation of the cytoskeleton and micro strips. The ability of adhesion to the enterocytes is decreased, resulting in an inhibition of the growth and multiplication of the parasite.

5.2 Pharmacokinetic properties

Absorption and biotransformation
Following the administration, the low proportion of albendazole is absorbed (< 5 %) is metabolised into albendazole sulfoxide and sulfone. The plasma concentration in sulfoxide, the main active circulating metabolite reaches its maximum about two and a half hours after its administration.
The systemic pharmacological effect of albendazole is increased if the dose is administered concomitantly with a fat-rich meal, improving absorption by about 5.
Elimination
The plasma half-life of albendazole sulfoxide is 8 and a half hours.
Albendazole sulfoxide and its metabolites seem to be mainly eliminated by biliary route and for a lower proportion by urinary route.

Specific population
Renal failure: albendazole pharmacokinetics has not been studied in patients with renal failure.
Haptic failure: albendazole pharmacokinetics has not been studied in patients with hepatic failure.

5.3 Preclinical safety data

Degeneration of the seminiferous tubules has been reported in cancerogenesis studies at dose of 100 mg/kg/day in mouse and 20 mg/kg/day in rat. A decrease in the testicle weight has been observed in dog treated with 60 mg/kg/day during 6 months. These doses correspond respectively to 2.4; 0.24 and 2.5 times the maximum therapeutic dose (based on the human equivalence). Albendazole has not altered fertility in males or female rat up to the maximum dose of 30 mg/kg/day, or 0.36 times the maximum therapeutic dose (based on the human equivalence).
Albendazole appeared to be teratogenic and embryotoxic in rat and rabbit.
No cancerogenic potential has been was shown during the cancerogenesis studies in rats (20 mg/kg/day) and in mice (400 mg/kg/day). Albendazole did show any genotoxic effects in *in vitro* trials carried out on bacteria and mammal cells cultures, as well as in an *in vivo* micronucleus trial in rodents. A positive result has been reported in another micronucleus study in omuse, and is regarded as resulting from an aneugenic effect of albendazole.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

200mg Tablets:
Lactose Monohydrate, Microcrystalline cellulose, Maize Starch, PVP K30, Croscarmellose Sodium, Sodium Lauryl Sulphate, Allura Red, Orange flavor, Sucralose, Magnesium Stearate.

400mg Tablets:
Lactose Monohydrate, Microcrystalline cellulose, Maize Starch, PVP K30, Croscarmellose Sodium, Sodium Lauryl Sulphate, Sunset Yellow, Orange flavor, Sucralose, Magnesium Stearate.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years.

6.4 Special precautions for storage

Keep out of sight and reach of children.
Protect from heat, light and moisture, store at a temperature not exceeding 30 °C.

6.5 Nature and contents of container

400mg Tablet
Box of 1 tablet in blister pack (PVC-aluminium).
200mg Tablet
Box of 2 tablet in blister pack (PVC-aluminium).

6.6 Special precautions for disposal and other handling

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER
May & Baker Nigeria Plc

8. CATEGORY OF DISTRIBUTION

☒ Over-the counter medicine ☐ Prescription only medicines

9. MANUFACTURER

May & Baker Nigeria Plc
1 May & Baker Avenue off Idiroko road
Ota
Ogun State

10. DATE OF REVISION OF THE TEXT

03/2024