

## **1. NAME OF THE MEDICINAL PRODUCT**

**CLOBICO** (Combined Clostridium Butyricum & Bifidobacterium powder, Live)

## **2. QUALITATIVE AND QUANTITATIVE COMPOSITION**

Each sachet contains 500mg of Clostridium Butyricum & Bifidobacterium powder, live.

{For a full list of excipients, see section 6.1}

## **3. PHARMACEUTICAL FORM**

Solid – White or Grayish white powder.

## **4. Clinical particulars**

### **4.1 Therapeutic indications**

**CLOBICO** (Combined Clostridium Butyricum & Bifidobacterium powder, Live) is indicated for:

- Indicated for intestinal flora imbalance and related acute and chronic diarrhea and dyspepsia.
- Antibiotic associated diarrhea.

### **4.2 Posology and method of administration**

#### **Posology**

Oral administration, 3 sachets a time, twice a day. For acute diarrhea, continuously use for 3-7 days: for chronic diarrhea, continuously use for 14- 21 days.

**Children:** 1 sachet a time, twice a day. It can be taken with cold boiled water, juice or milk.

#### **Method of administration**

Oral route of administration

### **4.3 Contraindications**

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

### **4.4 Special warnings and precautions for use**

Do not take clobico with hot water.

### **4.5 Interaction with other medicinal products and other forms of interaction**

Not to be taken with antibiotics at the same time. Some medications that may interact with certain probiotics include: antibiotics, antifungals (such as clotrimazole, ketoconazole, griseofulvin, nystatin).

### **4.6 Pregnancy and Lactation**

It can be taken by pregnant women and lactating mothers.

### **4.7 Effects on ability to drive and use machines**

Clobico has no or negligible influence on the ability to drive.

### **4.8 Undesirable effects**

The Phase I –III of clinical trial have showed that a few patients slightly developed skin rash and stomach upset. An increase in stomach gas or bloating may occur. If this effect persists or worsens, notify your doctor or pharmacist promptly.

Tell your doctor right away if any of these unlikely but serious side effects occur: signs of infection (such as high fever, chills, persistent cough).

A very serious allergic reaction to this product is rare. However, seek immediate medical attention if you notice any of the following symptoms of a serious allergic reaction: rash, itching/swelling (especially of the face/tongue/throat), severe dizziness, trouble breathing.

## **4.9 Overdose**

This product is probiotics. No overdose is reported.

## **5. PHARMACOLOGICAL PROPERTIES**

### **5.1 Pharmacodynamic properties**

The pharmacodynamics test in mice showed that this product can stop diarrhea caused by ampicillin. *Clostridium butyricum* can inhibit the growth of intestinal pathogenic bacteria such as *El Tor vibrio Cholerae* 01 group, *vibrio Cholerae* *Escherichia coli* 0157, etc. This product Can also inhibit the growth of *shigella* dysentery and *Salmonella porcine cholera*.

Acute toxicity experiment on small mice: This product is filled into stomach of small mice at 40g/kg and mice had no death for seven days. The dosage is 1666.6 times as much as the daily dosage of adult. Long -term toxicity test on rats: 80 wistar rats are divided to control groups, 0.75g/kg group, 1.5 g/kg group, 3.0g/kg group (25times and 50 times and 100 times the dosage of adult respectively) these drugs are filled into stomach of mice for 1.5 month and observe the influence of drug on animal's different indicators. The result shows that the drug had no remarkable influence on ten bio-chemical indicators such as weight, ingestion, hemogram, heart and liver, and renal function etc. and electrocardiogram of rats. The pathological intoxication changes are not found in general and microscopic check of different organs.

### **5.2 Pharmacokinetic properties**

*Clostridium butyricum* can be colonized temporarily in the intestinal tract and kept for about ten days before being eliminated from the body. *Bifidobacterium infantis* is a resident beneficial bacterium, which can be colonized and grown in the intestinal tract after oral administration.

### **5.3 Preclinical safety data**

Clobico contains live bacteria which is *bifidobacterium*, antibiotics may prevent these products from working well. Take any product containing live bacteria at least 2 to 3 hours before or after taking antibiotics.

## **6. PHARMACEUTICAL PARTICULARS**

### **6.1 List of excipients**

Corn Starch

Anhydrous glucose

### **6.2 Incompatibilities**

Not applicable

### **6.3 Shelf life**

24 months.

### **6.4 Special precautions for storage**

Store at 2-8 °C and protect from light.

*Keep the medicine out of the reach of children.*

### **6.5 Nature and contents of container**

Medicinal composite membrane - 500mg/ sachet. 10 sachet / box

### **6.6 Special precautions for disposal**

No special requirements.

## **7. APPLICANT/MANUFACTURER**

Devon Pharmaceuticals Co. LTD.

15 Oke-Afa Road, Ilupeju, Magboro,

Ogun state, Nigeria.

### **Manufactured by:**

Shandong Kexing Bioproducts Co. Ltd.

No. 2666 Chuangye Road, Mingshui Development Zone, Zhangqiu,

Shandong, China.