

# SMPC FOR TIXYCOF TODDLER COUGH SYRUP



National Agency for Food & Drug Administration & Control  
(NAFDAC)

Registration & Regulatory Affairs (R & R) Directorate

SUMMARY OF PRODUCT CHARACTERIZATION (SMPC) FOR  
TIXYCOF TODDLER COUGH SYRUP

# SMPC FOR TIXYCOF TODDLER COUGH SYRUP

## 1. Name of product

TIXYCOF TODDLER COUGH SYRUP

## 2. Qualitative and quantitative composition

Each 5ml contain Glycerol 0.75ML

## 3. Pharmaceutical form

Liquid.

## 4. Clinical particulars

### 4.1 Therapeutic indications

Tixycof Toddler Cough Syrup is use the relief of the symptoms of sore throats.

### 4.2 Posology and method of administration

1. Oral: 5-10ml, four hourly as required.

This product is suitable for use by adults, children and the elderly.

### 4.3 Contraindications

Contraindicated in patients with known hypersensitivity to glycerol.

Contraindicated in diabetics.

### 4.4 Special warnings and precautions for use

Glycerol should be administered with caution to patients with hypervolaemia, cardiac failure, renal disease or dehydration.

Labels to state: Use with caution if you suffer from heart or kidney disease.

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

None known.

### 4.6 Pregnancy and lactation

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No adverse effects are considered likely if this product is used in the above conditions. However, all medicines, should be avoided if possible during pregnancy and lactation, and should only be used under a doctor's instruction.

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

None.

### 4.8 Undesirable effects

Glycerol when taken orally may cause headache, nausea and vomiting, and less frequently, diarrhoea, thirst, dizziness and mental confusion. Cardiac arrhythmias have been reported.

Glycerol may cause severe dehydration in previously dehydrated patients.

### **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 Yellow Card Scheme at: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard).

### 4.9 Overdose

Glycerol acts as a mild laxative. Large oral doses taken inadvertently may cause headache, thirst, nausea, hyperglycaemia and dehydration. Medication should be stopped and if ingestion is recent gastric lavage should be administered, followed by supportive therapy.

## 5. Pharmacological properties

### 5.1 Pharmacodynamic properties

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Glycerol acts as a demulcent and is mildly laxative when taken by mouth.

### 5.2 Pharmacokinetic properties

Glycerol is readily absorbed from the intestine and is metabolised to carbon dioxide and glycogen or is used in the synthesis of body fats.

### 5.3 Preclinical safety data

None

## 6. Pharmaceutical particulars

### 6.1 List of excipients

None.

### 6.2 Shelf life

months

### 6.3 Special precautions for storage

Store below 30°C. Protect from light. Store in the original package.

### 6.4 Nature and contents of container

60ml Amber pet Bottles capped with white rop cap.

### 6.5 Special precautions for disposal and

other handling  
No special requirements

### 6.6 Marketing

authorisation holder

JEHYSON HEALTHCARE  
LIMITED

Jehyson Crescent, km 78

# SMPC FOR TIXYCOF TODDLER COUGH SYRUP

Lagos Abeokuta Express

way Apomu, Ewekoro

LGA, Ogun State