STADA

Product Title:

**Tixylix Infant Cough Syrup** 

Pack Size: 100ml Mat.No:93040182112\_100ML\_PIL

Dimensions: 148x 210mm (27 x 148 folded)

Keyline Ref:

Barcode:

Pharmacode:

Datamatrix: 3040182112

SAP Code:

Reason for Change:

Change of manufacturer from BCM to T&R

1. Colour: Black

2. Colour: Keyline (Non-Printing)

3. Colour: **Technical Info (Non-Printing)** 

4. Colour: Cirrus\_Info\_Box

5. Colour:

6. Colour:

7. Colour:

8. Colour:

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10.Colour:

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12.Colour:

1. Fonts Used: Futura Std

Point Size Used: Min:7.4pt 2. Fonts Used:

Point Size Used: Min: Max: 3. Fonts Used:

Point Size Used: Min: Max. 4. Fonts Used:

Point Size Used: Min: Max: 5. Fonts Used:

Point Size Used: Min Max. Proof Number: 3 Date: 30.09.2022

Operator: EBR Artwork Number: 1323150 CRN: M0C-2021-1195

Local Authority submission required: Yes Manufacturer Art No: N/A

Approved by:

APPROVED By Katie Irving at 4:14 pm, Oct 17, 2022 Recto

**★** <del>=</del> :

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Infant Cough Syrup



## PACKAGE LEAFLET: INFORMATION FOR THE USER

Read all of this leaflet carefully because it contains important information for you.

his medicine is available without a prescription. However, you still need to give Tixylix Infant Cough Syrup carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.

- Ask your pharmacist if you need more information or advice.
- You must contact a doctor if your child's symptoms worsen or do not improve after 3 days. If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your

## In this leaflet:

- What Tixylix Infant Cough Syrup is and what it is used for
- Before you give Tixylix Infant Cough Syrup
   How to give Tixylix Infant Cough Syrup
- 4 Possible side effects
- . How to store Tixylix Infant Cough Syrup

# 1. WHAT TIXYLIX INFANT COUGH SYRUP IS AND WHAT IT IS USED FOR

Tixylix Infant Cough Syrup is a soothing cough suppressant which relieves the symptoms of dry, tickly coughs. Each 5 ml dose of Tixylix Infant Cough Syrup contains 0.75 ml glycerol as the active ingredient. This medicine is intended for use in children aged 3 months to 5 years.

## 2. BEFORE YOU GIVE TIXYLIX INFANT COUGH SYRUP

**Do not give Tixylix Infant Cough Syrup**• If your child is allergic (hypersensitive) to any of the ingredients of Tixylix Infant Cough Syrup (see Section 6).

# Take special care with Tixylix Infant Cough Syrup

under 3 months

# Taking other medicines

Please tell your doctor or pharmacist if your child is taking, or has recently taken, any other medicines, including medicines obtained without a prescription.

There are no known interactions between Tixylix Infant Cough Syrup and other medicines.

# Taking Tixylix Infant Cough Syrup with food and drink

# Pregnancy and breast-feeding Ask your doctor or pharmacist for advice before taking any medicine. This medicine is intended for use in children. No information is available on the effect of glycerol taken during

pregnancy or use during breast-feeding. Caution is therefore advised if taking Tixylix Infant Cough Syrup

## **Driving and using machines**

his medicine is intended for use in children. Tixylix Infant Cough Syrup does not affect your ability to drive or

## Important information about some of the ingredients of Tixylix Infant Cough Syrup.

Tixylix Infant Cough Syrup contains:

Maliitol, may have a mild laxative effect. Calorific value 2.3Kcal/g maliitol.

f you have been told by your doctor that your child is intolerant to some sugars, contact your doctor before taking this medicinal product.

- This medicine contains 34mg propylene glycol (E1520) in each 5ml dose.
- Sodium benzoate (E211), 10mg per 5ml dose.

   Less than 1mmol sodium (23mg) per 5ml dose, that is to say essentially "sodium-free"

## 3. HOW TO GIVE TIXYLIX INFANT COUGH SYRUP

Always give Tixylix Infant Cough Syrup exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

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Using the measuring spoon provided, the following doses may be given 3 to 4 times daily, by mouth, as required Allow 3 to 4 hours between doses.

Age	Dose
Under 3 months	Do not give Tixylix Infant Cough Syrup
3 to 12 months	One 5 ml spoonful
1 to 5 years	Two 5 ml spoonfuls

After use, wipe the neck of the bottle clean and make sure the safety cap is properly closed.
You can help by keeping your child warm and giving plenty of fluids. Make sure the bedroom is well ventilated but not cold. If your child's condition does not get better in 3 days, talk to your doctor.

## If you give more Tixylix Infant Cough Syrup than you should

Giving your child too much Tixylix Infant Cough Syrup may cause diarrhoea. If you have accidentally given your child more medicine than you should, or if you suspect that your child has taken extra medicine, please contact our doctor. Take along the bottle and the label, and any medicine that is left.

## If you forget to give Tixylix Infant Cough Syrup

Do not give your child a double dose to make up for a forgotten dose. f you have any further questions on the use of this product, ask your doctor or pharmacist.

## 4. POSSIBLE SIDE EFFECTS

Like all medicines, Tixylix Infant Cough Syrup can cause side effects, although not everybody gets them. ixylix Infant Cough Syrup may cause diarrhoea in overdose.

## Reporting of side effects

If your child gets any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: ww.mhra.gov.uk./yellowcard. By reporting side effects you can help provide more information on the safety of

#### 5. HOW TO STORE TIXYLIX INFANT COUGH SYRUP

Keep out of the reach and sight of children.

Do not store above 25°C. Keep the container tightly closed.

Do not use Tixylix Infant Cough Syrup after the expiry date which is stated on the carton and the bottle label

The expiry date refers to the last day of that month.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of edicines no longer required. These measures will help to protect the environme

### 6. FURTHER INFORMATION

## What Tixylix Infant Cough Syrup contains

The active substance is glycerol (0.75 ml per 5ml dose).

- The other ingredients are liquid maltitol (Lycasin), hydroxyethylcellulose, sodium benzoate (E211), citric acid monohydrate, sodium citrate, vanilla flavour (contains propylene glycol E1520), blackcurrant flavour (contains propyléne glycol E1520), purified water.

## What Tixylix Infant Cough Syrup looks like and contents of the pack

Tixylix Infant Cough Syrup is a colour-fre The following pack sizes are available:

Amber-coloured glass bottle with tamper evident cap, containing 100ml.

Measurina spoon provided.

#### Marketing Authorisation Holder and Manufacturer

Thornton & Ross Ltd., Huddersfield, HD7 5QH, UK. For any information about this medicinal product, please contact the Marketing Authorisation Holder. This leaflet was last revised in October 2022

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