

MEDITHYME COUGH SYRUP

Thyme liquid extract

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you.
- Keep this leaflet. You may need to read it again.
 - Ask your pharmacist if you need more information or advice.
 - If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
 - You must talk to a doctor if you do not feel better or if you feel worse after 1 week.

What is in this leaflet

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1. WHAT MEDITHYME COUGH SYRUP IS AND WHAT IT IS USED FOR.

Medithyme Cough Syrup is a traditional herbal medicinal product used as an aid to facilitate coughing up phlegm (expectorant) in productive cough associated with cold.

It is a traditional herbal medicinal product for use in the specified indication exclusively based upon long-standing use. You must talk to a doctor if you do not feel better or if you feel worse after 7 days.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE MEDITHYME COUGH SYRUP.

Do not take Medithyme Cough Syrup

- If you are allergic to the thyme or any of the other ingredients of this traditional herbal medicine (listed in section 6).
- If you are allergic to plants belonging to the mint family (Lamiaceae family).

Warnings and precautions

Talk to your doctor or pharmacist before taking Medithyme Cough Syrup.

- In children younger than 12 years old.
- If you cannot take medicines containing alcohol and maltitol. Please also read the section "Medithyme Cough Syrup contains alcohol, and maltitol, benzoate salt and sodium".
- If you are using other medicines. Please also read the section "Other medicines and Medithyme Cough Syrup".

See your doctor or pharmacist if:

- shortness of breath (dyspnoea), fever or phlegm containing pus (purulent sputum) occurs while taking this traditional herbal medicine.
- symptoms worsen during the use of this traditional herbal medicine.

Children

The use in children under 12 years of age is not recommended.

Other medicines and Medithyme Cough Syrup

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

You should be careful if you are treated with disulfiram or metronidazole because of the presence of alcohol in Medithyme Cough Syrup. The concomitant use of multiple medicines that contain ethanol should be avoided.

Medithyme Cough Syrup with food and drink

There are no interactions known.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you might be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Medithyme Cough Syrup contains alcohol. Please also read the section "Medithyme Cough Syrup contains alcohol, and maltitol, benzoate salt and sodium" if you are pregnant or breast-feeding.

Pregnancy:

The use of Medithyme Cough Syrup during pregnancy is not recommended.

Breast-feeding:

The use of Medithyme Cough Syrup during breast-feeding is not recommended.

Fertility:

No fertility data available.

Driving and using machines

There are no studies known on the effect on the ability to drive and use machines.

Keep in mind however that Medithyme Cough Syrup contains alcohol. Please also read the section "Medithyme Cough Syrup contains alcohol, and maltitol, benzoate salt and sodium".

Medithyme Cough Syrup contains alcohol, maltitol, benzoate salt and sodium

This medicine contains 260 mg of alcohol (ethanol) in each dose (15 ml), which is equivalent to 2.2 % vol ethanol (alcohol). The amount in each dose (15 ml) of this medicine is equivalent to less than 7 ml beer or 3 ml wine. The small amount of alcohol in this medicine will not have any noticeable effects.

This medicine contains liquid maltitol. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product. Maltitol may have a mild laxative effect. Calorific value: 2.3 kcal/g maltitol.

This traditional herbal medicine contains 19.5 mg benzoate salt in each 15ml dose.

This traditional herbal medicine contains less than 1 mmol sodium (23 mg) per 15 ml dose, that is to say essentially 'sodium-free'.

3. HOW TO USE MEDITHYME COUGH SYRUP.

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you. Check with your doctor or pharmacist if you are not sure.

Method of administration: for oral short-term use only

The bottle is sealed with a child-resistant closure that should be opened as followed: push the closure down while turning counter-clockwise (see figure).



The recommended dose is:

Children from 12 years and adults: 15 ml, 4 times per day.

The interval between two intakes should be at least 4 hours.

The use in children under 12 years of age is not recommended.

If symptoms persist, worsen or do not improve after one week of use of Medithyme Cough Syrup, a qualified healthcare professional e.g. a doctor or pharmacist should be consulted.

If you take more Medithyme Cough Syrup than you should

If you have taken too much Medithyme Cough Syrup, immediately contact your doctor or your pharmacist

If you forget to take Medithyme Cough Syrup

Do not worry about a missed dose, take the next dose as usual. Do not take a double dose to make up for a forgotten dose.

If you stop taking Medithyme Cough Syrup

There are no special precautions needed.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS.

Like all medicines, Medithyme Cough Syrup can cause side effects, although not everybody gets them.

The following severe side effects may occur:

Allergic reactions including Quincke's oedema and anaphylactic shock have been reported. Stop taking the syrup and tell your doctor immediately if:

- you get any swelling of the face, lips, tongue or throat
- you have any difficulty in swallowing or breathing (including shortness of breath)
- you get a skin rash after taking the syrup.

The above symptoms may mean you are having a very rare, serious allergic reaction to this traditional herbal medicine.

The following side effects may occur as well:

- Stomach disorders

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist.

This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system:

HPRA Pharmacovigilance

Website: www.hpra.ie

By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE MEDITHYME COUGH SYRUP.

Keep this medicine out of the sight and reach of children. This medicinal product does not require any special storage conditions. Do not use Medithyme Cough Syrup after the expiry date which is stated on the label/the box after "EXP". The first two figures indicate the month, the following two or four figures the year. The expiry date refers to the last day of that month. Use within 6 months of opening.

6. CONTENTS OF THE PACK AND OTHER INFORMATION.

What Medithyme Cough Syrup contains

- The active substance is: Thymus vulgaris L. fluid extract [1:2-3] 6.5 g per 100 ml.
- Extraction solvent ammonia 10% (m/m) : glycerol 85% (m/m) : ethanol 90% (v/v) : water (1:20:70:109).
- The other ingredients are: citric acid, anhydrous - sodium benzoate - potassium sorbate - sodium citrate dihydrate - liquid maltitol - purified water

What Medithyme Cough Syrup looks like and content of the pack

Glass bottle of 125 ml or 180 ml syrup with child-resistant closure of polypropylene with a polyethylene sealing disk, delivered with a cup of 30 ml.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

TR Holder:

Clonmel Healthcare Ltd, Waterford Road, Clonmel, Co. Tipperary, Ireland

Manufacturer:

Laboratoria QUALIPHAR N.V./S. A., Rijksweg 9, 2880 Bornem, Belgium

Marketing Authorisation Number:

TR0126/319/001

General sale

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