

## PACKAGE LEAFLET: INFORMATION FOR THE USER

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### COMFORT-LAX

222 mg + 170 mg + 126 mg coated tablets

RHAMNUS FRANGULA L, DRY EXTRACT OF THE BARK;

RHAMNUS PURSHIANA D. C (CASCARA SAGRADA), DRY EXTRACT OF THE BARK;

FUCUS VESICULOSUS L., DRY EXTRACT OF THE STEM

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*• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.*

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*• Keep this leaflet • You may need to read it again • If you have any further questions, ask your doctor or pharmacist • This medicine has been prescribed for you only • Do not pass it on to others • It may harm them, even if their signs of illness are the same as yours • If you get any side effects, talk to your doctor or pharmacist • This includes any possible side effects not listed in this leaflet •*

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#### What is in this leaflet?

1. What COMFORT-LAX is and what it is used for
2. Before you take COMFORT-LAX
3. How to take COMFORT-LAX
4. Possible side effects
5. How to store COMFORT-LAX
6. Further information

#### 1. WHAT COMFORT-LAX IS AND WHAT IS IT USED FOR

COMFORT-LAX is a mixture of extracts of plant origin with laxative effects, and they stimulate digestion. This medicine induces the bowel movement, and it is used for the treatment of occasional constipation.

#### 2. BEFORE YOU TAKE COMFORT-LAX

##### **Do not take COMFORT-LAX**

- If you are hypersensitive (allergic) to any of the active ingredients, or any of the other ingredients of COMFORT-LAX
- If you have appendicitis or any abdominal pain of unknown origin
- If you have inflammatory bowel disease (e.g., Crohn's disease, ulcerative colitis)
- If you suffer from impaired function of the thyroid gland (hyperthyroidism)
- If you have liver and kidney problems
- If it is meant for a child under 12 years

- If you are pregnant or breastfeeding

### ***Take special care with COMFORT-LAX***

Treatment of constipation is primarily based on the following aspects:

- Diet based on high intake of fiber and plenty of fluids
- Physical activity
- Education related to habit of bowel movement

All this enhances and stimulates bowel movements, enabling facilitation of constipation.

If these measures are not sufficient to ease constipation, then you can take Comfort-Lax during a maximum of 6 days. If after four days medicine did not show the desired effect, and you still have a need for it, contact your doctor.

Avoid prolonged use of laxatives as they may cause side effects (see section 4 Possible side effects).

### ***Taking other medicines***

Please tell your doctor if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

In general, use of laxatives can interfere with the effect of medicines that you are already taking.

Do not take this medicine without consulting your doctor if you are taking medicines that regulate the heartbeat (antiarrhythmic agents, such as quinidine), astemizole and terfenadine (antihistamines), intravenous erythromycin, halofantrine and pentamidine (used to treat infections), bepridil (for heart attack infarction), sultopride (tranquilizer) or vincamine (peripheral vasodilator).

Follow the recommended duration of use of this medicine especially if you are being treated with the following medicines:

- Tetracosactide or other corticosteroids, or diuretics (which increase the excretion of urine).
- Cardiac glycosides (used for heart) because the excretion of potassium caused by Comfort-Lax, can increase the effect of these medicines.
- Oral antidiabetics and insulin, because Comfort-Lax can increase the effects of these medicines and cause hypoglycemia (decrease in blood sugar).

### ***Taking COMFORT-LAX together with food and drink***

Avoid taking licorice root while taking this medicine because it can enhance potassium loss.

### ***Pregnancy and breastfeeding***

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

The use of this medicine is not recommended during pregnancy, because although there were no reported problems related to pregnancy and the fetus when taking the recommended dose of this medicine, some experimental animal studies have suggested that some ingredients of the medicine indicate the risk of toxicity.

If you are pregnant, do not take this medicine without consulting a doctor.

Women who are breastfeeding should not take this medicine because of the possible laxative effect on the baby, because the active ingredients of this medicine are excreted into breast milk.

### ***Driving and using machines***

No available data on influence of medicine on the ability to drive and use machines.

### ***Important information about some ingredients of COMFORT-LAX***

This medicine contains glucose, sucrose and lactose. In case of intolerance to some sugars, contact your doctor before using this medicine.

This medicine also contains Methylparahydroxybenzoate, Propylparahydroxybenzoate and ethylparahydroxybenzoate which may cause allergic reactions (even delayed).

Comfort-Lax-coated tablets have a pretty intense characteristic smell that varies depending on the time of collection of one of the active components of the medicine (Fucus vesiculosus- seaweed); this does not affect the effect of the medicine.

### **3. HOW TO TAKE COMFORT-LAX**

Always take COMFORT-LAX exactly as indicated in this package leaflet. If you are unsure, please ask your doctor or pharmacist for advice.

Comfort-Lax is administered orally: take a tablet with a glass of water.

Adults, adolescents older than 12 years and older patients:

The recommended dose is one tablet after dinner. Laxative effect commences 6-12 hours after taking the tablet.

Older patients are more sensitive to the effects this medicine, depending on age and physical condition.

If the medicine is used in patients who cannot control the emptying of the bladder or bowels, special attention should be paid to changing the diapers of the patients in order to avoid contact with feces.

The maximum duration of treatment is 6 days; If after that time you still suffer from constipation, consult your doctor or pharmacist.

#### ***If you take more COMFORT-LAX than you should***

If you take more than you should by your doctor, talk to your doctor or pharmacist straight away.

If you take more Comfort-Lax than you should, you can experience stomach pains, stomach cramps, severe diarrhea with loss of water and electrolytes. This loss can cause confusion, cardiac arrhythmias (irregular heartbeat), cramps, fatigue or weakness. These symptoms are more pronounced in older people.

#### ***If you forget to take COMFORT-LAX***

If you forget to take a dose, do not take a double dose next time.

Talk to your doctor or pharmacist if you have any additional questions.

### **4. POSSIBLE SIDE EFFECTS**

Like all medicines, this medicine can cause side effects, although not everybody gets them.

This medicine can occasionally cause pain and stomach cramps, meteorism (presence of gas in the intestines), nausea, slimy stools and / or diarrhea, skin rash, allergic reactions. You may experience yellow-red-brown coloration of urine, but it is not clinically significant. All these symptoms disappear after discontinuation of the treatment.

#### ***Reporting of side effects***

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. By reporting side effects, you can help provide more information on the safety of this medicine.

### **5. HOW TO STORE COMFORT-LAX**

Keep out of the reach and sight of children.

This medicine should no longer be used after the expiry date printed on the container. The expiry date is the last day of the month indicated.

Shelf life: 3 years

Storage conditions:

Do not store above 30 °C. Store in the original package in order to protect from moisture.  
Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

## 6. FURTHER INFORMATION

### **What COMFORT-LAX contains**

Medicine contains only active substances:

Rhamnus frangula L, dry bark extract containing 6% glikofrangolina (corresponding to 13 mg of anthracene glycosides expressed in glikofrangulin A), extraction solvent: ethanol 60% V / V 222 mg

Rhamnus purshiana D.C. (Cascara Sagrada) dry bark extract containing 9% hidoksiantracenskih glycoside (corresponding to 15 mg expressed as the glycoside hidoksiantracenskih kaskarozid A), extraction solvent: ethanol 60% V / V 170 mg

Fucus vesiculosus L, dry extract of the stem (contains 12.6 mg - 37.8 mg of iodine) 126 mg

The other ingredients are:

Talc, sodium stearate, gum arabic, sucrose, glucose, iron oxide (E 172), an alkaline solution of ethyl parahydroxybenzoate (E214), methyl parahydroxybenzoate (E218) and propyl parahydroxybenzoate (E216), carnauba wax, lactose, silicon dioxide.

### **What COMFORT-LAX looks like and contents of the pack**

Oval coated tablets dark brown in color.

Inner packing: PVC / Aluminium blister.

The outer packaging: folding cardboard box with 20 tablets.

### **Regime of dispensing**

The medicine is issued without doctor's prescription.

### **Manufacturer**

URIACH AQUILEA OTC, SL

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