

## Package leaflet: Information for the user

### Levomethadone Molteni 5 mg/ml oral solution Levomethadone hydrochloride

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

- 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. See section 4.

#### What is in this leaflet

1. What Levomethadone Molteni is and what it is used for
2. What you need to know before you take Levomethadone Molteni
3. How to take Levomethadone Molteni
4. Possible side effects
5. How to store Levomethadone Molteni
6. Contents of the pack and other information

#### 1. What Levomethadone Molteni is and what it is used for

Levomethadone Molteni contains the active substance levomethadone hydrochloride. It belongs to a group of medicines which act on your nervous system.

Levomethadone Molteni is used to treat adults who are addicted to drugs called ‘opioids’ or ‘narcotic analgesics’ - such as heroin and morphine. It acts as a substitute for the addictive drugs.

#### 2. What you need to know before you take Levomethadone Molteni

##### Do not take Levomethadone Molteni if:

- you are allergic to levomethadone or any of the other ingredients of this medicine (listed in section 6)
- you are taking medicines for depression called ‘MAOIs’ (monoamine oxidase inhibitors) or have taken them in the last 2 weeks (see ‘Other medicines and Levomethadone Molteni’)
- you are taking medicines to treat addiction or strong painkillers (see ‘Other medicines and Levomethadone Molteni’)
- you have severe breathing or lung problems
- you are not addicted to opioid drugs.

Children and adolescents below 18 years of age must not take this medicine.

Do not take Levomethadone Molteni if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking Levomethadone Molteni.

#### Warnings and precautions

Talk to your doctor or pharmacist before taking Levomethadone Molteni if:

- you do not feel alert or completely awake (have ‘low levels of consciousness’)
- you have low blood pressure
- you have ever had heart problems, including heart disease or problems with your heart beat

- you have ever had breathing or lung problems such as asthma or ‘COPD’ (chronic obstructive pulmonary disease)
- you are unable to pass water
- you are a man who has prostate problems
- you have problems with your gall bladder or bile duct
- you have an inflamed pancreas
- you have bowel problems
- you have an ‘under-active’ thyroid gland
- you have a raised pressure inside your skull
- you have problems with your adrenal glands - either a ‘hyper-active’ adrenal gland, or a type of tumour (called ‘pheochromocytoma’)
- you have been told by your doctor that you have an ‘electrolyte imbalance’ such as ‘hypokalaemia’.

If any of the above apply to you (or you are not sure), talk to your doctor or pharmacist before taking Levomethadone Molteni.

- ▲ **When using levomethadone, it is important to consider that it is approximately twice as active as methadone** (see also section 3 “How to take Levomethadone Molteni”).
- ▲ Levomethadone Molteni is for oral use only and must not be injected. Use by injection is dangerous and may seriously harm your health: you may have an infection in your body, veins may become sore and swollen or you may have clogging of a blood vessel in the lungs.

### **Effects on test results**

The use of Levomethadone Molteni may lead to positive results in drug testing in sport (‘doping’ tests). Do not use Levomethadone Molteni as a doping drug - it may seriously harm your health.

### **Children and adolescents**

Children and adolescents below 18 years of age must not take this medicine.

### **Other medicines and Levomethadone Molteni**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines obtained without a prescription, and herbal medicines. This is because Levomethadone Molteni can affect the way some medicines work. Also some other medicines can affect the way Levomethadone Molteni works.

Do not take Levomethadone Molteni and tell your doctor or pharmacist if you are taking any of the following:

- medicines for depression called MAOIs (monoamine oxidase inhibitors), or if you have taken them in the last 2 weeks - this includes moclobemide, phenelzine and tranylcypromine
- medicines to treat addiction - such as buprenorphine. You must wait at least 20 hours after you have stopped taking Levomethadone Molteni before you start taking buprenorphine
- strong painkillers - such as morphine, butorphanol, nalbuphine and pentazocine.

If any of the above apply to you (or you are not sure), do not take Levomethadone Molteni, and talk to your doctor or pharmacist.

Talk to your doctor or pharmacist before taking Levomethadone Molteni if you are taking any of the following:

- medicines for a serious mental health problem called a ‘psychosis’, such as chlorpromazine
- medicines that dull your senses including:
  - other medicines for depression - such as amitriptyline and clomipramine
  - medicines to help you sleep - including anaesthetics
- medicines for high blood pressure - such as reserpine, clonidine, urapidil and prazosin

- medicines for fungal infections - such as fluconazole, itraconazole and ketoconazole
- medicines for heart problems - such as quinidine, verapamil and diltiazem
- cimetidine - to treat stomach ulcers
- rifampicin - an antibiotic
- oral contraceptive medicines ('the pill')
- medicines for epilepsy including barbiturates - such as phenytoin and carbamazepine
- medicines to calm you down called benzodiazepines - such as diazepam and flunitrazepam

Concomitant use of Levomethadone Molteni and sedative medicines such as benzodiazepines or related drugs increases the risk of drowsiness, difficulties in breathing (respiratory depression), coma and may be life-threatening. Because of this, concomitant use should only be considered when other treatment options are not possible.

However if your doctor does prescribe Levomethadone Molteni together with sedative medicines the dose and duration of concomitant treatment should be limited by your doctor.

Please tell your doctor about all sedative medicines you are taking, and follow your doctor's dose recommendation closely. It could be helpful to inform friends or relatives to be aware of the signs and symptoms stated above. Contact your doctor when experiencing such symptoms.

If any of the above apply to you (or you are not sure), talk to your doctor or pharmacist before taking Levomethadone Molteni.

#### **Levomethadone Molteni with alcohol**

Do not drink alcohol while you are taking this medicine. This is because alcohol may increase the side effects of Levomethadone Molteni.

#### **Pregnancy and breast-feeding**

- Talk to your doctor before taking Levomethadone Molteni if you are pregnant, think you may be pregnant or are planning to have a baby.
- Talk to your doctor before taking Levomethadone Molteni if you are breast-feeding. This is because small amounts may pass into your breast milk and this may affect your baby.

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

Do not drive or use any tools or machines while taking Levomethadone Molteni.

This is because you may feel sleepy and less alert while taking the medicine and for some time after you stop taking it.

You can only drive or use any tools or machines if your doctor tells you that it is okay to do so.

#### **Levomethadone Molteni contains methyl parahydroxybenzoate (E218)**

This may cause allergic reactions (possibly delayed).

### **3. How to take Levomethadone Molteni**

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

#### **How much to take**

Your dose will be decided by your doctor:

- it is chosen for you as an individual
- it is based on how soon your withdrawal symptoms start.

Always take the dose your doctor tells you to:

- do not take more or less of this medicine than you have been told
- do not take this medicine more or less often than you have been told.

Starting dose:

- The usual starting dose is 3 to 4 ml of oral solution each day (equal to 15 to 20 mg levomethadone hydrochloride).

Increasing the dose:

- Your doctor may increase your dose by 1 to 2 ml each day (equal to 5 to 10 mg levomethadone hydrochloride). This will depend on how the medicine affects you.
- The usual dose can be up to 12 ml of oral solution each day (equal to 60 mg levomethadone hydrochloride). In some cases your doctor may tell you to take a higher dose.

### **Elderly people and very ill people**

Your dose may be reduced if you are over 65 years of age. It may also be reduced if you have very poor health or if you have severe kidney problems or severe, long term liver problems. In these cases, your doctor may want to monitor you more closely.

### **Method of administration**

- Levomethadone Molteni is a liquid for oral use only.
- You can take this medicine on its own or diluted with water or non-alcoholic drinks - such as orange juice.
- Your dose will be measured and given to you by your doctor or pharmacist.

### **If you take more Levomethadone Molteni than you should**

If you take more Levomethadone Molteni than you should, talk to a doctor or go to hospital straight away.

Take the medicine pack with you. The following effects may happen:

- breathing problems
- feeling very sleepy, nearly passing out ('unconscious') or falling into a coma
- very small pupils in your eyes
- cold and clammy skin
- a very slow pulse
- muscle weakness.

In extreme cases your breathing or blood flow may stop and you may have a heart attack.

### **If you forget to take Levomethadone Molteni**

If you forget a dose, skip the forgotten dose then take your next dose as normal. Do not take a double dose to make up for a forgotten dose.

### **If you stop taking Levomethadone Molteni**

Do not stop taking Levomethadone Molteni without talking to your doctor first. This is because you may get side effects. If you need to stop taking Levomethadone Molteni, your doctor will stop it slowly.

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

## **4. Possible side effects**

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

**Tell your doctor if you notice any of the following side effects:**

**Side effects more likely to happen at the start of treatment:**

- feeling anxious, depressed, irritable or sleepy
- loss of appetite (anorexia), loss of weight or feeling sick (nausea)
- stomach or gut cramps, diarrhoea or being sick (vomiting)
- fever, alternating shivering and hot flushes, yawning, goose bumps, runny nose, sneezing
- jerky and quick movements or trembling (tremor)
- increased heart-beat (tachycardia)

- very small pupils in your eyes
- general pain in your body
- feeling weak or restless
- sweating more than usual or watery eyes.

**Other side effects include:**

**Uncommon (may affect up to 1 in 100 people) to common (may affect up to 1 in 10 people):**

- slow or shallow breathing
- headache or problems seeing
- feeling weak, feeling dizzy, faint, confused or disorientated
- feeling very sleepy or not being able to sleep
- feeling ‘high’ or feeling ‘down’,
- palpitations or decreased heart-beat
- low sex drive
- decreased libido or difficulty getting and maintaining an erection in men
- sweating
- skin rash, including nettle rash and other types of itchy rash
- dry mouth
- loss of appetite, nausea or vomiting
- constipation
- water retention (‘oedema’), ‘biliary cramps’ which can cause pain in the upper abdomen or back
- urinary problems including passing a low amount of water.

**Rare (may affect up to 1 in 1,000 people) to very rare (may affect up to 1 in 10,000 people):**

- red skin and feeling hot (‘flushing’)
- slow bleeding inside the body
- stopping breathing
- low blood pressure when standing or sitting up quickly
- missing heart-beats, heart attack, problems pumping blood around the body, going into ‘shock’.

You may notice some side effects become less severe with time. However, constipation and sweating more than usual are not likely to get better. Talk to your doctor or pharmacist about treatment to relieve the symptoms of these side effects.

**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 listed in Appendix V](#). By reporting side effects you can help provide more information on the safety of this medicine.

**5. How to store Levomethadone Molteni**

- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date which is stated on the label and the carton after ‘Exp.’. The expiry date refers to the last day of that month.
- Store below 25°C.
- Once the bottle is opened, use the oral solution within 12 weeks.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

**6. Contents of the pack and other information**

**What Levomethadone Molteni contains**

- The active substance is levomethadone hydrochloride. Each millilitre (ml) of oral solution contains

5 milligrams (mg) of levomethadone hydrochloride

- The other ingredients are methyl parahydroxybenzoate (E218), betaine hydrochloride, glycerol, purified water.

**What Levomethadone Molteni looks like and contents of the pack**

- Levomethadone Molteni is a clear and colourless oral solution.
- It is available in pack sizes of 100 ml, 3x100 ml, 500 ml and 1000 ml.
- Not all pack sizes may be marketed.

**Marketing Authorisation Holder**

[To be completed nationally]

**Manufacturer**

L. Molteni & C. dei F.lli Alitti Società di Esercizio S.p.A.

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**This medicinal product is authorised in the Member States of the EEA under the following names:**

Germany L-Polaflux

Italy Ellepalmiron

Poland Levomethadone Hydrochloride Molteni

Spain Levometadona Hidrocloruro Molteni

**This leaflet was last revised in July 2018.**

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