

<b>PRODUCT:</b> Methadone Teva 1mg/ml Oral Sol. All (bottle) TE1V2 (Opava)		<b>Colours:</b> Cutter Guide PMS Process Black PMS Green		<b>Fonts: (Artwork)</b> Body: Univers 55 Roman/ 65 Bold/55 Oblique 9pts Subhead: Univers 65 Bld 10pts Header: Univers 65 Bld 13pts	
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# METHADONE TEVA 1 mg/ml ORAL SOLUTION

## Methadone hydrochloride

### PACKAGE LEAFLET: INFORMATION FOR THE USER

Read all of this leaflet carefully before you start taking this medicine.

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

### IN THIS LEAFLET:

1. What Methadone Teva 1 mg/ml Oral solution is and what it is used for
2. Before you take Methadone Teva 1 mg/ml Oral solution
3. How to take Methadone Teva 1 mg/ml Oral solution
4. Possible side effects
5. How to store Methadone Teva 1 mg/ml Oral solution
6. Further information

## 1 WHAT METHADONE TEVA 1 mg/ml ORAL SOLUTION IS AND WHAT IT IS USED FOR

This medicine contains methadone hydrochloride, which belongs to a group of medicines called narcotic analgesics. It is used to treat opioid drug addiction.

## 2 BEFORE YOU TAKE METHADONE TEVA 1 mg/ml ORAL SOLUTION

**Do NOT take Methadone Teva 1 mg/ml Oral solution**

Do not take this medicine and tell your doctor if

- you are allergic (hypersensitive) to methadone or any other ingredients in this liquid (see section 6 below). An allergic reaction can include a rash, itching or shortness of breath.
- you have severe breathing problems.
- you are taking monoamine oxidase inhibitors (MAOIs) used to treat depression or if you have taken a MAOI medicine in the past two weeks (see 'Taking other medicines').
- you are not dependent on opioid drugs.
- you are in labour.

This medicine is not suitable for children.

Do not take this medicine if any of the above apply to you. If you are not sure, talk to your doctor before taking Methadone Teva 1 mg/ml Oral solution.

**Take special care with Methadone Teva 1 mg/ml Oral solution**

Before you take this medicine, tell your doctor if:

- you have liver or kidney problems.
- you have epilepsy.
- you are addicted to alcohol.
- you have or have recently had a head injury.
- you have low thyroid function (hypothyroid).
- you have problems with your adrenal glands. These are linked to your kidneys.
- you have an enlarged prostate gland.
- you have low blood pressure.
- you are in shock.
- you have a muscle weakness disease called myasthenia gravis.
- you have bowel problems.
- you have a history of irregular heart beat.
- you have a history of heart disease.
- you have a family history of people dying suddenly without cause.
- you have low potassium, sodium or magnesium levels.
- you are pregnant or breast-feeding.
- you are extremely ill or an older person. You may be more sensitive to the medicine.

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking Methadone Teva 1 mg/ml Oral solution.

You should not use this medicine during an asthma attack. If you give this medicine to yourself (self-administration), wait until the asthma attack has passed and you are fully recovered.

### Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines bought without a prescription, and herbal medicines. This is because Methadone Teva 1 mg/ml Oral solution can affect the way some other medicines work. Also some medicines can affect the way it works.

You must **not** take Methadone Teva 1 mg/ml Oral solution:

- at the same time or within 2 weeks of taking monoamine oxidase inhibitors (MAOIs).

Some medicines can increase the risk of heart problems when used with methadone. Talk to your doctor before taking methadone if you are taking:

- medicines for heart problems such as verapamil and enalapril.
- medicines which affect electrolyte balance such as diuretics (water tablets) or lithium.

Tell your doctor if you are taking any of the following medicines:

- medicines that dull your senses such as medicine for depression (for example, fluvoxamine, fluoxetine), medicines to help you sleep (including anaesthetics) and medicines to calm you down called tranquillisers.
- cimetidine, used to treat stomach ulcers.
- rifampicin, used to treat tuberculosis (TB).
- medicines used to treat epilepsy such as phenytoin, carbamazepine, phenobarbital and primidone.
- medicines that make your urine acidic such as ascorbic acid (vitamin C).
- narcotic painkillers such as codeine and pentazocine.
- naloxone used to reverse the effects of opioid drugs.
- medicines used to stop opioid drugs working such as naltrexone and buprenorphine.
- medicines used to treat HIV such as nevirapine, efavirenz and nelfinavir. The doctor may have to change the amount of methadone you take whilst on these medicines.
- antibiotics such as ciprofloxacin or macrolide antibiotics for example erythromycin.
- medicines used to treat fungal infections such as ketoconazole or fluconazole.
- St. John's Wort - a herbal preparation for depression.

If any of the above apply to you, talk to your doctor before taking Methadone Teva 1 mg/ml Oral solution.

**Taking Methadone Teva 1 mg/ml Oral solution with food and drink**

Do not drink alcohol whilst taking Methadone Teva 1 mg/ml Oral solution. This is because Methadone Teva 1 mg/ml Oral solution can make you feel sleepy and drinking alcohol will make you even more sleepy.

### Pregnancy and breast-feeding

- Talk to your doctor before taking Methadone Teva 1 mg/ml Oral solution if you are pregnant or likely to become pregnant.
- Take care if you are taking a pregnancy test as the methadone may interfere with the results.
- You should not take this medicine whilst you are in labour.
- Breast-feeding is possible if you are taking 20 mg a day or less of Methadone Teva 1 mg/ml Oral solution. Talk to your doctor before starting breast-feeding.

Ask your doctor or pharmacist for advice before taking any medicine.

### Driving and using machines

Methadone Teva 1 mg/ml Oral solution will severely affect your ability to drive or use machines, whilst taking it and afterwards. You should only start doing these activities again with the permission of your doctor.

**Important information about some of the ingredients of Methadone Teva 1 mg/ml Oral solution**

This medicine contains:

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- Methyl and propyl parahydroxybenzoates, which may cause an allergic reaction. This allergy may happen some time after starting the medicine
- 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.

### 3 HOW TO TAKE METHADONE TEVA 1 mg/ml ORAL SOLUTION

Always take Methadone Teva 1 mg/ml Oral solution exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Take this medicine by mouth.

#### Adults

The starting dose is 10 mg to 20 mg (10 ml to 20 ml) each day.

The doctor can increase this to 60 mg to 100 mg (60 ml to 100 ml) each day.

#### Older people and very ill people

If you have to have repeated doses of this medicine, the doctor may want to monitor you more closely.

#### Children

This medicine is not suitable for children.

#### If you take more Methadone Teva 1 mg/ml Oral solution than you should

If you take too much Methadone Teva 1 mg/ml Oral solution, you can experience the following:

- difficulty breathing
- extreme sleepiness, fainting or coma
- pin-point pupils
- muscle weakness
- cold and clammy skin
- slow heartbeat, low blood pressure, heart attack or shock
- in severe cases death may occur.

In the event of overdose you should seek medical assistance immediately even if you feel well as you may be suffering from methadone poisoning.

#### If you forget to take Methadone Teva 1 mg/ml Oral solution

If you forget a dose do not take it. Wait until the next dose is due and take only that amount. Do not take a double dose to make up for a forgotten dose.

#### If you stop taking Methadone Teva 1 mg/ml Oral solution

Do not stop taking this medicine unless your doctor tells you to as you may suffer withdrawal effects. Your doctor will tell you how to lower the dose gradually.

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

### 4 POSSIBLE SIDE EFFECTS

Like all medicines, Methadone Teva 1 mg/ml Oral solution can cause side effects, although not everybody gets them.

#### Stop taking this medicine and see a doctor straight away if you have any of the following:

- Heart problems. The signs of this may include changes in the way your heart beats, such as it beating faster or missed heart beats, breathing difficulties and dizziness if your breathing becomes slow and shallow. These side effects are rare and may affect 1 to 10 users in 10,000.

Other possible side effects include:

*Very common (these side effects may affect more than 1 user in 10 patients):*

- Feeling or being sick.

*Common (these side effects may affect 1 to 10 users in 100):*

- Weight increase.
- Water retention.
- Constipation.
- Feeling high (euphoria), seeing or hearing things that are not real (hallucinations), feeling sleepy.
- Feeling of dizziness or spinning.
- Blurred vision, pin point pupils.
- Skin rash, sweating.
- Feeling tired.

*Uncommon (these side effects may affect 1 to 10 users in 1,000):*

- Loss of appetite.
- Breathing difficulty (including with cough).

- Dry mouth, inflammation of the tongue.
- Feeling down (dysphoria), agitation, confusion, difficulty sleeping.
- Reduction of sex drive.
- Headache.
- Fainting, low blood pressure, swelling of the legs, facial flush.
- Itching, hives, rash.
- Weakness.
- Urine retention, difficulty in passing urine.
- Bile duct spasm (abdominal pain)
- Difficulty achieving or maintaining an erection.
- Disturbances of menstruation.

Blood potassium or magnesium deficiency or lower levels of platelets in blood may also occur, although the frequency of these side effects is not known.

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

### 5 HOW TO STORE METHADONE TEVA 1 mg/ml ORAL SOLUTION

#### Keep out of the reach and sight of children.

Do not use Methadone Teva 1 mg/ml Oral solution after the expiry date which is stated on the bottle and carton after 'EXP'. The expiry date refers to the last day of that month.

Keep the bottle tightly closed.

Use within 50 days after opening.

Do not freeze

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 Methadone Teva 1 mg/ml Oral solution contains

- The active ingredient is methadone hydrochloride. Each millilitre of solution contains 1 mg methadone hydrochloride.
- The other ingredients are methyl parahydroxybenzoate (E218), propyl parahydroxybenzoate (E216), propylene glycol (E1520), maltitol liquid (E965), caramel colour (E150d), patent blue 85 (E131) and purified water.

#### What Methadone Teva 1 mg/ml Oral solution looks like and contents of the pack

- Methadone Teva 1 mg/ml Oral solution is a clear green liquid.
- It is available in bottles of 30, 50, 100 and 500 ml. Not all bottle sizes may be marketed.
- Brown precipitate may appear in the bottle that does not affect quality of the product. The precipitate dissolves after shaking of the bottle.

#### Marketing Authorisation Holder

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#### This medicinal product is authorised in the Member States under the following names:

Ireland	Methadone Teva 1 mg/ml Oral solution
Netherlands	Methadone HCl 1mg/ml Teva, drank suikervrij
United Kingdom	Methadone Hydrochloride sugar Free 1 mg/ml Oral solution

**This leaflet was last revised in March 2013**

**TEVA**

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