

## PACKAGE LEAFLET: INFORMATION FOR THE USER

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### ORMIDOL

50mg and 100mg Film-coated tablets

#### ATENOLOL

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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 ORMIDOL is and what it is used for
2. Before you take ORMIDOL
3. How to take ORMIDOL
4. Possible side effects
5. How to store ORMIDOL

#### 1. WHAT ORMIDOL IS AND WHAT IS IT USED FOR

Atenolol belongs to a group of medicines called beta-blockers. It is used to:

- control high blood pressure.
- relieve chest pain (angina pectoris).
- control irregular heart beat.
- protect the heart in the early treatment after a heart attack.

#### 2. BEFORE YOU TAKE ORMIDOL

##### **Do not take Ormidol tablets and tell your doctor if you:**

- are **allergic** (hypersensitive) to atenolol or any of the other ingredients in Ormidol tablets.
- have second or third degree **heart block**.
- have **shock** caused by heart problems.
- have **heart failure** which is not under control.
- suffer with **heart conduction** or **rhythm problems**
- have a **slow heart rate**

- have **low blood pressure**.
- suffer from **severe blood circulation problems** (which may cause your fingers and toes to tingle or turn pale or blue)
- suffer from an **increased acidity of the blood** (metabolic acidosis)
- suffer from **untreated phaeochromocytoma** (high blood pressure due to a tumour near the kidney).
- have or have had **breathing problems** such as asthma, difficulty breathing due to narrowing of the airways or reversible obstructive airways disease. Do not take this medicine if you have a history of wheezing or asthma. Consult your doctor or pharmacist first.
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***Take special care with Ormidol tablets and tell your doctor if you:***

- have a **history of allergic reactions**
- have **heart problems** such as heart failure, untreated congestive heart failure, ischaemic heart disease, poor heart function (poor cardiac reserve) or first degree heart block.
- suffer from **blood circulation problems** (which may cause your fingers and toes to tingle or turn pale or blue) or cramping pain causing limping (intermittent claudication).
- suffer with **diabetes mellitus** (low blood sugar levels may be hidden by this medicine)
- have impaired **liver** or **kidney** function.
- are **elderly**.
- suffer from a tight, painful feeling in the chest in periods of rest (**Prinzmetal's angina**)
- have or have had **psoriasis**.
- suffer from **treated phaeochromocytoma** (high blood pressure due to a tumour near the kidney).
- have high levels of thyroid hormone in the body (**thyrotoxicosis**).
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***Taking other medicines***

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

- **clonidine** (to treat high blood pressure)
- **disopyramide, quinidine and amiodarone** (to treat irregular heartbeat (arrhythmia))
- medicines to **treat diabetes** including **insulin**
- Non-Steroidal Anti-Inflammatory Drug (**NSAIDs**) e.g. indometacin
- **digitalis glycosides** such as digoxin (to treat heart conditions)
- **nifedipine, diltiazem, verapamil, prazosin, alfuzosin and terazosin** (to treat high blood pressure)
- **sympathomimetic agents** (decongestant, asthma or heart medicine)
- **isoprenaline** or **dobutamine** (widens blood vessels)
- **tricyclic antidepressants** e.g. amitriptyline
- **barbiturates** e.g. phenobarbital (used for insomnia, epilepsy or as an anaesthetic)
- **phenothiazines** e.g. chlorpromazine (for mental illness).
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***Pregnancy and breast-feeding***

If you are pregnant or planning to become pregnant, speak to your doctor before taking this medicine. Breast-feeding is not recommended whilst taking Ormidol tablets.

***Alcohol intake***

You are advised to avoid alcohol whilst taking this medicine.

***Driving and using machines***

Ormidol tablets may cause dizziness or tiredness. Make sure you are not affected before driving or operating machinery.

***Anaesthetics and surgery***

If you are going to have an operation or an anaesthetic, please tell your doctor or dentist that you are taking Ormidol tablets as your heart beat might slow down too much and there may be an increased risk of developing low blood pressure.

### 3. HOW TO TAKE ORMIDOL

Always take Ormidol tablets exactly as your doctor has told you. If you are not sure, check with your doctor or pharmacist.

Take the tablets **with water**

#### Doses:

##### Adults and children over 12 years

- **High blood pressure:** 50-100mg a day as a single dose.
- **Angina:** 100mg once a day or 50mg twice a day.
- **Irregular heart beat:** initial treatment will usually be by injection, followed by a maintenance dose by mouth of 50-100mg a day as a single dose.
- **After a heart attack:** initial treatment will usually be by injection, if no response followed by 50mg by mouth 15 minutes after the injection. A further 50mg 12 hours later and then 100mg 12 hours later. 100mg to be taken once a day thereafter.

##### Elderly

Your doctor may prescribe you a lower dose if you are elderly, especially if you have impaired kidney function.

##### Children under 12 years

Not recommended.

##### Patients with kidney failure

Your doctor may prescribe you a lower dose if you have kidney failure.

- **Mild to moderate kidney failure** – 50mg a day or 100mg once every two days
- **Moderate to severe kidney failure** – 50mg once every two days or 100mg once every four days

Patients on haemodialysis should be given 50mg after each dialysis.

##### If you take more than you should

If you have accidentally taken more than the prescribed dose, contact your nearest casualty department or tell your doctor or pharmacist at once. Symptoms of an overdose include a slow or irregular heart beat, low blood pressure, difficulty breathing due to fluid on the lungs, acute impaired heart function and shock, fainting.

##### If you forget to take the tablets

If you forget to take a dose, take it as soon as you remember, unless it is nearly time for your next dose. Then go on as before. Never double up on the next dose to make up for the one missed.

##### If you stop taking the tablets

**Do not stop** treatment early, especially if you have ischaemic heart disease. **Talk to your doctor** before you stop taking the tablets and follow their advice.

### 4. POSSIBLE SIDE EFFECTS

Like all medicines, Ormidol tablets can cause side effects, although not everybody gets them.

#### Contact your doctor at once if you have the following:

- **an allergic reaction** such as itching, difficulty breathing or swelling of the face, lips, throat or tongue.
- **altered numbers and types of your blood cells.** If you notice increased bruising, nosebleeds, sore throats or infections, you should tell your doctor who may want to give you a blood test.
- **breathing difficulties** caused by narrowing of the airways in patients who have asthma or have had breathing problems.
- **heart attack or shock.**

**Tell your doctor if you notice any of the following side effects**, they get worse or you notice any not listed:

- Common (less than 1 in 10 users): slow heart beat, feeling sick, cold hands and feet, diarrhoea, tiredness, aching and tired muscles, GI disturbances such as stomach pains, heartburn and constipation.
- Uncommon (less than 1 in 100 users): increased levels of liver enzymes, sleep disturbances such as difficulty sleeping
- Rare (less than 1 in 1000 users): disturbances in thinking (depression, mood swings, hallucinations, paranoia - psychoses), confusion, reduced sexual potency in men (impotence), nightmares, headaches, dizziness, 'pins and needles' or tingling in the hands or feet, dry eyes, impaired vision, heart conduction problems (slowed AV-conduction or increase of existing AV-block causing dizziness, fainting or tiredness), heart failure deterioration, Raynauds phenomenon (condition causing pain, numbness, coldness and blueness of the fingers), liver disorders, disorder of the skin especially a rash, hair loss (alopecia), worsening of psoriasis or skin reactions similar to psoriasis, insomnia, worsening of existing cramping pains causing limping (intermittent claudication), dry mouth, low blood pressure on standing
- Very Rare (less than 1 in 10,000 users): an increase in anti nuclear antibodies
- Unknown (cannot be estimated from available data): depression, hands and feet which may be blue, being sick, pale or red irregular raised patches with severe itching (hives), Lupus-like syndrome (a disease where the immune system produces antibodies that attacks mainly skin and joints)
- Other: symptoms of an overactive thyroid (increased heart rate and appetite, sweating, tremor, anxiety, weight loss and heat intolerance) or low blood sugar (muscle weakness, reduced movements, mental confusion and sweating) may be hidden by Ormidol tablets

#### **5. HOW TO STORE ORMIDOL**

Keep out of the reach and sight of children.

Do not store above 25°C.

Store in the original package.

Keep container in the outer carton.

Do not use after the expiry date stated on the label/carton/bottle. The expiry date refers to the last day of that month.

Ask your pharmacist how to dispose of medicines no longer required.