PACKAGE LEAFLET: INFORMATION FOR THE USER

Meto AIWA 50 mg tablets

metoprolol tartrate

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 Meto AIWA is and what it is used for

Meto AIWA belongs to a group of medicines called cardioselective beta-blockers.

Meto AIWA is used to treat:
- high blood pressure (arterial hypertension)
- coronary artery disease (coronary heart disease)
- functional heart trouble (hyperkinetic heart syndrome)
- heart rhythm disorders with increased heart rate (tachyarrhythmias)
- acute treatment of heart attack and long-term treatment after a heart attack (prevention of secondary heart attack)
- preventive treatment of migraine (migraine prophylaxis).

2. What you need to know before you take Meto AIWA

Do not take Meto AIWA
- if you are allergic to metoprolol, other beta-blockers or any of the other ingredients of Meto AIWA (listed in section 6),
- if you have a weak heart (congestive or manifest heart failure),
- if you are suffering from cardiogenic shock,
- if you have 2nd or 3rd degree AV block (conduction disturbances from the upper to the lower chambers of the heart).
- if you have sick sinus syndrome,
- if you experience sudden, oppressive chest pain, as a sign of a heart attack,
- if you have sinoatrial block (heart conduction disturbances between the sinus node and upper chamber),
- if you have a resting pulse below 50 beats per minute before the start of treatment (bradycardia),
- if you have extremely low blood pressure (hypotension; systolic blood pressure less than 90 mmHg),
- if you have too much acid in your blood (acidosis),
- if you are prone to bronchial spasms (bronchial hyperreactivity, e.g. if you have bronchial asthma),

- if you have severe blood circulation problems in the arms or legs (peripheral circulatory disorders),
- if you have an untreated hormone-producing tumour of the adrenal medulla (phaeochromocytoma),
- if you have severe bronchial asthma or if you have a history of bronchospasm (constriction of the bronchial tubes),
- if you are currently receiving MAO inhibitors (exception: MAO-B inhibitors).

After a heart attack, do not use Meto AIWA if:
- your pulse is less than 45 to 50 heartbeats per minute,
- your ECG has revealed certain changes (PR interval > 0.24 s),
- your systolic blood pressure is less than 100 mmHg,
- you have severe heart failure (weak heart).

During treatment with Meto AIWA, you must not be given intravenous treatment with verapamil- or diltiazem-type calcium channel blockers or other medicines for heart rhythm disorders (antiarrhythmic agents such as disopyramide) (exception: intensive-care medicine).

Warnings and precautions
Talk to your doctor or pharmacist before taking Meto AIWA.

Take special care with Meto AIWA in the following cases:
- 1st degree AV block (minor conduction disturbances from the upper to the lower chambers of the heart).
- Prolonged strict fasting and severe physical exertion (extremely low blood sugar episodes are possible).
- Patients with a known or suspected hormone-producing tumour of the adrenal medulla (phaeochromocytoma; previous treatment with alpha-blockers required).
- Patients with impaired liver function (see section 3 “How to take Meto AIWA”).
- Patients with diabetes mellitus and severe fluctuations in blood sugar levels (extremely low blood sugar episodes are possible).
- Patients with diabetes mellitus, especially if you are using insulin or other blood sugar-lowering agents. Meto AIWA may suppress signs of low blood sugar (hypoglycaemia) such as racing heart.
- Patients with certain vascular disorders (Raynaud’s syndrome or certain forms of peripheral occlusive disease [intermittent claudication]).
- Patients prone to bronchial spasms.
- Patients with a certain type of angina (Prinzmetal’s angina).
- Patients at increased risk of severe hypersensitivity reactions (anaphylactic reactions).
- Patients with a history of severe hypersensitivity reactions and in patients on treatment to make them less prone - or immune - to allergic reactions (desensitisation therapy).
  Note: severe hypersensitivity reactions caused by other agents may be particularly serious during treatment with Meto AIWA and may be resistant to usual doses of adrenaline.
- Patients with a known or suspected overactive thyroid.
- Patients with a personal or family history of psoriasis.

If your pulse falls below 50-55 beats per minute during treatment, the dose must be reduced gradually by the doctor and/or treatment with Meto AIWA must be tapered off completely. If you notice an irregular heartbeat, please consult your doctor.

Treatment with Meto AIWA should, especially in patients with ischaemic heart disease, not be discontinued suddenly. To avoid worsening angina, the dose should be gradually reduced by the doctor over 1-3 weeks. If required, an alternative treatment should be instituted at the same time.

If you should notice spontaneous bleeding or bruising (haematoma) with Meto AIWA, please tell your doctor immediately.

If you experience yellowing of the skin and eyes, loss of appetite and dark urine, please tell your doctor immediately.
You should also consult your doctor if you experience hallucinations whilst on Meto AIWA.

Tell your doctor if symptoms occur such as dry eyes, either alone or at the same time as a rash. In this case, discontinuation of treatment should be considered.

If you are on permanent treatment with a beta-blocker and need surgery, a cardiologist should check whether the beta-blocker must be discontinued before surgery. The risk of anaesthesia or surgery may be increased. The benefits of continuing treatment with Meto AIWA should always be weighed against the risks of stopping it. Before anaesthesia, the anaesthetist should be told about the treatment with Meto AIWA. If it is deemed necessary to stop Meto AIWA before surgery, this should be done gradually and should be complete about 48 hours before anaesthesia.

What to consider in elderly people?
Caution is advised in elderly people. If their blood pressure or number of heartbeats per minute is too low, they may not get enough blood supply to vital organs.

Effects if misused for doping purposes
The use of Meto AIWA can lead to positive results in doping controls.

Other medicines and Meto AIWA
Tell your doctor or pharmacist if you are taking/using, have recently taken/used or might take/use any other medicines.

Effect of other medicines on Meto AIWA
The effect of Meto AIWA and other medicines for high blood pressure may be increased. Patients concurrently receiving other beta-blockers (including as eye drops), monoamine oxidase (MAO) inhibitors, medicines that block the sympathetic nervous system or medicines that lower catecholamine levels, should be carefully monitored.

The following medicines can increase the effect of Meto AIWA
Calcium channel blockers such as verapamil or diltiazem
Increase in the depressant effect on the blood pressure and heart. Careful monitoring is therefore required during combined use.
Note: During treatment with Meto AIWA, you must not be given intravenous treatment with verapamil- or diltiazem-type calcium channel blockers or other medicines for heart rhythm disorders (antiarrhythmic agents such as disopyramide) (exception: intensive-care medicine).

Calcium channel blockers of the nifedipine type
If Meto AIWA is used at the same time as calcium channel blockers of the nifedipine type, there may be a marked reduction in blood pressure and, in isolated cases, heart failure (weak heart) may develop.

Medicines for heart rhythm disorders (amiodarone, propafenone and other class I antiarrhythmic agents such as quinidine and disopyramide)
Increase in the depressant effect of Meto AIWA on the heartbeat and heart conduction (atrioventricular conduction).

Certain medicines for depression (tricyclic antidepressants), sedatives (barbiturates, phenothiazines), glyceryl trinitrate, water tablets (diuretics) or medicines to widen the blood vessels (vasodilators)
Marked reduction in blood pressure.

Anaesthetics
Marked reduction in blood pressure and marked depressant effect on heart contractility.
Note: If you need to have surgery, your anaesthetist must be told about your treatment with Meto AIWA.

The active substance of Meto AIWA (metoprolol tartarte) is broken down in the body by a certain liver enzyme (cytochrome P450 2D6). For this reason, special care is needed when Meto AIWA is used at the same time as medicines that inhibit this enzyme and may therefore increase the effect of Meto AIWA.

For example, these include medicines for:
- depression, such as fluoxetine, paroxetine or bupropion
- psychiatric disorders, such as thioridazine
- heart rhythm disorders, such as quinidine or propafenone
- viral infections, such as ritonavir
- allergies (antihistamines), such as diphenhydramine
- malaria, such as hydroxychloroquine or quinine
- fungal disease, such as terbinafine
- stomach ulcers, such as cimetidine

The following medicines may reduce the effect of Meto AIWA
Certain painkillers (non-steroidal anti-inflammatory drugs, such as indomethacin)
Reduction in the blood pressure-lowering effect.

Enzyme inducers, such as rifampicin
Reduction in blood levels and hence possible reduction in the effect of Meto AIWA.

Effect of Meto AIWA on other medicines
Prazosin
If you are already receiving Meto AIWA, you may experience a marked drop in blood pressure when changing body position (e.g. when getting up from lying down) after your first dose of prazosin. For this reason, take special care when taking your first doses of Meto AIWA and prazosin.

Digitalis, reserpine, alpha-methyldopa, guanfacine or clonidine
Marked decrease in heart rate or delayed heart conduction.

To avoid an excessive rise in blood pressure, clonidine must not be stopped until a few days after treatment with Meto AIWA has already ended. Subsequently, clonidine can be discontinued gradually.

Medicines used in anaesthesia to relax the muscles (peripheral muscle relaxants, e.g. suxamethonium, tubocurarine)
Meto AIWA can increase the effect of these medicines.

Substances that activate the sympathetic nervous system (noradrenaline, adrenaline or other substances with a similar effect (e.g. those found in cough medicines and nasal/eye drops)
Possible significant rise in blood pressure.

Note: During therapy with Meto AIWA, adrenaline may become less effective in the treatment of allergic reactions.

Monoamine oxidase (MAO) inhibitors
Possible excessive rise in blood pressure. For this reason, MAO inhibitors should not be used together with Meto AIWA..

Insulin and sulphonylureas
In patients with diabetes treated with insulin, Meto AIWA can cause a marked or prolonged decrease in blood sugar levels (hypoglycaemia) or even cancel the blood sugar-lowering effect of sulphonylureas. Regular blood glucose monitoring is therefore required.

Ergot alkaloids

Meto AIWA, when given at the same time as ergot alkaloids (class of medicines used to prevent and treat migraine) can increase their vasoconstrictor (blood vessel-narrowing) effect.

Dipyridamole
As with all beta-blockers, Meto AIWA should only be used with caution at the same time as dipyridamole (a medicine to prevent blood clots), together with monitoring of the heart rate.

Other possible interactions
Meto AIWA can reduce the excretion of other medicines (e.g. lidocaine), thus making them more potent.

Please note that this information may also apply to recently used medicines.

Meto AIWA with food, drink and alcohol
Concomitant alcohol consumption may alter the effect of Meto AIWA and that of alcohol.

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

Pregnancy
Metoprolol should be used only when strictly indicated and after benefit-risk assessment during pregnancy (especially during the first three months).

There is evidence to suggest that metoprolol reduces blood flow to the placenta and may thereby lead to foetal growth disturbances. Miscarriage, premature births and intrauterine death of the foetus have been observed after administration of other beta-blockers.

Due to the possibility of a decrease in heart rate (bradycardia), low blood pressure (hypotension) or low blood sugar levels (hypoglycaemia) in the newborn infant, treatment with metoprolol must be stopped 48-72 hours before the estimated delivery date. If this is not possible, newborn infants must be carefully monitored by a doctor for a period of 48-72 hours after delivery.

Breast-feeding
Metoprolol, compared to blood levels in the mother, accumulates in breast milk. Breast-fed infants must be monitored for signs of an effect from the medicine. The amount of metoprolol absorbed with breast milk can be reduced by not breast-feeding for 3-4 hours after taking this medicine.

Fertility
There are no studies on the effect of Meto AIWA on fertility in humans.

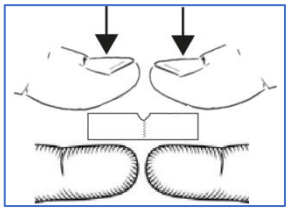
Driving and using machines
Various reactions occur in some individuals (e.g. dizziness, tiredness or visual disturbances), which can alter reaction skills to such an extent that the ability to drive, use machines or perform hazardous tasks is impaired. This applies particularly at the start of treatment, when increasing the dose or switching medications and in interaction with alcohol.

Meto AIWA contains lactose
If you have been told by a doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take Meto AIWA

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

The Meto AIWA 50 mg tablet can be divided into equal doses along the break line. The whole or half tablet is taken with some water.



Dividing the tablet:
The tablet is held between the index finger and thumb of both hands with the break line facing upwards and broken in half by pressing the thumbs downwards along the break line.

The tablets should be taken with plenty of liquid (preferably a glass of water). They should be swallowed whole and always taken at the same time before or after meals (e.g. always after breakfast). They should be taken as a single dose in the morning or a divided dose in the morning and evening.

The dosage should be determined individually – based mainly on response to treatment – and must not be changed unless instructed by your doctor.

The recommended dose is:

High blood pressure (arterial hypertension)
1 Meto AIWA tablet once or twice daily or 1-2 tablets once daily (equivalent to 50-100 mg metoprolol tartrate).
If required, the dose can be increased to 2 Meto AIWA tablets twice daily (equivalent to 200 mg metoprolol tartrate).

Coronary artery disease (coronary heart disease)
1 Meto AIWA tablet once or twice daily or 1-2 tablets once daily (equivalent to 50-100 mg metoprolol tartrate).
If required, the dose can be increased to 2 Meto AIWA tablets twice daily (equivalent to 200 mg metoprolol tartrate), under blood pressure monitoring.

Functional heart trouble (hyperkinetic heart syndrome)
1 Meto AIWA tablet once or twice daily or 1-2 tablets once daily (equivalent to 50-100 mg metoprolol tartrate).
If required, the dose may be increased to 2 Meto AIWA tablets twice daily (equivalent to 200 mg metoprolol tartrate), under blood pressure monitoring.

Heart rhythm disorders with increased heart rate (tachyarrhythmias)
2 Meto AIWA tablets once or twice daily (equivalent to 100-200 mg metoprolol tartrate).

Acute treatment of heart attack and long-term treatment after a heart attack (prevention of secondary heart attack)
Meto AIWA should only be used in hemodynamically stable patients (systolic blood pressure >100 mmHg, heart rate >60 bpm, no symptoms of heart failure) with no contraindications to the treatment with beta-receptor blockers.

a) Acute treatment
In the case of an acute heart attack, treatment starts as soon as possible after hospitalisation under continuous ECG and blood pressure monitoring. Treatment is started with 5 mg metoprolol tartrate intravenously. Depending on tolerance, additional single doses of 5 mg metoprolol tartrate can be

administered intravenously at 2-minute intervals up to a maximum total dose of up to 15 mg metoprolol tartrate.

If the full intravenous dose of 15 mg metoprolol tartrate is tolerated, the patient is given a single dose of 1 Meto AIWA tablet (equivalent to 50 mg metoprolol tartrate), starting 15 minutes after the last intravenous injection. Over the following 48 hours, 1 Meto AIWA tablet is administered every 6 hours.
In patients who have tolerated less than 15 mg metoprolol tartrate intravenously, follow-up oral treatment should be started with caution with a single dose of ½ tablet of Meto AIWA 50 mg (equivalent to 25 mg metoprolol tartrate).

b) Maintenance dose
Following acute treatment, 2 Meto AIWA tablets are given twice daily (equivalent to 200 mg metoprolol tartrate).

In the event of a decrease in heart rate and/or blood pressure requiring treatment or other complications, Meto AIWA must be discontinued immediately.

Preventive treatment of migraine (migraine prophylaxis):
2 Meto AIWA tablets, once or twice daily (equivalent to 100-200 mg metoprolol tartrate).

Elderly patients
No dose adjustment is required for elderly patients.

Children and adolescents
Meto AIWA is not recommended for use in children.

Impaired liver function
Elimination of Meto AIWA will be reduced in patients with severely impaired liver function, meaning that a dose reduction may possibly be required.

Impaired kidney function
No dose adjustment is required in patients with impaired kidney function.

If you take more Meto AIWA than you should
If you suspect an overdose, tell a doctor/emergency doctor immediately, so that he/she can decide what to do next. Depending on the extent of overdose, a sharp drop in blood pressure (hypotension), reduced heart rate (bradycardia) to the point of cardiac arrest, heart failure and cardiogenic shock may occur. Furthermore, breathing difficulties, constriction of the airway muscles (bronchospasm), vomiting, impaired consciousness and, occasionally, epileptic fits (generalised seizures) may occur.

In the event of an overdose or a serious drop in heart rate and/or blood pressure, treatment with Meto AIWA must be stopped.

If you forget to take Meto AIWA
If you happen to forget a dose of Meto AIWA, take the missed tablet immediately as soon as you remember. However, if it is almost time for the next dose, do not take a double dose. Simply continue your treatment at the prescribed dose.

If you stop taking Meto AIWA
Do not stop this medicine or alter the dosage unless instructed by a doctor. Abrupt discontinuation can lead to cardiac ischaemia (reduced blood flow through the heart muscle) with worsening recurrent angina or a heart attack, or a return of high blood pressure.

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.

Common (may affect up to 1 in 10 patients)
- Tiredness, sleepiness, dizziness, headache, fatigue
- Reduced heart rate (bradycardia)
- Sharp drop in blood pressure, also when moving from a lying to a sitting position (orthostatic hypotension), occasionally with short-term unconsciousness (syncope)
- Shortness of breath with physical exertion
- Nausea, vomiting, stomach ache

Uncommon (may affect up to 1 in 100 patients)
- Depression, confusion, nightmares or increased dream activity, hallucinations
- Abnormal sensations (paraesthesia), drowsiness, sleep disorders
- Diarrhoea, constipation
- Sweating, allergic skin reactions (redness, itching, exanthema, skin rashes on exposure to light (photosensitivity))

Rare (may affect up to 1 in 1,000 patients)
- Appearance or worsening of pre-existing diabetes. Low blood sugar after prolonged strict fasting and severe physical exertion. The warning signs of low blood sugar (particularly increased heart rate (tachycardia) and tremor in the fingers) may be hidden.
- Reduced state of consciousness
- Conjunctivitis, reduced tear flow (note when wearing contact lenses)
- Heart palpitations, heart rhythm disorders (arrhythmia), conduction disturbances from the upper to the lower chambers of the heart (atrioventricular conduction disturbance), heart failure (weak heart) with fluid accumulation in the arms and legs (peripheral oedema) and/or shortness of breath with physical exertion (exertional dyspnoea)
- Oedema, cold feeling in the extremities, Raynaud's syndrome, poor peripheral blood circulation (including patients with Raynaud's syndrome or intermittent claudication)
- Constriction of the airway muscles (bronchospasm and shortness of breath, even in patients without a history of obstructive respiratory diseases)
- Dry mouth
- Rash (in the form of hives [urticaria]), skin dystrophy or psoriasiform dermatitis)
- Muscle weakness, muscle cramps

Very rare (may affect up to 1 in 10,000 patients)
- Spontaneous bleeding or bruising (haematoma) as a sign of a decrease in blood platelets (thrombocytopenia), decrease in white blood cells (leukopenia)
- Changes in personality (e.g. mood swings, short-term memory loss)
- Visual disturbances (e.g. blurred vision), dry and/or inflamed eye/eye irritation
- Tinnitus, ear noises and, at doses exceeding the recommended dose, hearing disorders (e.g. hearing loss, deafness)
- Pain in the heart area, increase in seizures in patients with angina, cardiogenic shock
- Gangrene (in patients with pre-existing severe peripheral circulatory disorders)
- Cold (rhinitis)
- Pathological proliferation of connective tissue behind the dorsal peritoneum (retroperitoneal fibrosis; the relationship to Meto AIWA has not been clearly proven)
- Inflammation of the liver (hepatitis)
- Hair loss, causing or worsening the symptoms of psoriasis
- Joint disease (arthropathy), which may affect one or more joints (mono- and polyarthritis)

– Erectile dysfunction and sexual desire disorders (libido disorders), induratio penis plastica (Peyronie's disease; the relationship to Meto AIWA has not been clearly proven)
– Weight gain, change in liver function values (e.g. transaminases increased)

Special notes
Disorders of fat metabolism may occur during therapy with Meto AIWA. In patients with mostly normal total cholesterol, a decrease in HDL cholesterol and an increase in blood triglycerides have been observed.

Meto AIWA may mask the symptoms of severe overactive thyroid gland (thyrotoxicosis).

Beta-blockers may increase sensitivity to allergens and the severity of anaphylactic reactions, i.e. acute generalised allergic reactions. In patients with a history of severe hypersensitivity reactions and patients on treatment to make them less prone – or immune – to allergic reactions (desensitisation therapy), excessive anaphylactic reactions may therefore occur.

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 *Bundesinstitut für Arzneimittel und Medizinprodukte* (Federal Institute for Drugs and Medical Devices), *Abt. Pharmakovigilanz* (Department of Pharmacovigilance), Kurt-Georg-Kiesinger-Allee 3, D-53175 Bonn, website: www.bfarm.de. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Meto AIWA

Keep this medicine out of the sight and reach of children.

Do not store above 25°C.
Store in the original packaging to protect the content from moisture.

Do not use this medicine after the expiry date which is stated on the blister and/or carton after “EXP”. The expiry date refers to the last day of that month.

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 Meto AIWA contains
- The active substance is: metoprolol tartrate. 1 tablet Meto AIWA contains 50 mg metoprolol tartrate.

– The other ingredients are: lactose monohydrate, povidone K30, highly dispersed silicon dioxide, croscarmellose sodium, talc, magnesium stearate (Ph.Eur.)

What Meto AIWA looks like and contents of the pack
The tablets are white, round, flat on two sides, and have a break line on one side.

Meto AIWA is available in packs of 30, 50 and 100 tablets.

Not all pack sizes may be marketed.

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