

Moclobemide Sandoz®

moclobemide tablets

Consumer Medicine Information

WHAT IS IN THIS LEAFLET

This leaflet answers some common questions about Moclobemide Sandoz.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking this medicine against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

WHAT MOCLOBEMIDE SANDOZ IS USED FOR

This medicine is used to treat depression.

It contains the active ingredient moclobemide.

Moclobemide belongs to a group of medicines called antidepressants.

Antidepressants are used to treat depression and work on the central nervous system. They are thought to work by their action on brain chemicals called amines, which are involved in controlling mood.

There are many different types of medicines used to treat depression. Moclobemide Sandoz belongs to a group of medicines called reversible inhibitors of monoamine oxidase A (RIMA).

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

This medicine is available only with a doctor's prescription.

BEFORE YOU TAKE MOCLOBEMIDE SANDOZ

When you must not take it

Do not take this medicine if you have an allergy to:

- moclobemide, the active ingredient, or to any of the other ingredients listed at the end of this leaflet under Product Description.

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin.

Do not take this medicine if you are suffering from severe confusion.

Do not take this medicine if you are taking any of the following:

- clomipramine (Anafranil®), used to treat conditions such as depression
- selegiline (Eldepryl®), used to treat Parkinson's disease
- bupropion.
- selegiline (Eldepryl)

- triptans (a family of medicines commonly used to treat migraines eg. Triptazig)
- pethidine
- tramadol (Durotram, Zydol)
- dextromethorphan (often found in cough and cold medicines)
- linezolid (Zyvox).
- you are taking other medications known as selective serotonin reuptake inhibitors or tricyclic antidepressants.

A serious reaction called serotonin syndrome may occur if you take Moclobemide Sandoz with the above medicines. This can cause a sudden increase in body temperature, high blood pressure and convulsions.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any of the following medical conditions:

- liver disease
- high blood pressure
- a personal history or family history of bipolar disorder
- mental illness other than depression, including schizophrenia, agitation and excitement
- thyrotoxicosis (a condition of excessive thyroid hormones)
- pheochromocytoma (a rare tumour of the adrenal gland)
- rare hereditary problems of galactose intolerance, the Lapp lactose deficiency or glucose-galactose malabsorption.

Tell your doctor if you are pregnant or plan to become pregnant or are breastfeeding.

Your doctor can discuss with you the risks and benefits involved.

If you have not told your doctor about any of the above, tell him/her before you start taking Moclobemide Sandoz.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and Moclobemide Sandoz may interfere with each other. These include:

- other antidepressant medicines such as fluoxetine, fluvoxamine, paroxetine, sertraline, amitriptyline and nortriptyline, trimipramine and maprotiline, venlafaxine, clomipramine and citalopram
- cimetidine (Tagamet®), a medicine used to treat stomach ulcers or reflux

- dextromethorphan, found in cough and cold preparations
- pethidine, a strong pain reliever
- metoprolol, used to treat high blood pressure. Moclobemide may cause an additional drop in blood pressure if you are taking metoprolol.
- serotonin agonists e.g. sumatriptan (used to relieve migraine attacks) and buspirone (used to treat anxiety)
- selegiline
- triptans
- tramadol
- linezolid
- opiates e.g. morphine, fentanyl and codeine
- adrenergics
- sibutramine
- bupropion
- proton pump inhibitors
- St John's wort (Hypericum)- containing phytotherapeutic products.

These medicines may be affected by Moclobemide Sandoz or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

HOW TO TAKE MOCLOBEMIDE SANDOZ

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions, ask your doctor or pharmacist for help.

How much to take

The usual dose is between 300 mg and 600 mg per day. The tablets are taken twice daily after meals.

Ask your doctor or pharmacist if you are unsure of the correct dose for you.

They will tell you exactly how much to take.

Follow the instructions they give you.

If you take the wrong dose, Moclobemide Sandoz may not work as well and your problem may not improve.

How to take it

Swallow the tablets whole with a full glass of water.

You should follow your doctor's instructions carefully if changing from one antidepressant to another and report any unexpected effects if they occur.

When to take Moclobemide Sandoz

Take your medicine in the morning and in the evening at the end of a meal.

How long to take Moclobemide Sandoz

Continue taking your medicine for as long as your doctor tells you.

This medicine helps to control your condition, but does not cure it. It is important to keep taking your medicine even if you feel well.

For depression, the length of treatment will depend on how quickly your symptoms improve. Most antidepressants take time to work so don't be discouraged if you don't feel better right away. Some of your symptoms may improve in 1 or 2 weeks but it can take up to 4 or 6 weeks to feel any real improvement.

Even when you feel well, you will usually have to take Moclobemide Sandoz for several months or even longer to make sure the benefits will last. Continue taking it until your doctor tells you to stop.

If you forget to take it

Take your dose as soon as you remember, and continue to take it as you would normally.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Do not take a double dose to make up for the dose that you missed.

This may increase the chance of you getting an unwanted side effect.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much Moclobemide Sandoz. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Symptoms of an overdose may include nausea, vomiting, drowsiness, disorientation, slurred speech, reduced reflexes and agitation.

WHILE YOU ARE TAKING MOCLOBEMIDE SANDOZ

Things you must do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking Moclobemide Sandoz.

Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.

If you become pregnant while taking this medicine, tell your doctor immediately.

Tell your doctor if, for any reason, you have not taken your medicine exactly as prescribed.

Otherwise, your doctor may think that it was not effective and change your treatment unnecessarily.

If you have any suicidal thoughts or other mental/mood changes, tell your doctor immediately or go to the nearest hospital for treatment.

Occasionally, the symptoms of depression may include thoughts of suicide or self-harm. These symptoms may continue or get worse during the first one to two months of treatment until the full antidepressant effect of the medicine becomes apparent. This is more likely to occur if you are a young adult i.e. under 24 years of age.

If you or someone you know is showing any of the following warning signs of suicide while taking Moclobemide Sandoz, contact your doctor or a mental health professional immediately or go to the nearest hospital for treatment.

These signs include:

- thoughts or talk about death or suicide
- thoughts or talk of self-harm or harm to others
- any recent attempts of self-harm
- increase in aggressive behaviour, irritability or agitation
- worsening of depression.

Any mention of self-harm, violence or suicide must be taken seriously.

Keep all of your doctor's appointments so that your progress can be checked.

Things you must not do

Do not take Moclobemide Sandoz to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

Do not stop taking your medicine or lower the dosage without checking with your doctor.

Do not let yourself run out of medicine over the weekend or on holidays.

Your doctor may want you to gradually reduce the amount you are taking before stopping completely.

Things to be careful of

Be careful driving or operating machinery until you know how Moclobemide Sandoz affects you.

This medicine may cause dizziness or light-headedness in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

Although drinking alcohol is unlikely to affect your response to Moclobemide Sandoz, your doctor may suggest avoiding alcohol while you are being treated for depression.

SIDE EFFECTS

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Moclobemide Sandoz.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

In the first week or two, you may experience:

- sleep disturbances
- dizziness
- nausea
- headache
- dry mouth.

Occasionally, the symptoms of depression may include thoughts of suicide or self-harm. These symptoms may continue or get worse during the first one to two months of treatment until the full antidepressant effect

of the medicine becomes apparent. This is more likely to occur if you are a young adult i.e. under 24 years of age.

Contact your doctor or a mental health professional right away, or go to Accident and Emergency at your nearest hospital for treatment if you or someone you know is demonstrating any of the following warning signs of suicide while taking Moclobemide:

- swelling of the face, lips, mouth or throat which may cause difficulty in swallowing or breathing
- sudden increase in body temperature, agitation, shivering, severe convulsions
- thoughts or talk of death or Suicide
- thoughts or talk of self-harm or harm to others
- any recent attempts of self-harm
- increase in aggressive behaviour, irritability or agitation
- worsening of depression
- insomnia, nervousness, Jitteriness
- mania or hypomania (or onset of early symptoms).

All thoughts or talk of suicide or violence must be taken seriously.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- nausea
- agitation
- paraesthesia
- dry mouth
- insomnia or disturbed sleep
- anxiety
- restlessness
- diarrhoea, constipation or upset stomach
- vomiting
- feeling of fullness in the stomach
- dizziness
- headache
- blurred vision
- skin rash, flushing
- hypotension
- feeling of confusion.

This is not a complete list of all possible side effects. Others may occur in some people and there may be some side effects not yet known.

You may need urgent medical attention or hospitalisation. These side effects are very rare.

Tell your doctor or pharmacist if you notice anything else that is making you feel unwell, even if it is not on this list.

Ask your doctor or pharmacist if you don't understand anything in this list.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

AFTER TAKING MOCLOBEMIDE SANDOZ

Storage

Keep your medicine in the original container. If you take it out of its original container it may not keep well.

Keep your medicine in a cool dry place where the temperature stays below 25°C.

Do not store Moclobemide Sandoz or any other medicine in the bathroom or near a

sink. Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

PRODUCT DESCRIPTION

What it looks like

Moclobemide Sandoz comes in two types of tablets:

Moclobemide Sandoz 150mg - beige, oval, film-coated, scored on both sides.

Moclobemide Sandoz 300mg - white, oval, film-coated, scored on both sides.

Available in blister packs containing 60 tablets.

Ingredients

Active ingredients:

- Moclobemide Sandoz 150 mg - 150 mg moclobemide
- Moclobemide Sandoz 300 mg - 300 mg moclobemide.

Inactive ingredients:

Moclobemide Sandoz 150mg tablets:

- Lactose monohydrate
- maize starch
- copovidone
- microcrystalline cellulose
- colloidal anhydrous silica
- magnesium stearate
- sodium starch glycollate
- hypromellose
- titanium dioxide
- macrogol 4000
- iron oxide yellow.

Moclobemide Sandoz 300mg tablets:

- lactose monohydrate
- maize starch
- povidone
- microcrystalline cellulose
- colloidal anhydrous silica
- magnesium stearate
- sodium starch glycollate
- hypromellose
- titanium dioxide
- macrogol 4000.

This medicine does not contain sucrose, gluten, tartrazine or any other azo dyes.

Supplier

Moclobemide Sandoz is supplied in Australia by:

Sandoz Pty Ltd
ABN 60 075 449 553
54 Waterloo Road
Macquarie Park NSW 2113
Australia
Tel: 1800 726 369

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Australian Register Numbers

150mg tablets: AUST R 76934 (blisters)

300mg tablets: AUST R 76935 (blisters)