

Apo-Moclobemide

Contains the active ingredient, moclobemide

Consumer Medicine Information

For a copy of a large print leaflet, Ph: 1800 195 055

What is in this leaflet

Read this leaflet carefully before taking your medicine.

This leaflet answers some common questions about moclobemide.

It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

The information in this leaflet was last updated on the date listed on the last page. More recent information on this medicine may be available.

Ask your doctor or pharmacist:

- if there is anything you do not understand in this leaflet,
- if you are worried about taking your medicine, or
- to obtain the most up-to-date information.

You can also download the most up to date leaflet from www.apotex.com.au.

All medicines have risks and benefits. Your doctor has weighed the risks of you using 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 your medicine. You may want to read it again.

What this medicine is used for

The name of your medicine is Apo-Moclobemide. It contains the active ingredient moclobemide.

It is used to treat depression.

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

Your doctor may have prescribed moclobemide for another reason.

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

How it works

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

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.

Depression is longer lasting and/or more severe than the "low moods" everyone has from time to time due to the stress of everyday life. It is thought to be caused by a chemical imbalance in parts of the brain. This imbalance affects your whole body and can cause emotional and physical symptoms such as feeling low in spirit, loss of interest in activities, being unable to enjoy life, poor appetite or overeating, disturbed sleep, often waking up early, loss of sex drive, lack of energy and feeling guilty over nothing.

Moclobemide helps to correct this chemical imbalance and may help relieve the symptoms of depression.

There is no evidence that this medicine is addictive.

Use in children

There is not enough information to recommend the use of this medicine in children and adolescents under 18 years of age.

Before you take this medicine

When you must not take it

Do not take this medicine if:

- **You are hypersensitive to, or have had an allergic reaction to, moclobemide or any of the ingredients listed at the end of this leaflet.**

Symptoms of an allergic reaction may include cough, shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue, throat or other parts of the body; rash, itching or hives on the skin; fainting or hayfever-like symptoms.

If you think you are having an allergic reaction do not take any more of the medicine and contact your doctor immediately or go to the Accident and Emergency department at the nearest hospital.

- **You are taking other medications known as selective serotonin reuptake inhibitors, tricyclic antidepressants, or selegiline, bupropion, triptans, pethidine, tramadol, dextromethorphan or linezolid**

A serious reaction called Serotonin Syndrome may occur if you take moclobemide with the above medicines. This can cause a sudden increase in body temperature, high blood pressure and convulsions (fits).

- **You are suffering from or have had recent episodes of severe confusion.**

- **The expiry date (EXP) printed on the pack has passed.**
- **The packaging is torn, shows signs of tampering or if it does not look quite right.**

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:

1. You have allergies to:

- any other medicines
- any other substances, such as foods, preservatives or dyes.

2. You have or have had any medical conditions, especially the following:

- bipolar disorder or a family history of suicide, bipolar disorder or depression
- liver disease
- high blood pressure
- any mental illness other than depression including schizophrenia, agitation and excitation
- thyrotoxicosis (excessive amount of thyroid hormone)
- phaeochromocytoma (a rare tumour of the adrenal gland).

3. You are currently pregnant or you plan to become pregnant.

Do not take this medicine whilst pregnant until you and your doctor have discussed the risks and benefits involved.

4. You are currently breastfeeding or you plan to breastfeed.

A small amount of moclobemide passes into breast milk and may affect your baby. Your doctor will discuss with you the risks and benefits of taking moclobemide when breast-feeding.

5. You are planning to have surgery or an anaesthetic.

6. You are currently receiving or are planning to receive dental treatment.

7. You are taking or are planning to take any other medicines,

This includes vitamins and supplements that are available from your pharmacy, supermarket or health food shop.

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

You MUST NOT take moclobemide with

- clomipramine
- selegiline

- selective serotonin reuptake inhibitors, such as fluoxetine, paroxetine, sertraline
- tricyclic antidepressants, such as amitriptyline or nortriptyline
- dextromethorphan, a cough suppressant (ingredient in some cold & flu preparations)
- a class of medicines called triptans, used for treating migraine for example sumatriptan
- pethidine, a pain reliever
- bupropion, an antidepressant
- tramadol
- linezolid.

Taking these medicines may increase the chance of you developing Serotonin Syndrome.

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

- cimetidine, an anti-ulcer drug
- opiate pain killers, such as dextropropoxyphene, morphine, fentanyl and codeine
- other types mood disorder therapies called MAOI and venlafaxine or St John's wort (herbal)

- omeprazole, a medication used for stomach acid reduction
- metoprolol, used for treating certain heart problems, angina, or high blood pressure.

These medicines may be affected by moclobemide 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 may have more information on medicines to be careful with or avoid while taking moclobemide.

Other interactions not listed above may also occur.

In addition, do not eat large quantities of tyramine-containing food (mature cheese, yeast extract, fermented soya bean products) while you are taking moclobemide, especially if you have high blood pressure.

How to take this medicine

Follow all directions given to you by your doctor carefully.

They may be different to the information in this leaflet.

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

How much to take

Your doctor will tell you how much of this medicine you should take. This will depend on your condition and whether you are taking any other medicines.

The usual dose is between 300 mg and 600 mg per day, but you usually start on a lower dose to begin with.

If you have liver problems your doctor may prescribe a lower dose.

If you are changing from one antidepressant to another, follow your doctor's instructions carefully and report any unexpected effects if they occur.

How to take it

Swallow the tablet(s) with a glass of water.

When to take it

Moclobemide is usually taken twice a day (e.g. morning and evening), at the end of a meal.

Take this medicine at the same time each day. Taking it at the same time each day will have the best effect and will also help you remember when to take it.

How long to take it for

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

The length of treatment with an antidepressant 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

1-2 weeks, but it can take up to 4-6 weeks to feel any real improvement.

Even when you feel well, you will usually have to take your medicine for several months or even longer to make sure the benefits will last.

Make sure you have enough to last over weekends and holidays.

Occasionally the symptoms of depression or other psychiatric conditions may include thoughts of harming yourself or committing suicide. It is possible that these symptoms may continue or increase until the full anti-depressant effect of your medicine becomes apparent (i.e. one to two months).

You or anyone close to you or caring for you should watch for these symptoms and tell your doctor immediately or go to the nearest hospital if you have any distressing thoughts or experiences during this initial period or at any other time.

Also contact your doctor if you experience any worsening of your depression or other symptoms at any time during your treatment.

If you forget to take it

If it is almost time to take your next dose, skip the missed dose and take your next dose at the usual time. Otherwise, take it as soon as you remember, and then go back to taking your medicine as you would normally.

Do not take a double dose to make up for missed doses.

This may increase the chance of unwanted side effects.

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

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If you take too much (overdose)

If you think that you or anyone else may have taken too much of this medicine, immediately telephone your doctor or the Poisons Information Centre (Tel: 13 11 26 in Australia) for advice. Alternatively go to the Accident and Emergency Department at your nearest hospital.

Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

If you take too much moclobemide, you may get nausea, vomiting, drowsiness, disorientation, memory loss, slurred speech, reduced reflexes, agitation, high blood pressure and/or convulsions (fits).

While you are taking this medicine

Things you must do

If you or someone you know or care for demonstrates any of the following warning signs of suicide-related behaviour

while taking moclobemide, contact a doctor immediately, or even go to the nearest hospital for treatment:

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

All mentions of suicide or violence must be taken seriously.

Tell your doctor that you are taking this medicine if:

- you are about to be started on any new medicine
- you plan to have any vaccinations or immunisations
- you become pregnant or plan to breastfeed (tell your doctor immediately)
- you are about to have any blood tests
- you are going to have surgery or an anaesthetic or are going into hospital.

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.

Tell your doctor if you feel the tablets are not helping your condition.

When you are being treated for depression, be sure to discuss with your doctor any problems you may have and how you feel.

This will help your doctor to determine the best treatment for you.

Your doctor may occasionally do tests to make sure the medicine is working and to prevent side effects. Go to your doctor regularly for a check-up.

Tell any other doctors, dentists and pharmacists who are treating you that you take this medicine.

Things you must not do

Do not give this medicine to anyone else, even if their symptoms seem similar to yours.

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

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

Things to be careful of

Be careful when driving or operating machinery until you know how this medicine affects you.

Moclobemide generally does not cause any problems with your ability to drive a car or operate machinery. However, as

with many other medicines, moclobemide may cause dizziness or tiredness in some people.

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

Possible side effects

Tell your doctor as soon as possible if you do not feel well while you are taking moclobemide or if you have any questions or concerns.

Do not be alarmed by the following lists of side effects. You may not experience any of them. All medicines can have side effects. Sometimes they are serious but most of the time they are not.

In the first week or two you may experience:

- sleep disturbances
- dizziness
- nausea
- headache
- nervousness
- 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 under 24 years of age.

Tell your doctor or if you notice any of the following:

This list includes the more common side effects and some rarer ones. Mostly, these are mild:

- insomnia
- disturbed sleep
- restlessness
- dizziness
- nausea
- headache or migraine
- anxiety or tense feelings
- feeling of confusion or being disoriented
- diarrhoea
- constipation
- feeling of fullness
- decreased appetite
- upset stomach, heartburn or stomach pain
- dry mouth

- blurred vision
- mild skin rash
- flushing or cold sensation
- changed taste sensation
- shaking or twitching
- forgetfulness
- feeling apathetic or tired
- numbness or tingling in the fingers
- ringing in the ears
- problems speaking
- trapped wind
- sore mouth or gums
- muscle or bone pain
- red, itchy eyes
- an urge to urinate or defecate

Tell your doctor immediately if you notice any of the following.

These may be serious side effects. You may need medical attention.

- change in the colour, frequency or volume of urine
- sight problems, seeing flashing lights
- troubled breathing
- high blood pressure
- slow heart beat
- hallucinations (seeing, feeling or hearing things that are not there)
- swollen veins
- dry skin, itchy skin or hives
- unusual vaginal bleeding, or prolonged menstruation.

If you or someone you know or care for experience any of the following, stop taking moclobemide and contact your doctor immediately or go to the Accident and Emergency department at your nearest hospital.

You may need urgent medical attention or hospitalisation.

- early signs of mania, such as sense of grandeur, hyperactivity (including increased speech), reckless and impulsive behaviour.
- 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.

All mentions of suicide or violence must be taken seriously.

- sudden increase in body temperature, agitation, shivering, severe convulsions
- fast heartbeat, sweating, muscle spasm, racing thoughts, restlessness
- angina or chest pain.

Other side effects not listed above may occur in some patients.

Allergic reactions

If you think you are having an allergic reaction to moclobemide, do not take any more of this medicine and tell your doctor immediately or go to the Accident and Emergency department at your nearest hospital.

Symptoms of an allergic reaction may include some or all of the following:

- cough, 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
- fainting
- hayfever-like symptoms.

Storage and disposal

Storage

Keep your tablets in their original packaging until it is time to take them.

If you take them out of their original packaging they may not keep well.

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

Do not store your medicine, 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 it has passed its expiry date, ask your pharmacist what to do with any medicine that is left over.

Product description

What Apo-Moclobemide looks like

150 mg tablets:

Pale yellow, oval, biconvex, film-coated tablets, scored on one side and engraved "APO" over "150" on the other.

300 mg tablets:

White, oval, biconvex, film-coated tablets, scored on one side and engraved "APO" over "300" on the other.

Available in blister packs of 60 tablets.

Ingredients

Each tablet contains 150 mg or 300 mg of moclobemide as the active ingredient.

The 150 mg tablets also contain the following inactive ingredients:

- dextrates
- croscarmellose sodium

- magnesium stearate
- colloidal anhydrous silica
- hypromellose
- polydextrose
- macrogol 3350
- titanium dioxide
- iron oxide yellow
- carnauba wax.

The 300 mg tablets also contain the following inactive ingredients:

- methylcellulose
- microcrystalline cellulose
- croscarmellose sodium
- magnesium stearate
- colloidal anhydrous silica
- hypromellose
- hyplosemacrogol 8000
- titanium dioxide.

This medicine is gluten-free, lactose-free, sucrose-free, tartrazine-free and free of other azo dyes.

Australian Registration Numbers

Apo-Moclobemide 150 mg tablets:

AUST R 73831.

Apo-Moclobemide 300 mg tablets:

AUST R 73835.

Sponsor

Apotex Pty Ltd

16 Giffnock Avenue

Macquarie Park NSW 2113.

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