

Moclobemide 150mg Tablets

Patient Information Leaflet

Please 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. 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.

Your medicine is called Moclobemide 150mg Tablets, but will be referred to as Moclobemide throughout the rest of this leaflet. Please note that the leaflet also contains information about another strength of the medicine, Moclobemide 300mg Tablets.

What is in this leaflet:

- 1 What Moclobemide is and what it is used for
- 2 What you need to know before you take Moclobemide
- 3 How to take Moclobemide
- 4 Possible side effects
- 5 How to store Moclobemide
- 6 Contents of the pack and other information
- 7 More information about your condition

1 What Moclobemide is and what it is used for

Moclobemide contains a medicine called moclobemide. This belongs to a group of medicines called antidepressants. Moclobemide is used to treat depression and social phobia. For further information about these conditions, see Section 7. Moclobemide works by increasing the levels of important chemical messengers in your brain. This increase can help your depression or social phobia.

2 What you need to know before you take Moclobemide

Do not take Moclobemide if:

- * You are allergic to moclobemide or any of the other ingredients of this medicine (listed in Section 6).
- * You have a severe mental problem which may make you confused, lose contact with reality or become unable to think and judge clearly.
- * You have a growth on one of your adrenal glands (phaeochromocytoma).
- * You are taking or have recently stopped taking any other medicines to treat your depression or anxiety, such as fluoxetine, paroxetine or clomipramine. See the section 'Taking other medicines'.
- * You are taking dextromethorphan, which is found in many cough medicines. See the section 'Taking other medicines'.
- * You are taking pethidine (for pain relief). See the section 'Taking other medicines'.
- * You are taking selegiline (for Parkinson's disease). See the section 'Taking other medicines'.

Children

- * Moclobemide is not suitable for children or adolescents

Do not take Moclobemide if any of the above applies to you. If you are not sure, talk to your doctor or pharmacist before taking Moclobemide.

Take special care with Moclobemide

Check with your doctor or pharmacist before taking Moclobemide if:

- * You have a 'bi-polar disorder', sometimes called manic depression.
- * You have ever thought about, or tried to harm or kill yourself.
- * You have an overactive thyroid.
- * You have serious liver disease.
- * You require pain relief with buprenorphine. The use of buprenorphine together with Moclobemide can lead to serotonin syndrome, a potentially life-threatening condition (see "Possible side effects").

If any of the above apply to you, or if you are not sure, talk to your doctor or pharmacist before you take Moclobemide.

Thoughts of suicide and worsening of your depression or anxiety disorder

If you are depressed and/or have anxiety disorders you can sometimes have thoughts of harming or killing yourself. These may be increased when first starting antidepressants, since these medicines all take time to work, usually

about two weeks but sometimes longer. You may be more likely to think like this if:

- * You have previously had thoughts about killing or harming yourself.
- * You are a young adult. Information from clinical trials has shown an increased risk of suicidal behaviour in adults aged less than 25 years with psychiatric conditions who were treated with an antidepressant. If you have thoughts of harming or killing yourself at any time, **contact your doctor or go to a hospital straight away.**

You may find it helpful to tell a relative or close friend that you are depressed or have an anxiety disorder, and ask them to read this leaflet. You might ask them to tell you if they think your depression or anxiety is getting worse, or if they are worried about changes in your behaviour.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines that you buy without a prescription and herbal medicines. This is because Moclobemide can affect the way some medicines work. Also some other medicines can affect the way Moclobemide works.

Do not take Moclobemide, and tell your doctor or pharmacist, if you are taking the following:

- * Other medicines for your depression or anxiety, such as fluoxetine, bupropion, paroxetine or clomipramine
- * Buprenorphine
- * Dextromethorphan, which is found in many cough medicines
- * Pethidine (for pain relief)
- * Selegiline (for Parkinson's disease)
- * Triptans (for migraines)
- * Tramadol (for pain relief)
- * Linezolid (for the treatment of infections)
- * St John's Wort (for anxiety)

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

- * Cimetidine (used to treat stomach ulcers and acid indigestion or reflux).
- * Ephedrine, pseudoephedrine and phenylpropanolamine, found in many cough and cold medicines.
- * Morphine, Codeine or fentanyl (for pain relief).

Taking Moclobemide with food and drink

Do not eat large quantities of foods containing tyramine when you are taking Moclobemide. These include:

- * Mature cheese
- * Yeast extract
- * Fermented soya bean products.

If you are not sure about this talk to your doctor or pharmacist before you take Moclobemide.

Pregnancy and breast-feeding

Do not take Moclobemide if you are pregnant, trying to get pregnant or are breast-feeding, unless your doctor has told you to.

Driving and using machines

The medicine can affect your ability to drive as it may make you sleepy or dizzy.

- * Do not drive while taking this medicine until you know how it affects you.
- * It is an offence to drive if this medicine affects your ability to drive.
- * However, you would not be committing an offence if:
 - The medicine has been prescribed to treat a medical or dental problem and
 - You have taken it according to the instructions given by the prescriber or in the information provided with the medicine and
 - It was not affecting your ability to drive safely

Talk to your doctor or pharmacist if you are not sure whether it is safe for you to drive while taking this medicine.

Moclobemide contains lactose and sodium

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

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3 How to take Moclobemide

Always take Moclobemide exactly as your doctor has told you. You should check with your doctor if you are not sure.

Moclobemide is not suitable for children or adolescents.

Take your tablets at the end of a meal. Swallow each tablet with a drink of water.

Moclobemide 150mg Tablets

Patient Information Leaflet (continued)

Depression:

- * The usual starting dose is 300 mg a day, split into two-three doses.
- * Your doctor will adjust the dose up or down to find the right dose for you.
- * The maximum dose is 600 mg a day.

Social phobia:

- * The usual starting dose is 150 mg twice a day for three days.
- * Your doctor will increase the dose to 300 mg twice a day.

People with severe liver disease:

Your doctor will decide the right dose for you. This will usually be lower than the doses stated above.

If you take more Moclobemide than you should

If you take more Moclobemide than you should or someone else takes your medicine by mistake, talk to a doctor or go to a hospital straight away. Take the medicine pack with you.

If you forget to take Moclobemide

- * If you forget to take a dose, take it as soon as you remember.
- * If it is nearly time for the next dose, skip the missed dose.
- * Do not take a double dose to make up for a forgotten dose.

If you stop taking Moclobemide

Even when you start to feel better, you should keep taking your tablets for as long as your doctor tells you to.

Do not stop taking this medicine without talking to your doctor first.

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

4 Possible side effects

Like all medicines Moclobemide can cause side effects, although not everyone will get them.

Some side effects could be serious. If you have any of the side effects listed below, stop taking this medicine and seek urgent medical advice:

- * swelling of your throat, face, lips and mouth. This may make it difficult to breathe or swallow.
- * sudden swelling of your hands, feet or ankles.
- * A raised, itchy skin rash (hives), itchy skin or flushing.

Other side effects include the following, if they get serious, please tell your doctor:

Very common (affects more than 1 in 10 people):

- * Trouble sleeping
- * Headache
- * Feeling dizzy
- * Dry mouth
- * Feeling sick

Common (affects 1 in 100 people):

- * Feeling nervous, twitchy (restless), anxious or bad-tempered (irritable)
- * Pins and needles or numbness of your hands and feet
- * Low blood pressure (hypotension)
- * Being sick
- * Diarrhoea
- * Constipation

Uncommon (affects 1 in 1,000 people):

- * Thoughts about killing yourself
- * Feeling confused and lost (disorientated)
- * Loss of taste in your mouth
- * Changes to your eyesight (vision)
- * Swelling (fluid retention)
- * Feeling weak or tired

Rare (affects 1 in 10,000 people):

- * Loss of appetite
- * Not enough sodium in your blood. Signs of this may be feeling sleepy, confused or having fits (seizures)
- * Attempting to kill yourself
- * Delusion
- * Serotonin syndrome, you may experience symptoms such as involuntary, rhythmic contractions of muscles, including the muscles that control movement of the eye, agitation, hallucinations, coma, excessive sweating, tremor, exaggeration of reflexes, increased muscle tension, body temperature above 38 °C, irregular heartbeat, losing consciousness or having fits (seizures). Contact your doctor when experiencing such symptoms.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5 How to store Moclobemide

- * KEEP OUT OF THE SIGHT AND REACH OF CHILDREN.
- * Moclobemide tablets do not need any special storage conditions.
- * Store in the original package.
- * Do not use Moclobemide after the expiry date printed on the pack.
- * If your doctor tells you to stop taking this medicine, take any remaining medicine back to the pharmacist for safe disposal. Only keep this medicine if your doctor tells you to.
- * If your medicine becomes discoloured or shows any other signs of deterioration, ask your pharmacist who will advise you what to do.
- * 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 Contents of the pack and other information

What Moclobemide contains:

The active substance in Moclobemide tablets is moclobemide.

Each film-coated tablet contains 150mg of moclobemide.

Sodium Content: not more than 0.052 mmol/tablet

The other ingredients are: lactose monohydrate, corn starch, povidone, sodium carboxymethyl starch, magnesium stearate, ethylcellulose, macrogol 6000, hypromellose, talc, titanium dioxide (E171) and yellow iron oxide (E172).

What Moclobemide looks like and contents of the pack

Moclobemide tablets are oval, pale yellow tablets with a score mark on one side and 150 on the reverse side.

Each pack contains 30 film-coated tablets.

Manufacturer and Licence Holder

This medicine is manufactured by Mylan Hungary Kft. H-2900 Komárom, Mylan utca 1, Hungary and is procured from within the EU and repackaged by the Product Licence Holder: Lexon (UK) Limited, Unit 18, Oxleasow Road, East Moons Moat, Redditch, Worcestershire, B98 0RE.

If you have any questions or are not sure about anything, ask your doctor or pharmacist. They will have additional information about this medicine and will be able to advise you.

POM PL 15184/1476 Moclobemide 150mg Tablets

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Blind or partially sighted?
Is this leaflet hard to see or read?
Phone Lexon (UK) Limited,
Tel: 01527 505414 to obtain the leaflet
in a format suitable for you

7 More Information about your condition

What is depression?

The signs of this problem (condition) can include extreme feelings of sadness, low mood, tearfulness, worry, changes in sleep pattern (such as difficulty sleeping) or difficulty enjoying life as you used to. If these feelings affect your everyday life or last for a long time it is important to get help from your doctor. Depression is a common medical problem affecting around one in four women and one in ten men at some time in their lives.

What is social phobia?

Social phobia is a common medical problem that can affect both men and women. The signs of this condition are an extreme fear of being seen doing something embarrassing or humiliating. This can cause problems even when taking part in simple social activities such as eating, drinking, speaking, meeting people and going to parties. People with this condition will be too afraid to take part in social occasions.