

Patient Information Leaflet

Manerix® 150 mg and 300 mg film-coated Tablets

Moclobemide

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

1. What Manerix is and what it is used for

Manerix contains a medicine called moclobemide. This belongs to a group of medicines called antidepressants. Manerix is used to treat depression and social phobia. For further information about these conditions, see Section 7.

Manerix 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 Manerix

Do not take Manerix 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

- Manerix is not suitable for children or adolescents

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

Take special care with Manerix

Check with your doctor or pharmacist before taking Manerix if:

- You have a ‘bi-polar disorder’, sometimes call manic depression.
- You have ever thought about, or tried to harm or kill yourself.
- You have an overactive thyroid.
- You have serious liver disease.

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

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 Manerix can affect the way some medicines work. Also some other medicines can affect the way Manerix works.

Do not take Manerix, 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.
- 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 Manerix with food and drink

Do not eat large quantities of foods containing tyramine when you are taking Manerix. 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 Manerix.

Pregnancy and breast-feeding

Do not take Manerix if you are pregnant, trying to get pregnant or are breastfeeding, 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.

Manerix 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 Manerix

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

Manerix is not suitable for children or adolescents.

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

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 Manerix than you should

If you take more Manerix 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 Manerix

- 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 Manerix

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 Manerix can cause side effects, although not everyone 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 breath 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 Signs of this may be High fever, irregular heartbeat, losing consciousness or having fits (seizures)

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 Manerix

- Manerix tablets do not need any special storage conditions.
- Keep out of the sight and reach of children.
- Do not use Manerix after the expiry date printed on the pack.
- 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 Manerix contains

The active substance in Manerix tablets is moclobemide. The tablets come in two different strengths:

- Manerix 150 mg tablets – each tablet contains 150 mg (milligrams) of moclobemide.
- Manerix 300 mg tablets – each tablet contains 300 mg (milligrams) of moclobemide.

Other ingredients in both tablets are: lactose, maize starch, povidone K30, sodium starch glycollate, magnesium stearate, hypromellose, ethylcellulose, polyethylene glycol 6000, talc and titanium dioxide (E171). The 150 mg tablets also contain yellow iron oxide (E172).

What Manerix looks like and contents of the pack

Manerix 150 mg tablets are oval and pale yellow in colour. They have a score line on one side and are marked 150 on the other.

Manerix 300 mg tablets are oval and white to off-white in colour. They have a score line on one side and are marked 300 on the other.

Manerix is supplied in blister packs containing either 28, 30, 60, 84 or 100 tablets. Not all pack sizes may be marketed.

The Marketing Authorisation holder is:

Mylan Products Ltd. Station Close, Potters Bar, Hertfordshire, EN6 1TL, United Kingdom

The manufacturer responsible for batch release is:

MEDA Pharma GmbH & Co. KG, Benzstrasse 1, 61352 Bad Homburg, Germany

Cenexi S.A.S. 52, rue Marcel et Jacques Gaucher, 94120 Fontenay-sous-Bois, France

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.

This leaflet was last revised in 09/2020

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