Manerix®
150 mg and 300 mg film-coated Tablets
Moxolide

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 though 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 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 moxolide. 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 6.

Manerix works by increasing the levels of important chemicals 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 moxolide 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 (pheochromocytoma).
- You are taking or have recently stopped taking any other medicines to treat your depression or anxiety, such as fluoxetine, paroxetine or domperidone. See the section "Taking other medicines".
- You are taking desmethylmorphine, which is found in many cough medicines.
- You are taking sedative (for Parkinson's disease).
- You are taking antacid (for Parkinson's disease).
- You are taking cyproheptadine (for anxiety).
- You are taking theophylline (for asthma).
- You are taking antacid (for Parkinson's disease).
- You are taking theophylline (for asthma).

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 bipolar 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.

If you are not sure about this talk to your doctor or pharmacist before taking Manerix.

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.

Important information about some of the ingredients of Manerix
This medicine contains lactose, which is a type of sugar. If you have been told by your doctor that you cannot tolerate or digest some sugars (have an intolerance to some sugars), talk to your doctor before taking this medicine.

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 or 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 your 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 make 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.

6. POSSIBLE SIDE EFFECTS:
Like all medicines Manerix can cause side effects, although not everyone will get them.
- Some side effects can 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 (twitches), anxious or bad-tempered (irritable)
- Pins and needles or numbness of your hands and feet.
- Low blood pressure (hypotension).
- Loss of taste in your mouth.
- Changes to your eyesight (vision).
- Swelling (fluid retention).
- Feel faint 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.
- The symptoms during this condition are usually 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.
- 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 waste-water or household waste. Ask your pharma-
cist 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 mianserimide. The tablets come in two different strengths:
  - Manerix 150 mg tablets—each tablet contains 150 mg (milligrams) of mianserimide.
  - Manerix 300 mg tablets—each tablet contains 300 mg (milligrams) of mianserimide.
- Other ingredients in both tablets are: lactose, maize starch, preacid K35, sodium starch gly-
celate, magnesium stearate, hypromellose, ethylcellulose, polyethylene glycol 6000, and titaniu-
um dioxide (E171). The 150 mg tablets also contain yellow iron oxide (E172).
- 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, 56, 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:
MDE Pharma GmbH & Co, KG
Bavariastraße 1
61352 Bad Homburg, Germany

Cenevi S.A.S.
52, rue Marcel et Jacques Gauhar
94120 Fontenay-Saint-Cloud 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 (as difficulty sleeping) or difficulty enjoying life as you used to. If these feelings affect your everyday life for last for a long time it is important to get help from your doctor. Depression is a common medical problem affecting many people 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 02/2018.
Manerix is a registered trade mark.
<table>
<thead>
<tr>
<th>Specification Box: Leaflet</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Manufacturer:</strong> Meda Pharma GmbH &amp; Co. KG</td>
</tr>
<tr>
<td><strong>Product:</strong> Aurenix (Manerix) 150 + 300 mg</td>
</tr>
<tr>
<td><strong>Material No.:</strong> MSAUK1953226-01</td>
</tr>
<tr>
<td><strong>MFS-No.:</strong> 28052115</td>
</tr>
<tr>
<td><strong>Pharmacode:</strong> 28052115</td>
</tr>
<tr>
<td><strong>Pack Size:</strong> 125 x 315 mm</td>
</tr>
<tr>
<td><strong>Font Size:</strong> 8.0 pt / 9.0 pt</td>
</tr>
<tr>
<td><strong>Colours Used:</strong> Black</td>
</tr>
<tr>
<td><strong>Country:</strong> United Kingdom UK</td>
</tr>
<tr>
<td><strong>Language:</strong> English</td>
</tr>
<tr>
<td><strong>Correction:</strong> 1.</td>
</tr>
<tr>
<td><strong>Date:</strong> 05. 03. 2018</td>
</tr>
</tbody>
</table>