

Package leaflet:
Information for the user

Manerix

150mg film-coated Tablets

Moclobemide

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.

The name of your medicine Manerix 150mg Film-coated Tablets, which will be called Manerix Tablets throughout this leaflet.

What is in this leaflet:

1. What Manerix tablets are and what they are used for
2. What you need to know before you take Manerix tablets
3. How to take Manerix tablets
4. Possible side effects
5. How to store Manerix tablets
6. Contents of the pack and other information

1. What Manerix tablets are and what they are used for

Manerix tablets contain the active ingredient moclobemide which belongs to a group of medicines called monoamine oxidase inhibitors. Manerix tablets are used for the treatment of moderate or severe depression.

2. What you need to know before you take Manerix tablets.

Do not take Manerix tablets:

- If you are taking pethidine (a painkiller)
- If you are taking selegiline (a treatment for Parkinson's disease)
- If you are taking bupropion (an antidepressant)
- If you are taking medicines for severe headaches (triptans)

- If you are taking tramadol
- If you are taking dextromethorphan (cough suppressant)
- If you are taking linezolid (an antibiotic)
- If you are suffering from confusion
- If you are allergic to moclobemide or any of the other ingredients of this medicine (listed in section 6). An allergic reaction may include rash, itching, difficulty breathing or swelling of the face, lips, throat or tongue.

Manerix tablets should not be taken by children.

Warnings and precautions

Talk to your doctor or pharmacist before taking Manerix tablets:

- If you develop drowsiness, confusion or have a fit
- If you become excited or agitated
- If you have epilepsy
- If you have schizophrenia
- If you have thyrotoxicosis (an overactive thyroid)
- If you have a phaeochromocytoma (a rare tumour of the adrenal gland)
- If you are hypersensitive, e.g. prone to rashes or swellings
- If you have liver disease
- If you have bipolar disorder (periods both of depression and very good or excited mood)
- If you have been told by your doctor that you are a poor metaboliser of mephenytoin
- If you have suicidal thoughts or thoughts of harming yourself

You should avoid large amounts of food rich tyramine such as aged cheese, smoked foods and alcohol- these may cause high blood pressure.

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.
- If you are a young adult. Information from clinical trials has shown increased risk of suicidal behaviour in adults ages 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.

Children

Manerix tablets not recommended for use in children

Other medicines and Manerix tablets

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. If you take these tablets with some other medicines, the effect of these tablets or the other medicine may be changed. Tell your doctor or pharmacist if you are taking:

- Tricyclic antidepressants (e.g. trimipramine, maprotiline)
- Any other antidepressants and selective serotonin reuptake inhibitors such as clomipramine, citalopram, sertraline, venlafaxine, fluvoxamine, escitalopram, paroxetine, bupropion
- Proton pump inhibitors (e.g. omeprazole), Mephenytoin (a treatment for epilepsy)
- Opiates (painkillers such as oxycodone or methadone)
- Cimetidine (a treatment for stomach or duodenal ulcers)
- Buspirone (used to treat anxiety)
- Dextropropoxyphene (an opioid analgesic)
- St Johns wort

It may still be all right for you to be given Manerix tablets and your doctor will be able to decide what is suitable for you.

Manerix tablets with food, drink and alcohol

It is advisable not to drink too much alcohol while taking Manerix tablets. Drink alcohol only in moderation.

You should avoid large amounts of food rich in tyramine such as aged cheese and smoked foods while taking Manerix tablets. These may cause high blood pressure.

Pregnancy and breast-feeding

If you are pregnant or you think you may be pregnant, you should inform your doctor who will decide whether or not you should be given Manerix tablets. Manerix may get into breast milk. If you are breast-feeding you should discuss options with your doctor. If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines

There is no evidence that Manerix tablets affect the ability to drive or use machines. You should check yourself especially during treatment.

Manerix tablets contain lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking Manerix tablets.

3. How to take Manerix tablets

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. The tablets should be taken at the end of a meal.

The usual doses are as follows:

Adults and the elderly

The usual dose is 300mg in two to three divided doses daily. The maximum dose is 600mg daily. The dose might be reduced by the doctor after four weeks.

The treatment should be continued until the patient has been free of symptoms for four to six months and then gradually tapered off.

Patients with liver disease or taking certain drugs e.g. cimetidine, may require a reduced dose.

If you take more Manerix tablets than you should

Contact your doctor immediately. Signs of overdose are increasing agitation, aggressiveness, and changes in behaviour.

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

All medicines can cause allergic reactions, although serious allergic reactions are very rare. Tell your doctor straight away if you get any sudden wheeziness, difficulty in breathing, swelling of the eyelids, face or lips, rash or itching (especially affecting your whole body).

The following side effects have been reported:

Very common side effects: sleep disorders, dizziness, headache, dry mouth, nausea,

Common side effects: agitation, anxiety, restlessness, paraesthesia, hypotension, vomiting, diarrhoea, constipation, rash, irritability

Uncommon side effects: Dysgeusia, visual impairment, flushing, oedema (swelling), pruritus (itching), urticaria (nettle rash), asthenia, suicidal ideation, confusional state

Rare side effects: serotonin syndrome, increased hepatic enzymes, decreased appetite, hyponatraemia, suicidal behaviours, delusion

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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Manerix tablets

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton after "EXP". The expiry date refers to the last day of that month.

Manerix tablets require no special storage conditions.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. Their measure will help protect the environment.

6. Contents of the pack and other information.

What Manerix tablets contain

Each tablet contains 150mg of the active ingredient moclobemide. The other ingredients are: maize starch, lactose, magnesium stearate, povidone and sodium starch glycolate (Type A)

Film coating; hypromellose, ethylcellulose, macrogol 6000, talc, titanium dioxide (E171), yellow iron oxide (E172).

What Manerix tablets look like and contents of the pack

Manerix oblong pale yellow tablets with '150' printed on one face, scored on the reverse. Manerix are supplied in blister packs of 28, 30, 84, and 100 tablets. Not all packs may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

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