PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S5

PROPRIETARY NAME AND DOSAGE FORM

LANTANON® 10 mg Tablets

LANTANON® 30 mg Tablets

Read all of this leaflet carefully before you start taking LANTANON.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or pharmacist.
- LANTANON has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

WHAT LANTANON CONTAINS

Each LANTANON 10 mg tablet contains as active ingredient 10 mg mianserin hydrochloride.

Each LANTANON 30 mg tablet contains as active ingredient 30 mg mianserin hydrochloride.

Inactive ingredients: Potato starch, Aerosil, magnesium stearate, methyl cellulose, calcium hydrogen phosphate.

Film-coating solution: macrogol, titanium dioxide, hypromellose.

WHAT LANTANON IS USED FOR

LANTANON belongs to a group of medicines known as antidepressants. LANTANON Tablets alleviate depressed mood, which is the most common characteristic of depression. In general it may take up to 4 weeks before you experience an improvement.

BEFORE YOU TAKE LANTANON

Do not take LANTANON

LANTANON may not be suitable for you if you suffer from certain other medical conditions. Before you start to take LANTANON, make sure you tell your doctor if the answer is “YES” to any of the following questions:

- Do you suffer from mania (state of elation and overactivity)?
- Do you suffer from liver disease?
- Are you allergic to any of the ingredients in this medicine?
- Are you on treatment with a class of medicines called monoamine oxidase inhibitors (MAO-inhibitors)?

LANTANON is not intended for use in children and adolescents under the age of 18 years.

Take special care with LANTANON

Use in children and adolescents under 18 years of age

LANTANON should not be used for children and adolescents under 18 years. Patients under 18 have an increased risk of side effects such as suicide attempt, suicidal thoughts and hostility (predominantly aggression, oppositional behaviour and anger) when they take LANTANON. Also, the long-term safety effects concerning growth, maturation and cognitive and behavioural development of LANTANON in this age group have not been demonstrated.

Thoughts of suicide and worsening of your depression

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 LANTANON, since LANTANON takes time to work, usually about 2 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 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.

Medical checks may be necessary in some conditions. Therefore, tell your doctor if you have or have ever had:

- epilepsy (seizures)
- diabetes
- liver disease such as jaundice
- kidney disease
- problems in urinating due to enlarged prostate
- heart disease, including certain kinds of heart conditions that change your heart rhythm, a recent heart attack, heart failure, or taking certain medicines known to change heart rhythm.
- blood pressure problems

- glaucoma (increased pressure in the eye)
- psychiatric diseases such as schizophrenia or manic depression (alternating periods of elation/overactivity and depressed mood).

Taking LANTANON with food and drink

The tablets should be swallowed with some water without chewing. It may be taken with food and drink.

Do not take alcoholic drinks during treatment with LANTANON, because LANTANON can enhance the effect of alcohol.

Pregnancy and breastfeeding

If you are pregnant, or think that you may be pregnant **or if you are breastfeeding**, do not take LANTANON without asking your doctor first.

If you are using LANTANON and become pregnant, ask your doctor whether you may continue taking LANTANON.

Driving and using machinery

LANTANON may cause drowsiness, which may influence the ability to drive or use machines.

Using other medicines with LANTANON

- If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of LANTANON with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or healthcare professional for advice.

- Medicines that may affect the heart rhythm such as certain antibiotics and some antipsychotics.

Do not take LANTANON in combination with:

- **monoamine oxidase inhibitors** (MAO-inhibitors). Also, do not take LANTANON during the 2 weeks after you have stopped taking MAO-inhibitors. If you stop taking LANTANON, do not take MAO-inhibitors during the next 2 weeks either.

Take care when taking LANTANON in combination with:

- **medicines for epilepsy** such as carbamazepine and phenytoin.
- **medicines to prevent blood clotting** such as warfarin.

LANTANON can increase the effects of warfarin on the blood. Inform your doctor if you are using this medicine. In case of combination, it is advised that a doctor monitors your blood carefully.

Alcohol

Do not take alcoholic drinks during treatment with LANTANON as LANTANON can enhance the effect of alcohol.

HOW TO TAKE LANTANON

LANTANON Tablets should only be taken according to the dose and directions prescribed by your doctor. You should also read the instructions on the label of your medicine. If you are not sure how to take these medicines, ask your doctor or pharmacist.

If you have the impression that the effect of LANTANON is too strong or too weak, talk to your doctor or pharmacist.

Children

LANTANON should not be given to children and adolescents under the age of 18 years.

Adults

Your doctor will decide on the correct dose for you. The dosage depends on the severity of your conditions and your response. In general you will start with a low dose (30 mg per day), which may then be gradually increased by the doctor to the most effective daily dose. For successful treatment it is very important that you take your tablet(s) every day.

The tablet(s) should be taken at the same time each day, preferably as a single night time dose before going to bed. If recommended by your doctor, LANTANON may be taken in equally divided doses over the day (once in the morning and once at night time before going to bed).

Swallow the tablet(s), without chewing, together with some water or other fluid.

Do not stop taking LANTANON just because your complaints seem to have disappeared. If you stop too early or too suddenly your condition may worsen. Always discuss your treatment with your doctor who will tell you how to reduce the dose gradually if treatment can be stopped.

If you take more LANTANON than you should

- In the event of overdosage, consult your doctor or pharmacist. If neither is available, seek help at the nearest hospital or poison control centre.
- The symptoms of a possible overdose may include changes to your heart rhythm (fast, irregular heartbeat) and/or fainting which could be symptoms of a life-threatening condition known as Torsades de Pointes.

If you forget to take LANTANON

- If you are supposed to take your **once-daily** dose before going to bed and you forget to do so, **do not** take the missed dose the next morning, because it may cause drowsiness or sleepiness during the day. Continue treatment in the evening with your normal dose.
- If you are supposed to take tablets **twice a day** (once in the morning after breakfast and once in the evening at bedtime) and if you have forgotten to take one or both doses:
  - If you forget your **morning dose**, simply take it together with your evening dose
  - If you forget your **evening dose**, do **not** take it with the next morning dose; continue treatment with your normal morning and evening doses
  - If you have forgotten **both doses**, you should **not** attempt to make up for the missed tablets; the next day you should continue with your normal morning and evening doses.

POSSIBLE SIDE EFFECTS

In general

This medicine may cause side effects such as:

- drowsiness or sleepiness.
- weight gain.
- thoughts of harming or killing yourself.

  Contact your doctor or go to a hospital straight away.

In some cases LANTANON can cause a shortage of white blood cells, resulting in a lowering of the body resistance to infection. If you get a fever, sore throat, mouth ulcers or other signs of infection during use of LANTANON, you should immediately contact your doctor and have your blood checked. These symptoms mostly appear after 4 to 6 weeks of treatment and are in general reversible after termination of treatment with LANTANON.

Other possible effects are

- low blood pressure, marked by dizziness, light-headedness or fainting, especially when you get up quickly
- epileptic attacks (seizures)
- hypomania (abnormal mood resembling mania but of lesser intensity)
- swollen ankles or feet as a result of fluid accumulation (oedema)
- yellow colouring of eyes or skin; this may suggest disturbance in liver function
- pain in the joints
- restlessness (e.g. continual movement/shaking of the legs)
- rash
- breast development in men
- vomiting
- dilated pupils
- coordination problems e.g. difficulty walking, swallowing, speaking (ataxia)
- changes to your heart rhythm (fast, irregular heartbeat) and/or fainting which could be symptoms of a life-threatening condition known as Torsades de Pointes.

Tell your doctor if any side effect becomes troublesome or persists. It is also important to tell your doctor or pharmacist if you experience other unusual or unexpected symptoms during treatment with LANTANON.

Not all side effects reported for this medicine are included in this leaflet. Should your general health worsen while taking this medicine, please consult your doctor, pharmacist or other healthcare professional for advice.

STORING AND DISPOSING OF LANTANON

Keep your LANTANON Tablets in the original package in a safe place out of the reach of children. Check if there are special storage conditions given on the carton. The expiry date (sometimes written as "EXP.:") is also printed on the strip of tablets - do not use after this date.

- LANTANON should be stored at or below 30 °C and protected from light.
- Return unused medicines to your pharmacist for proper disposal.

PRESENTATION OF LANTANON

LANTANON 10 mg: Press-through strips with 30 and 90 tablets.

LANTANON 30 mg: Press-through strips with 40 tablets.

IDENTIFICATION OF LANTANON

LANTANON 10 mg: White, round and biconvex film-coated tablets, CT above 4 on one side and ORGANON on the reverse side.

LANTANON 30 mg: White, oval and biconvex film-coated tablets, coded CT above 7 on both sides of the score on one side and Organon on the reverse side.

REGISTRATION NUMBERS

LANTANON 10 mg: J/1.2/64

LANTANON 30 mg: N/1.2/180

NAME AND ADDRESS OF THE REGISTRATION HOLDER

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