

Clean proposed patient information leaflet for LORDYNO**PATIENT INFORMATION LEAFLET****SCHEDULING STATUS****S2****LORDYNO, 10 mg, tablets****Loratadine****Contains sugar (69,175 mg lactose monohydrate per tablet)****Read all of this leaflet carefully because it contains important information for you**

LORDYNO is available without a doctor's prescription, for you to treat a mild illness.

Nevertheless, you still need to take LORDYNO carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share LORDYNO with any other person.
- Ask your health care provider or pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve.

What is in this leaflet

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

1. What LORDYNO is and what it is used for

LORDYNO contains loratadine which belongs to a class of medicines called antihistamines.

LORDYNO is indicated for the relief of the symptoms of

- perennial (symptoms are present throughout the year) and/or seasonal (symptoms are present during the spring and summer months) allergic rhinitis (inflammation of the nose), such as sneezing, runny or itchy nose and burning or itchy eyes
- chronic urticaria, such as itchy, raised, red or skin-coloured welts on your skin
- allergic skin disorders, such as itching, redness and swelling of areas on your skin.

2. What you need to know before you take LORDYNO

Do not take LORDYNO:

If you are hypersensitive (allergic) to loratadine or any of the other ingredients of LORDYNO (listed in section 6).

Warnings and precautions

Take special care with LORDYNO:

- if you are elderly, as the safety of LORDYNO in elderly patients has not been established
- if you have liver problems talk to your doctor before you take LORDYNO because you should take a lower dose of LORDYNO, either 5 mg daily or 10 mg every second day
- if your body mass increase while you take LORDYNO
- if you are scheduled for a skin allergy test, you should stop taking LORDYNO 48 hours (two days) before you must go for the skin allergy test.

Other medicines and LORDYNO

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

Tell your doctor or pharmacist if you are currently taking:

- cimetidine (used to treat heartburn)

- erythromycin, clarithromycin (used to treat bacterial infections)
- ketoconazole, fluconazole (used to treat fungal infections)
- quinidine (used to treat heart rhythm disorders)
- fluoxetine (used to treat depression).

LORDYNO with food and alcohol

LORDYNO can be taken with or without food.

LORDYNO does not add to the effects of an alcoholic drink.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking LORDYNO.

Driving and using machines

LORDYNO may cause side effects, such as dizziness and fits and can affect your ability to drive a vehicle and use machines (see section 4). It is not always possible to predict to what extent LORDYNO may interfere with your daily activities. You should ensure that you do not engage in these activities until you know how LORDYNO affects you.

LORDYNO contains lactose monohydrate

LORDYNO contains lactose monohydrate. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking LORDYNO.

3. How to take LORDYNO

Do not share your medicine with any other person.

Always take LORDYNO exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The usual dose is one (1) tablet daily, taken orally.

If you have the impression that the effect of LORDYNO is too strong or too weak, tell your doctor or pharmacist.

If you take more LORDYNO than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to take LORDYNO

If you have missed your dose by only a few hours, take the missed dose as soon as you remember. If it is almost time for your next dose, skip the missed dose and take LORDYNO at the next regularly scheduled time.

Do not take a double dose to make up for forgotten individual doses.

4. Possible side effects

LORDYNO can have side effects.

Not all side effects reported for LORDYNO are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking LORDYNO, please consult your health care provider for advice.

If any of the following happens, stop taking LORDYNO and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing
- rash or itching
- fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to

LORDYNO. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

Less frequent side effects:

- convulsions (fits)
- changes in the way your heart beats, for example, if you notice it beating faster or skipping beats
- yellowing of the skin and eyes and dark urine, which may be symptoms of liver problems.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Less frequent side effects:

- dizziness, headache
- drowsiness (sleepiness), nervousness
- nausea (feeling sick), dry mouth, stomach pain
- hair loss (temporary)
- tiredness.

Side effects that occur with unknown frequency:

- increased appetite and body mass (weight).

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the “Adverse Drug Reaction Reporting Form”, found online under SAHPRA’s publications: <https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can

help provide more information on the safety of LORDYNO.

5. How to store LORDYNO

- Store all medicines out of reach of children.
- Store at or below 25 °C.
- Protect from excessive moisture.
- Do not use after the expiry date printed on the carton.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What LORDYNO contains:

The active substance is 10 mg loratadine.

The other ingredients are colloidal anhydrous silica, lactose monohydrate, magnesium stearate and maize starch.

What LORDYNO looks like and contents of the pack

White, oval tablets, notched and coded LT/10 on one side (length: 7,5 to 7,9 mm and width: 4,9 to 5,3 mm).

LORDYNO is packed into white, opaque PVC/aluminium blister strips containing 10 tablets each.

Pack sizes: 10, 30 or 250 tablets per carton.

Not all pack sizes may be marketed.

Holder of Certificate of Registration:

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