

# 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:

Biotech Laboratories (Pty) Ltd  
Ground floor, Block K West, Central Park  
400 16<sup>th</sup> Road, Randjespark, Halfway House  
Midrand 1685

#### This leaflet was last revised in

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#### Registration number

35/5.7.1/0355

# LORDYNO

## PASIENT INLIGTINGSBLAD

### SKEDULERING STATUS

S2

LORDYNO 10 mg, tablette  
Loratadien  
Bevat suiker (69,175 mg laktose monohidraat per tablet)

### Lees hierdie blad noukeurig deur aangesien dit belangrike inligting bevat

LORDYNO is beskikbaar sonder 'n voorskrif van 'n dokter, vir jou om matige siekte te behandel. Nietemin moet jy steeds LORDYNO versigtig neem om die beste resultate daaruit te kry.

- Bewaar hierdie pamflet. Jy sal dit dalk weer moet lees.
- Moenie LORDYNO met enige ander persoon deel nie.
- Vra jou gesondheidsorgverskaffer of apteker as jy meer inligting of advies benodig.
- Jy moet 'n dokter sien as jou simptome vererger of nie verbeter nie.

### Wat hierdie blad bevat

1. Wat LORDYNO is en waarvoor dit gebruik word
2. Wat jy moet weet voordat jy LORDYNO neem
3. Hoe om LORDYNO te neem
4. Moontlike nuwe-effekte
5. Hoe om LORDYNO te bewaar
6. Inhoud van die pakkie en ander inligting.

### 1. Wat LORDYNO is en waarvoor dit gebruik word

LORDYNO bevat loratadien wat aan 'n klas medisyne behoort wat antihistamiene genoem word. LORDYNO word aangedui vir die verligting van die simptome van meerjarig (simptome is regdeur die jaar teenwoordig) en/of seisoenaal (simptome is teenwoordig gedurende die lente- en somermaande) allergiese rinitis (ontsteking van die neus), soos nie, loopneus of jeukerige neus en brandende of jeukerige oë

- chroniese urtikaria, soos jeukerige, opgehewe, rooi of velkleurige kolle op jou vel
- allergiese velafwykings, soos jeuk, rooiheid en swelling van areas op jou vel.

### 2. Wat jy moet weet voordat jy LORDYNO neem

#### Moet nie LORDYNO neem:

As jy hipersensitief (allergies) is vir loratadien of enige van die ander bestanddele van LORDYNO (gelys in afdeling 6).

### Waarskuwings en voorsorgmaatreëls

#### Wees veral versigtig met LORDYNO

- as u bejaard is, aangesien die veiligheid van LORDYNO by bejaarde pasiënte nie vasgestel is nie
- as jy lewerprobleme het, praat met jou dokter voordat jy LORDYNO neem omdat jy 'n laer dosis LORDYNO moet neem, óf 5 mg daaglik of 10 mg elke tweede dag
- as jou liggaamsmassa toeneem terwyl jy LORDYNO neem
- as jy geskeduleer is vir 'n velallergietoets, moet jy 48 uur (twee dae) ophou om LORDYNO te neem voordat jy vir die velallergietoets moet gaan

### Ander medisyne en LORDYNO

Vertel altyd jou gesondheidsorgverskaffer as jy enige ander medisyne gebruik. (Dit sluit alle komplementêre of tradisionele medisyne in.)

### Vertel jou dokter of apteker as jy tans:

- simetdien (gebruik om sooi-brand te behandel)
- eritromisien, klaritromisien (gebruik om bakteriële infeksies te behandel)
- ketokonasool, flukonasool (gebruik om swaminfeksies te behandel)
- kindien (gebruik om hartritmestoornisse te behandel)
- fluoksetien (gebruik om depressie te behandel).

### LORDYNO met kos en alkohol

LORDYNO kan met of sonder kos geneem word. LORDYNO dra nie by tot die effekte van 'n alkoholiese drankie nie.

### Swangerskap, borsvoeding en vrugbaarheid

As jy swanger is of borsvoed, dink jy is dalk swanger of beplan om 'n baba te hê, raadpleeg asseblief jou dokter, apteker of ander gesondheidsorgverskaffer vir advies voordat jy LORDYNO neem.

### Bestuur en gebruik van masjiene

LORDYNO kan nuwe-effekte veroorsaak, soos duiseligheid en aanvalle en kan jou vermoë om 'n voertuig te bestuur en masjiene te gebruik, beïnvloed (sien afdeling 4). Dit is nie altyd moontlik om te voorskop tot watter mate LORDYNO jou daaglikse aktiwiteite kan inmeng nie. Jy moet seker maak dat jy nie by hierdie aktiwiteite betrokke raak voordat jy weet hoe LORDYNO jou beïnvloed nie.

### LORDYNO bevat laktosemonohidraat

LORDYNO bevat laktosemonohidraat. As jou dokter jou meegeedeel het dat jy 'n onverdraagsaamheid teenoor sommige suikers het, kontak jou dokter voordat jy LORDYNO neem.

### 3. Hoe om LORDYNO te neem

Moenie jou medisyne met enige ander persoon deel nie. Neem altyd LORDYNO presies soos beskryf in hierdie pamflet of soos jou dokter of apteker vir jou gesê het. Praat met jou dokter of apteker as jy nie seker is nie. Die gewone dosis is een (1) tablet daaglik, mondelings ingeneem.

As jy die indruk het dat die effek van LORDYNO te sterk of te swak is, vertel jou dokter of apteker.

### As jy meer LORDYNO neem as wat jy behoort

In die geval van oordosis, raadpleeg jou dokter of apteker. Indien nie een beskikbaar is nie, kontak die naaste hospitaal of gifsentrum.

### As jy vergeet om LORDYNO te neem

As jy jou dosis net 'n paar uur gemis het, neem die gemiste dosis sodra jy onthou. As dit amper tyd is vir jou volgende dosis, slaan die gemiste dosis oor en neem LORDYNO op die volgende gereelde geskeduleerde tyd. Moenie 'n dubbeldosis neem om vergete individuele dosisse in te haal nie.

### 4. Moontlike nuwe-effekte

LORDYNO kan nuwe-effekte hê.

Nie alle nuwe-effekte wat vir LORDYNO aangemeld is, is in hierdie pamflet ingesluit nie. Indien jou algemene gesondheid versleg of as jy enige nadelige effekte ervaar terwyl jy LORDYNO neem, raadpleeg asseblief jou gesondheidsorgverskaffer vir advies.

### Indien enige van die volgende gebeur, hou op om LORDYNO te neem en vertel jou dokter dadelik of gaan na die ongevalle-afdeling by jou naaste hospitaal:

- swelling van die hande, voete, enkels, gesig, lippe, mond of keel, wat probleme kan veroorsaak om te sluk of asem te haal
- uitslag of jeuk
- flou word.

Dit is alles baie ernstige nuwe-effekte. As jy dit het, het jy dalk 'n ernstige reaksie op LORDYNO gehad. Jy mag dalk dringende mediese aandag of hospitalisasie benodig.

### Vertel jou dokter dadelik of gaan na die ongevalle-afdeling by jou naaste hospitaal as jy enige van die volgende opmerk:

#### Minder gereelde nuwe-effekte:

- stuiptrekkings (aanvalle)
- veranderinge in die manier waarop jou hart klop, byvoorbeeld as jy agterkom dat dit vinniger klop of slae oorsla
- vergeling van die vel en oë en donker urine, wat simptome van lewerprobleme kan wees.

Dit is alles ernstige nuwe-effekte. Jy mag dalk dringende mediese hulp benodig.

### Vertel jou dokter as jy enige van die volgende opmerk:

#### Minder gereelde nuwe-effekte:

- duiseligheid, hoofpyn
- lomerigheid (slaperigheid), senuweeagtigheid
- naarheid (siek voel), droë mond, maagpyn
- haarverlies (tydelik)
- moegheid.

#### Neuwe-effekte wat met onbekende frekwensie voorkom:

- verhoogde eetlus en liggaamsmassa (gewig).
- Indien u enige nuwe-effekte opmerk wat nie in hierdie pamflet genoem word nie, stel asseblief u dokter of apteker in kennis.

### Rapportering van nuwe-effekte

As jy nuwe-effekte kry, praat met jou dokter of apteker. Jy kan ook nuwe-effekte aan SAHPRA rapporteer via die **"Adverse Drug Reaction Reporting Form"**, wat aanlyn gevind word onder SAHPRA se publikasies: <https://www.sahpra.org.za/Publications/Index/8>. Deur nuwe-effekte aan te meld, kan jy help om meer inligting te verskaf oor die veiligheid van LORDYNO

### 5. Hoe om LORDYNO te bewaar

- Berg alle medisyne buite bereik van kinders.
- Berg by of benede 25 °C.
- Beskerm teen oormatige vog.
- Moet nie gebruik na die vervaldatum wat op die karton gedruk is nie.
- Gee alle ongebruikte medisyne terug aan u apteker.
- Moenie ongebruikte medisyne in dreine en rioolstelsels (bv. toilette) weggooi nie.

### 6. Inhoud van die pakkie en ander inligting

#### Wat LORDYNO bevat:

Die aktiewe bestanddeel is 10 mg loratadien. Die ander bestanddele is kolloïdale watervrye silika, laktosemonohidraat, magnesiumstearaat en mieliestysel.

### Hoe LORDYNO lyk en inhoud van die verpakking

Wit, ovaal tablette, gekerf en gekodeer LT/10 aan die een kant (lengte: 7,5 tot 7,9 mm en breedte: 4,9 tot 5,3 mm). LORDYNO word in wit, ondeursigtige PVC/aluminium blisterstroke verpak wat elk 10 tablette bevat. **Verpakkingsgroottes:** 10, 30 of 250 tablette per karton. Nie alle verpakkingsgroottes word altyd bemark nie.

### Houer van Registrasiesertifikaat:

Biotech Laboratories (Edms) Bpk  
Grondvloer, Blok K Wes, Central Park  
400 16<sup>de</sup> Weg, Randjiespark, Halfway House  
Midrand 1685

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