PACKAGE LEAFLET

PACKAGE LEAFLET
For medicinal products available on prescription

Package leaflet: Information for the user

Zyrlex 1 mg/ml oral lösning

Cetirizine dihydrochloride

Read all of this leaflet carefully before you start using 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. See section 4.

What is in this leaflet:

1. What <Invented name> is and what it is used for

Cetirizine dihydrochloride is the active ingredient of <Invented name>.
<Invented name> is an antiallergic medication.

In adults and children aged 2 years and above, <Invented name> 1 mg/ml oral solution is indicated
- for the relief of nasal and ocular symptoms of seasonal and perennial allergic rhinitis.
- for the relief of urticaria.

2. What you need to know before you take <Invented name>

Do not take <Invented name>
- if you have a severe kidney disease (severe renal failure with creatinine clearance below 10 ml/min);
- if you are allergic to cetirizine dihydrochloride or any of the other ingredients of this medicine (listed in section 6), to hydroxyzine or to any piperazine derivatives (closely related active ingredients of other medicines).

Warning and precautions
Talk to your doctor or pharmacist before taking <Invented name>.

If you are a patient with renal insufficiency, please ask your doctor for advice; if necessary, you will take a lower dose. The new dose will be determined by your doctor.

If you have problems passing urine (like spinal cord problems or prostate or bladder problems), please ask your doctor for advice.

If you are an epileptic patient or a patient at risk of convulsions, you should ask your doctor for advice.

No clinically significant interactions have been observed between alcohol (at the blood level of 0.5 per mille (g/l) corresponding to one glass of wine) and cetirizine used at the recommended doses.

However, there are no data available on the safety when higher doses of cetirizine and alcohol are taken together. Therefore, as it is the case with all antihistamines, it is recommended to avoid taking <Invented name> with alcohol.

If you are scheduled for allergy testing, ask your doctor if you should stop taking <Invented name> for several days before testing. This medicine may affect your allergy test results.

Other medicines and <Invented name>
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

<Invented name> with food and drink
Food does not affect absorption of <Invented name>.

Pregnancy and breast-feeding
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

<Invented name> should be avoided in pregnant women. Accidental use of the drug by a pregnant woman should not produce any harmful effects on the foetus. Nevertheless, the medicine should only be administered if necessary and after medical advice.

Cetirizine passes into breast milk. A risk of side effects in breastfed infants cannot be excluded. Therefore, you should not take <Invented name> during breast-feeding unless you have contacted a doctor.

Driving and using machines
Clinical studies have produced no evidence of impaired attention, alertness and driving capabilities after taking <Invented name> at the recommended dose.
You should closely observe your response to the drug after you have taken <Invented name> if you are intending to drive, engage in potentially hazardous activities or operate machinery. You should not exceed the recommended dose.

<Invented name> oral solution contains sorbitol
This medicine contains 4.5 g sorbitol in each 10 ml. Sorbitol is a source of fructose. If your doctor has told you that you (or your child) have an intolerance to some sugars or if you have been diagnosed with hereditary fructose intolerance (HFI), a rare genetic disorder in which a person cannot break down fructose, talk to your doctor before you (or your child) take or receive this medicine.
<Invented name> oral solution contains methylparahydroxybenzoate (E 218), propylparahydroxybenzoate (E 216) that may cause allergic reactions (possibly delayed).

<Invented name> oral solution contains sodium
This medicine contains 42 mg sodium (main component of cooking/table salt) in each 10 ml. This is equivalent to 2.1% of the recommended maximum daily dietary intake of sodium for an adult.

<Invented name> oral solution contains propylene glycol
This medicine contains 500 mg propylene glycol in each 10 ml.

3. How to take <Invented name>

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 solution can be swallowed as such.

Adults and adolescents above 12 years old:

The recommended dose is 10 mg once daily as 10 ml oral solution (2 full measuring spoons)

Use in children between 6 and 12 years old:
The recommended dose is 5 mg twice daily as 5 ml (one full measuring spoon) twice daily.

Use in children between 2 and 6 years old
The recommended dose is 2.5 mg twice daily as 2.5 ml oral solution (a half-measuring spoon) twice daily

Patients with renal impairment
Patients with moderate renal impairment are recommended to take 5 mg once daily.
If you suffer from severe kidney disease, please contact your doctor or pharmacist who may adjust the dose accordingly.
If your child suffers from kidney disease, please contact your doctor or pharmacist who may adjust the dose according to your child's needs.

If you feel that the effect of <Invented name> is too weak or too strong, please consult your doctor.

Duration of treatment
The duration of treatment depends on the type, duration and course of your complaints and is determined by your doctor.

If you take more <Invented name> than you should
If you think you have taken an overdose of <Invented name> please inform your doctor.
Your doctor will then decide what measures, if any, should be taken.

After an overdose, the side effects described below may occur with increased intensity. Adverse effects such as confusion, diarrhoea, dizziness, tiredness, headache, ailing, dilating of pupil, itching, restlessness, sedation, somnolence, stupor, abnormal rapid heart rate, tremors and urinary retention have been reported.

If you forget to take <Invented name>
Do not take a double dose to make up for a forgotten dose.

If you stop taking <Invented name>
Rarely, pruritus (intense itching) and/or urticaria may return if you stop taking <Invented name>.

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.

The following side effects are rare or very rare, but you must stop taking the medicine and speak to your doctor straight away if you notice them:
- Allergic reactions, including severe reactions and angioedema (serious allergic reaction which causes swelling of the face or throat).

These reactions may start soon after you first take the medicine, or it might start later.

Common side effects (may affect up to 1 in 10 patients)
- Somnolence (sleepiness)
- Dizziness, headache
- Pharyngitis, rhinitis (in children)
- Diarrhea, nausea, dry mouth
- Fatigue

Uncommon side effects (may affect up to 1 in 100 patients)
- Agitation
- Paresthesia (abnormal feelings of the skin)
- Abdominal pain
- Pruritus (itchy skin), rash
- Asthenia (extreme fatigue), malaise

Rare side effects (may affect up to 1 in 1,000 patients)
- Allergic reactions, some severe (very rare)
- Depression, hallucination, aggression, confusion, insomnia
- Convulsions
- Tachycardia (heart beating too fast)
- Liver function abnormal
- Urticaria (hives)
- Oedema (swelling)
- Weight increased

Very rare side effects (may affect up to 1 in 10,000 patients)
- Thrombocytopenia (low levels of blood platelets)
- Tics (habit spasm)
- Syncope, dyskinesia (involuntary movements), dystonia (abnormal prolonged muscular contractions), tremor, dysgeusia (altered taste)
- Blurred vision, accommodation disorder (difficulty focusing), oculogyration (eyes having uncontrolled circular movements)
- Angioedema (serious allergic reaction which causes swelling of the face or throat), fixed drug eruption
- Abnormal elimination of urine (bed wetting, pain and/or difficulty passing water)

Not known frequency of side effects (frequency cannot be estimated from the available data)
- Increased appetite
- Suicidal ideation (recurring thoughts of or preoccupation with suicide), nightmare
- Amnesia, memory impairment
- Vertigo (sensation of rotation or movement)
- Urinary retention (inability to completely empty the urinary bladder)
- Pruritus (intense itching) and/or urticaria upon discontinuation
- Joint pain
- Rash with blisters containing pus
- Hepatitis (inflammation of the liver)

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in Appendix V*. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store <Invented name>

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 box and bottle. The expiry date refers to the last day of that month.

Do not use after 3 months of first opening the bottle.

This medicine does not require any special storage conditions.

6. Contents of the pack and other information

What <Invented name> contains
- The active substance is cetirizine. 10 ml (equals to 2 measuring spoons) contain 10 mg of cetirizine dihydrochloride.
- The other ingredients are sorbitol (E 420), glycerol, propylene glycol, saccharin sodium, methylparahydroxybenzoate (E 218), propylparahydroxybenzoate (E 216), banana flavor 54.330/A (Firmenich), sodium acetate, glacial acetic acid, purified water.
- 10 ml <Invented name> oral solution (=2 measuring spoons) contain: 3.15 g glucose equivalents (sorbitol).

What <Invented name> looks like and contents of the pack
Clear and colorless liquid with slightly sweet taste and a banana flavor.

Pack with a bottle containing volumes of 60, 75, 100, 150, or 200 ml solution.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:
[To be completed nationally]
{Name and address}
{tel}
{fax}
{e-mail}

Manufacturer:
<Aesica Pharmaceuticals S.r.l., Via Praglia 15, I-10044 Pianezza (TO), Italy>
<UCB Pharma Limited, 208 Bath Road, Slough, Berkshire, SL1 3WE, United Kingdom>
<Phoenix Pharma Polska Sp. z o.o., ul. Oplotek 26, 01-940 Warsaw, Poland>
< Movianto Polska Sp. z o.o, ul. Artura i Franciszka Radziwiłłów 5,05-850 Ożarów Mazowiecki>

This leaflet was last revised in 2021-01-28.

[To be completed nationally]

PACKAGE LEAFLET
For medicinal products available without a prescription

Package leaflet: Information for the user

Zyrlex 1 mg/ml oral lösning

Cetirizine dihydrochloride

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you.
- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- 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.
- You must talk to a doctor if you do not feel better or if you feel worse after 3 days.

What is in this leaflet:

1. What <Invented name> is and what it is used for

Cetirizine dihydrochloride is the active ingredient of <Invented name>.
<Invented name> is an antiallergic medication.

In adults and children aged 2 years and above, <Invented name> 1 mg/ml oral solution is indicated
- for the relief of nasal and ocular symptoms of seasonal and perennial allergic rhinitis.
- for the relief of urticaria.

2. What you need to know before you take <Invented name>

Do not take <Invented name>
- if you have a severe kidney disease (severe renal failure with creatinine clearance below 10 ml/min);
- if you are allergic to cetirizine dihydrochloride or any of the other ingredients of this medicine (listed in section 6), to hydroxyzine or to any piperazine derivatives (closely related active ingredients of other medicines).

Warnings and precautions
Talk to your doctor or pharmacist before taking <Invented name>.

If you are a patient with renal insufficiency, please ask your doctor for advice; if necessary, you will take a lower dose. The new dose will be determined by your doctor.

If you have problems passing urine (like spinal cord problems or prostate or bladder problems), please ask your doctor for advice.

If you are an epileptic patient or a patient at risk of convulsions, you should ask your doctor for advice.

No clinically significant interactions have been observed between alcohol (at the blood level of 0.5 per mille (g/l) corresponding to one glass of wine) and cetirizine used at the recommended doses. However, there are no data available on the safety when higher doses of cetirizine and alcohol are taken together. Therefore, as it is the case with all antihistamines, it is recommended to avoid taking <Invented name> with alcohol.

If you are scheduled for allergy testing, ask your doctor if you should stop taking <Invented name> for several days before testing. This medicine may affect your allergy test results.

Other medicines and <Invented name>
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

<Invented name> with food and drink
Food does not affect absorption of <Invented name>.

Pregnancy and breast-feeding
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

<Invented name> should be avoided in pregnant women. Accidental use of the drug by a pregnant woman should not produce any harmful effects on the foetus. Nevertheless, the medicine should only be administered if necessary and after medical advice.

Cetirizine passes into breast milk. A risk of side effects in breastfed infants cannot be excluded. Therefore, you should not take <Invented name> during breast-feeding unless you have contacted a doctor.

Driving and using machines
Clinical studies have produced no evidence of impaired attention, alertness and driving capabilities after taking <Invented name> at the recommended dose.
You should closely observe your response to the drug after you have taken <Invented name> if you are intending to drive, engage in potentially hazardous activities or operate machinery. You should not exceed the recommended dose.

<Invented name> oral solution contains sorbitol
This medicine contains 4.5 g sorbitol in each 10 ml. Sorbitol is a source of fructose. If your doctor has told you that you (or your child) have an intolerance to some sugars or if you have been diagnosed with hereditary fructose intolerance (HFI), a rare genetic disorder in which a person cannot break down fructose, talk to your doctor before you (or your child) take or receive this medicine.

<Invented name> oral solution contains methylparahydroxybenzoate (E 218), propylparahydroxybenzoate (E 216) that may cause allergic reactions (possibly delayed).

<Invented name> oral solution contains sodium
This medicine contains 42 mg sodium (main component of cooking/table salt) in each 10 ml. This is equivalent to 2.1% of the recommended maximum daily dietary intake of sodium for an adult.

<Invented name> oral solution contains propylene glycol
This medicine contains 500 mg propylene glycol in each 10 ml.

3. How to take <Invented name>

Always take this medicine 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 solution can be swallowed as such.

Adults and adolescents above 12 years old:
The recommended dose is 10 mg once daily as 10 ml oral solution (2 full measuring spoons)

Use in children between 6 and 12 years old:
The recommended dose is 5 mg twice daily as 5 ml (one full measuring spoon) twice daily.

Use in children between 2 and 6 years old
The recommended dose is 2.5 mg twice daily as 2.5 ml oral solution (a half-measuring spoon) twice daily

Patients with renal impairment
Patients with moderate renal impairment are recommended to take 5 mg once daily.
If you suffer from severe kidney disease, please contact your doctor or pharmacist who may adjust the dose accordingly.
If your child suffers from kidney disease, please contact your doctor or pharmacist who may adjust the dose according to your child's needs.

If you feel that the effect of <Invented name> is too weak or too strong, please consult your doctor.

Duration of treatment
The duration of treatment depends on the type, duration and course of your complaints. Please ask your doctor or pharmacist for advice.

If you take more <Invented name> than you should
If you think you have taken an overdose of <Invented name> please inform your doctor.
Your doctor will then decide what measures, if any, should be taken.

After an overdose, the side effects described below may occur with increased intensity. Adverse effects such as confusion, diarrhoea, dizziness, tiredness, headache, ailing, dilating of pupil, itching, restlessness, sedation, somnolence, stupor, abnormal rapid heart rate, tremors and urinary retention have been reported.

If you forget to take <Invented name>
Do not take a double dose to make up for a forgotten dose.

If you stop taking <Invented name>
Rarely, pruritus (intense itching) and/or urticaria may return if you stop taking <Invented name>.

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.

The following side effects are rare or very rare, but you must stop taking the medicine and speak to your doctor straight away if you notice them:
- Allergic reactions, including severe reactions and angioedema (serious allergic reaction which causes swelling of the face or throat).

These reactions may start soon after you first take the medicine, or it might start later.

Common side effects (may affect up to 1 in 10 patients)
- Somnolence (sleepiness)
- Dizziness, headache

- Pharyngitis, rhinitis (in children)
- Diarrhea, nausea, dry mouth
- Fatigue

Uncommon side effects (may affect up to 1 in 100 patients)
- Agitation
- Paresthesia (abnormal feelings of the skin)
- Abdominal pain
- Pruritus (itchy skin), rash
- Asthenia (extreme fatigue), malaise

Rare side effects (may affect up to 1 in 1,000 patients)
- Allergic reactions, some severe (very rare)
- Depression, hallucination, aggression, confusion, insomnia
- Convulsions
- Tachycardia (heart beating too fast)
- Liver function abnormal
- Urticaria (hives)
- Oedema (swelling)
- Weight increased

Very rare side effects (may affect up to 1 in 10,000 patients)
- Thrombocytopenia (low levels of blood platelets)
- Tics (habit spasm)
- Syncope, dyskinesia (involuntary movements), dystonia (abnormal prolonged muscular contractions), tremor, dysgeusia (altered taste)
- Blurred vision, accommodation disorder (difficulty focusing), oculogyration (eyes having uncontrolled circular movements)
- Angioedema (serious allergic reaction which causes swelling of the face or throat), fixed drug eruption
- Abnormal elimination of urine (bed wetting, pain and/or difficulty passing water)

Not known frequency of side effects (frequency cannot be estimated from the available data)
- Increased appetite
- Suicidal ideation (recurring thoughts of or preoccupation with suicide) , nightmare
- Amnesia, memory impairment
- Vertigo (sensation of rotation or movement)
- Urinary retention (inability to completely empty the urinary bladder)
- Pruritus (intense itching) and/or urticaria upon discontinuation
- Joint pain
- Rash with blisters containing pus
- Hepatitis (inflammation of the liver)

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in Appendix V*. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store <Invented name>

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 box and bottle. The expiry date refers to the last day of that month.

Do not use after 3 months of first opening the bottle.

This medicine does not require any special storage conditions.

6. Contents of the pack and other information

What <Invented name> contains
- The active substance is cetirizine. 10 ml (equals to 2 measuring spoons) contain 10 mg of cetirizine dihydrochloride.
- The other ingredients are sorbitol (E 420), glycerol, propylene glycol, saccharin sodium, methylparahydroxybenzoate (E 218), propylparahydroxybenzoate (E 216), banana flavor 54.330/A (Firmenich), sodium acetate, glacial acetic acid, purified water.
- 10 ml <Invented name> oral solution (=2 measuring spoons) contain: 3.15 g glucose equivalents (sorbitol).

What <Invented name> looks like and contents of the pack
Clear and colorless liquid with slightly sweet taste and a banana flavor.

Pack with a bottle containing volumes of 60, 75, 100, 150, or 200 ml solution.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:
[To be completed nationally]
{Name and address}
{tel}
{fax}
{e-mail}

Manufacturer:
<Aesica Pharmaceuticals S.r.l., Via Praglia 15, I-10044 Pianezza (TO), Italy>
<UCB Pharma Limited, 208 Bath Road, Slough, Berkshire, SL1 3WE, United Kingdom>
<Phoenix Pharma Polska Sp. z o.o., ul. Oplotek 26, 01-940 Warsaw, Poland>
< Movianto Polska Sp. z o.o, ul. Artura i Franciszka Radziwiłłów 5,05-850 Ożarów Mazowiecki>

This leaflet was last revised in 2021-01-28.

[To be completed nationally]