

PACKAGE LEAFLET: INFORMATION FOR THE USER
ZIRPINE 10 mg TABLETS
Cetirizine dihydrochloride

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

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

What is in this leaflet:

1. What Zirpine 10 mg Tablets are and what they are used for
2. What you need to know before you take Zirpine 10 mg Tablets
3. How to take Zirpine 10 mg Tablets
4. Possible side effects
5. How to store Zirpine 10 mg Tablets
6. Contents of the pack and other information

1. What Zirpine 10 mg Tablets are and what they are used for

Zirpine 10 mg Tablets contain the active ingredient cetirizine dihydrochloride. This is an antihistamine used to treat seasonal allergic rhinitis (hay fever) and perennial rhinitis, and urticaria (hives) in adults and children over 6 years of age.

Antihistamines like Zirpine relieve the symptoms and discomfort associated with these conditions, such as sneezing, an itchy, runny and blocked nose, itchy, red and watering eyes and itchy skin rashes.

2. What you need to know before you take Zirpine 10 mg Tablets

Do NOT take Zirpine 10 mg Tablets:

- if you have had an allergic reaction to cetirizine or hydroxyzine or any of the other ingredients listed in this medicine (*see Section 6 and end of Section 2*).
- if you have severe kidney problems

Zirpine is not recommended for use in children under 6 years.

Warnings and Precautions

Talk to your doctor before taking Zirpine 10 mg Tablets:

- if you have kidney or liver problems which are not severe
- if you have a hereditary problem of galactose intolerance, Lapp lactase deficiency or glucose-galactose malabsorption (*see end of Section 2 "Important information about the ingredients"*)
- if you have difficulty passing urine
- if you are due to have an allergy test, as this medicine may affect your allergy test result
- if you are an epileptic patient or a patient at risk of convulsions.

Other medicines and Zirpine 10 mg Tablets:

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription, but particularly if you are taking:

- any antidepressants (affecting your central nervous system)
- any other medicines which can cause drowsiness or affect your level of alertness.

Zirpine 10 mg Tablets with food and drink:

Tablets should be swallowed whole with a glass of water. Avoid consuming excess alcohol when taking these tablets.

Pregnancy and Breast-feeding:

Tell your doctor if you are pregnant, think you may be pregnant or are planning to become pregnant, or if you are breast-feeding. Zirpine 10 mg Tablets are not recommended during pregnancy. If you are breast-feeding, be aware that Zirpine passes into breast milk. Ask your doctor or pharmacist for advice before taking any medicine during pregnancy, or if you are breast-feeding.

Driving and using machines:

This medicine should not make you sleepy and should not interfere with activities requiring mental alertness. However, some people (less than 10% of patients) might experience drowsiness; if this happens to you do not drive or operate machinery. This effect can be reduced by halving the dose and taking it twice a day instead of the full dose once a day. Avoid consuming excess alcohol as this may reduce your alertness or reduce your ability to perform certain tasks.

Important information about some of the ingredients of Zirpine 10 mg Tablets:

Zirpine 10 mg Tablets contain:

- **Lactose:** if you have an intolerance to some sugars, contact your doctor before taking these tablets.

3. How to take Zirpine 10 mg Tablets

Always take this medicine exactly as your doctor or pharmacist has told you; you should check with him/her if you are not sure. The tablets should be taken by mouth and swallowed with a glass of liquid. You should check with your doctor or pharmacist if you are uncertain what dose to take.

Adults and adolescents over 12 years of age

The recommended dose is one 10 mg tablet once a day.

Children aged 6 to 12 years

The recommended dose is 5 mg twice daily (a half tablet twice daily)

Children under 6 years

This medicine must NOT be given to children under 6 years of age.

Patients with kidney problems

If you have moderate to severe kidney function problems, your dose and when to take it will be advised by your doctor depending on your condition.

If you are a child over 6 years old with kidney problems, your dose and when to take it will be advised by your doctor.

Patients with liver problems

This will be the same as the adult dose. No dose adjustment is needed.

Patients with liver problems and kidney problems

Dose adjustment is recommended and will be advised by your doctor.

24LF01683PD





PHARMACODE



PHARMACODE

If you take more Zirpine 10 mg Tablets than you should

If you have taken more tablets than you should, contact your doctor immediately or go to your nearest hospital accident and emergency department. Take this leaflet and/or the pack with you.

Symptoms of overdose: confusion, diarrhoea, dizziness, tiredness, headache, feeling weary, abnormal dilation of the pupil, severe itching, restlessness, sedation, sleepiness, stupor, rapid heartbeat, tremor, retention of urine.

If you forget to take Zirpine 10 mg Tablets

If you forget to take a dose, take another one as soon as you remember but wait at least 12 hours before taking the next dose. Do not take a double dose to make up for the forgotten dose.

4. Possible side effects

Like all medicines, Zirpine 10 mg Tablets can cause side effects, although not everybody gets them.

STOP taking these tablets and **seek medical help immediately** if you have any of the following which may be signs of an **allergic reaction**:

- difficulty breathing or swallowing
- swelling of the face, lips, tongue or throat
- severe itching of the skin, with a red rash or raised bumps

In rare cases people have thought about committing suicide and if you feel this way then stop taking the tablets and see your doctor.

Mild side effects have been reported; if any of these happen, halve your tablet and take your dose twice daily – see Section 3.

- headache
- difficulty in urinating
- dry mouth.
- dizziness, drowsiness, tiredness
- vision problems

The following side-effects may occur:

- feeling sick, diarrhoea
- rhinitis and pharyngitis (inflammation of the nose and pharynx).
- abdominal pain

Other side effects, not known (frequency cannot be estimated from the available data)

- anaemia (low number of red blood cells)
- photosensitivity (allergic reaction caused by the sun)
- bronchospasm (difficulty breathing)
- anorexia (loss of appetite)
- tics, tremor
- lack of coordination
- involuntary movements and/or jerking of the limbs
- vertigo (the sensation of movement when no movement is taking place)
- rotation of the eyes
- vomiting
- alopecia (hair loss)
- abnormal elimination of urine (bed wetting, pain and/or difficulty passing water)
- increased appetite
- hallucinations (hearing or seeing things)
- memory loss and/or impairment
- muscle spasms
- palpitations (feeling your heartbeat)
- constipation
- recurring rash

In some cases high levels of liver enzymes and bilirubin have been reported, however these effects usually wear off as soon as you stop taking Zirpine.

Other rare side effects which have occurred in isolated cases include:

- low blood cell counts, rapid heartbeat, blurred vision, weakness, upset stomach/general discomfort, swelling, allergic reaction/shock, weight increase, convulsions, unusual taste or touch sensation, fainting, aggression, agitation, confusion, depression, insomnia, itching, skin rash or hives.

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 Zirpine 10 mg Tablets

Keep this medicine out of the sight and reach of children. There are no special storage conditions for this medicine. Do not use this medicine after the expiry date (shown as 'EXP') on the label. The expiry refers to the last day of that month. Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Zirpine 10 mg Tablets contains:

- The **active ingredient** is cetirizine (as cetirizine dihydrochloride). Each tablet contains 10 mg cetirizine dihydrochloride.
- The **other ingredients** are: lactose monohydrate (see also end of Section 2 for further information on lactose), microcrystalline cellulose (E460(i)), colloidal anhydrous silica, magnesium stearate, titanium dioxide (E171), hypromellose (E464) and macrogol 400.

What Zirpine looks like and contents of the pack:

Zirpine 10 mg Tablets are white, round, film-coated tablets marked 'AG' on one side with a breakline on the other side. The tablets are available in a pack size of 30 tablets.

Marketing Authorisation Holder:

Pinewood Laboratories Ltd., Ballymacarby, Clonmel, Co. Tipperary.

Manufactured by:

Chanelle Medical, Loughrea, Co. Galway, Ireland.

PA 281/110/1

This leaflet was last revised in August 2019.

POM



PINEWOOD
HEALTHCARE
Ballymacarby, Co. Tipperary.

24LF01683PD

PACKAGE LEAFLET: INFORMATION FOR THE USER
ZIRPINE 10 mg TABLETS
Cetirizine dihydrochloride

Read all of this leaflet carefully because it contains important information for you.

This medicine is available without a prescription. However, you still need to take Zirpine 10 mg Tablets carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must contact a doctor if your symptoms worsen or do not improve.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

What is in this leaflet:

1. What Zirpine 10 mg Tablets are and what they are used for
2. What you need to know before you take Zirpine 10 mg Tablets
3. How to take Zirpine 10 mg Tablets
4. Possible side effects
5. How to store Zirpine 10 mg Tablets
6. Contents of the pack and other information

1. What Zirpine 10 mg Tablets are and what they are used for

Zirpine 10 mg Tablets contain the active ingredient cetirizine dihydrochloride. This is an antihistamine used to treat seasonal allergic rhinitis (hay fever) and perennial rhinitis, and urticaria (hives) in adults and children over 6 years of age.

Antihistamines like Zirpine relieve the symptoms and discomfort associated with these conditions, such as sneezing, an itchy, runny and blocked nose, itchy, red and watering eyes and itchy skin rashes.

2. What you need to know before you take Zirpine 10 mg Tablets

Do NOT take Zirpine 10 mg Tablets:

- if you have had an allergic reaction to cetirizine or hydroxyzine or any of the other ingredients listed in this medicine (see Section 6 and end of Section 2).
- if you have severe kidney problems

Zirpine is not recommended for use in children under 6 years.

Warning and Precautions

Talk to your doctor before taking Zirpine 10 mg Tablets:

- if you have kidney or liver problems which are not severe
- if you have a hereditary problem of galactose intolerance, Lapp lactase deficiency or glucose-galactose malabsorption (see end of Section 2 "Important information about the ingredients")
- if you have difficulty passing urine
- if you are due to have an allergy test, as this medicine may affect your allergy test result
- if you are an epileptic patient or a patient at risk of convulsions.

Other medicines and Zirpine 10 mg Tablets:

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription, but particularly if you are taking:

- any antidepressants (affecting your central nervous system)
- any other medicines which can cause drowsiness or affect your level of alertness.

Zirpine 10 mg Tablets with food and drink:

Tablets should be swallowed whole with a glass of water. Avoid consuming excess alcohol when taking these tablets.

Pregnancy and Breast-feeding:

Tell your doctor if you are pregnant, think you may be pregnant or are planning to become pregnant, or if you are breast-feeding. Zirpine 10 mg Tablets are not recommended during pregnancy. If you are breast-feeding, be aware that Zirpine passes into breast milk. Ask your doctor or pharmacist for advice before taking any medicine during pregnancy, or if you are breast-feeding.

Driving and using machines:

This medicine should not make you feel sleepy and should not interfere with activities requiring mental alertness. However, some people (less than 10% of patients) might experience drowsiness; if this happens to you do not drive or operate machinery. This effect can be reduced by halving the dose and taking it twice a day instead of the full dose once a day. Avoid consuming excess alcohol as this may reduce your alertness or reduce your ability to perform certain tasks.

Important information about some of the ingredients of Zirpine 10 mg Tablets:

Zirpine 10 mg tablets contain:

- **Lactose:** if you have an intolerance to some sugars, contact your doctor before taking these tablets.

3. How to take Zirpine 10 mg Tablets

Always take this medicine exactly as your doctor or pharmacist has told you; you should check with him/her if you are not sure. The tablets should be taken by mouth and swallowed with a glass of liquid. You should check with your doctor or pharmacist if you are uncertain what dose to take.

Adults and adolescents over 12 years of age

The recommended dose is one 10 mg tablet once a day.

Children aged 6 to 12 years

The recommended dose is 5 mg twice daily (a half tablet twice daily)

Children under 6 years

This medicine must NOT be given to children under 6 years of age.

Patients with kidney problems

If you have moderate to severe kidney function problems, your dose and when to take it will be advised by your doctor depending on your condition.

If you are a child over 6 years old with kidney problems, your dose and when to take it will be advised by your doctor.

Patients with liver problems

This will be the same as the adult dose. No dose adjustment is needed.

Patients with liver problems and kidney problems

Dose adjustment is recommended and will be advised by your doctor.

24LF01514PD



**If you take more Zirpine 10 mg Tablets than you should**

If you have taken more tablets than you should, contact your doctor immediately or go to your nearest hospital accident and emergency department. Take this leaflet and/or the pack with you.

Symptoms of overdose: confusion, diarrhoea, dizziness, tiredness, headache, feeling weary, abnormal dilation of the pupil, severe itching, restlessness, sedation, sleepiness, stupor, rapid heartbeat, tremor, retention of urine.

If you forget to take Zirpine 10 mg Tablets

If you forget to take a dose, take another one as soon as you remember but wait at least 12 hours before taking the next dose. Do not take a double dose to make up for the forgotten dose.

4. Possible side effects

Like all medicines, Zirpine 10 mg Tablets can cause side effects, although not everybody gets them.

STOP taking these tablets and **seek medical help immediately** if you have any of the following which may be signs of an **allergic reaction**:

- difficulty breathing or swallowing
- swelling of the face, lips, tongue or throat
- severe itching of the skin, with a red rash or raised bumps

In rare cases people have thought about committing suicide and if you feel this way then stop taking the tablets and see your doctor.

Mild side effects have been reported; if any of these happen, halve your tablet and take your dose twice daily – *see Section 3*.

- headache
- difficulty in urinating
- dry mouth.
- dizziness, drowsiness, tiredness
- vision problems

The following side-effects may occur:

- feeling sick, diarrhoea
- rhinitis and pharyngitis (inflammation of the nose and pharynx).
- abdominal pain

Other side effects, not known (frequency cannot be estimated from the available data)

- anaemia (low number of red blood cells)
- photosensitivity (allergic reaction caused by the sun)
- bronchospasm (difficulty breathing)
- anorexia (loss of appetite)
- tics, tremor
- lack of coordination
- involuntary movements and/or jerking of the limbs
- vertigo (the sensation of movement when no movement is taking place)
- rotation of the eyes
- vomiting
- alopecia (hair loss)
- abnormal elimination of urine (bed wetting, pain and/or difficulty passing water)
- increased appetite
- hallucinations (hearing or seeing things)
- memory loss and/or impairment
- muscle spasms
- palpitations (feeling your heartbeat)
- constipation
- recurring rash

In some cases high levels of liver enzymes and bilirubin have been reported, however these effects usually wear off as soon as you stop taking Zirpine.

Other rare side effects which have occurred in isolated cases include:

- low blood cell counts, rapid heartbeat, blurred vision, weakness, upset stomach/general discomfort, swelling, allergic reaction/shock, weight increase, convulsions, unusual taste or touch sensation, fainting, aggression, agitation, confusion, depression, insomnia, itching, skin rash or hives.

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 Zirpine 10 mg Tablets

Keep this medicine out of the sight and reach of children. There are no special storage conditions for this medicine. Do not use this medicine after the expiry date (shown as 'EXP') on the label. The expiry refers to the last day of that month. Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information**What Zirpine 10 mg Tablets contains:**

- The **active ingredient** is cetirizine (as cetirizine dihydrochloride). Each tablet contains 10 mg cetirizine dihydrochloride.
- The **other ingredients** are: lactose monohydrate (*see also end of Section 2 for further information on lactose*), microcrystalline cellulose (E460(i)), colloidal anhydrous silica, magnesium stearate, titanium dioxide (E171), hypromellose (E464) and macrogol 400.

What Zirpine looks like and contents of the pack:

Zirpine 10 mg tablets are white, round, film-coated tablets marked 'AG' on one side with a breakline on the other side. The tablets are available in a pack size of 7 tablets.

Marketing Authorisation Holder:

Pinewood Laboratories Ltd., Ballymacarby, Clonmel, Co. Tipperary.

Manufactured by:

Chanelle Medical, Loughrea, Co. Galway, Ireland.

PA 281/110/1

This leaflet was last revised in August 2019.

