PACKAGE LEAFLET

Package leaflet: Information for the patients

Zirtek Plus Decongestant 5 mg/120 mg prolonged-release tablets

(5 mg cetirizine dihydrochloride - 120 mg pseudoephedrine hydrochloride)

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 has 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 7 days.

What is in this leaflet:

1. What Zirtek Plus Decongestant is and what it is used for

Zirtek Plus Decongestant 5mg/120mg prolonged release tablets contains two active substances: cetirizine dihydrochloride which is an antihistamine and pseudoephedrine hydrochloride which is a decongestant.

Zirtek Plus Decongestant is a medicine that is used to relieve allergic symptoms, especially when the anti-allergy properties of cetirizine are combined with the effects of pseudoephedrine in reducing swelling of the mucous membranes inside the nose.

Zirtek Plus Decongestant is indicated for the treatment of symptoms such as blocked nose, sneezing, runny nose, itchy nose or itchy eyes, which occur in seasonal allergic rhinitis (hay fever) or perennial allergic rhinitis (house-dust allergy).

Zirtek Plus Decongestant is indicated for adults and adolescents from 12 years of age and above.

2. What you need to know before you take Zirtek Plus Decongestant

Do not take Zirtek Plus Decongestant
- if you are allergic to cetirizine, ephedrine or any of the other ingredients of this medicine (listed in section 6) or to piperazine derivative (closely related active sustances of other medicines).
- if you have very high blood pressure (severe hypertension) or hypertension not controlled by your

medication or coronary heart disease.
- - if you have severe acute (sudden) or chronic (long-term) kidney diseaseor kidney failure requiring dialysis /, if you suffer from impaired thyroid function or a tumour called a phaeochromocytoma
- if you have serious disturbances of heart rhythm, increased intraocular pressure (inside the eye) or urination problems.
- if you are taking medication for high blood pressure such as beta-blockers, sympathomimetics (medicines that reduce swelling), dihydroergotamine (for problems with the circulation) or amphetamines (stimulants).
- if you are receiving treatment with monoamine oxide inhibitors (MAOI; antidepressants) or have taken these within the last two weeks.
- if you have had a cerebrovascular event (stroke) or display risk factors that increase the risk of a cerebrovascular haemorrhage, due to the blood-vessel-narrowing action of Zirtek Plus Decongestant in combination with medicines such as bromocriptine, pergolide, lisuride, cabergoline, ergotamine, dihydroergotamine or any other medicines that reduce swelling (phenylpropanolamine, phenylephrine, ephedrine etc.), irrespective of the method of administration.
- if you are under 12 years of age

Warnings and precautions
Talk to your doctor or pharmacist before taking Zirtek Plus Decongestant:
- if you are over 50 years of age.
- if you are a diabetic or suffer from hyperthyroidism (overactive thyroid) or heart problems (too fast or irregular rhythm, angina pectoris).
- if you suffer from moderate liver or kidney impairment.
- if your prostate is enlarged or you have problems urinating.
- if you regularly consume alcohol or take medication that depresses the central nervous system.
- if you are taking/using medicines that belong to the class of drugs called sympathomimetics (medicines that reduce swelling, appetite suppressants, stimulants such as amphetamines).
- if you are at risk of excessive blood clotting e.g. from chronic inflammatory bowel disease.
- if you are taking medications for depression (tricyclic antidepressants), medication for the heart (cardiac glycosides such as digoxin or digitoxin), linezolide (antibiotic), guanethidine, reserpine, phenothiazine or antihypertensives.
- if you have a medical condition that could lead to inability to empty the bladder (urinary retention) [e.g. *spinal cord damage (spinal cord lesion), enlarged prostate gland (prostatic hypertrophy, prostatic hyperplasia) or difficulty passing urine (bladder outflow obstruction*)] as Zirtek Plus Decongestant may increase the risk of urinary retention.
- if you suffer from high blood pressure and are taking non-steroidal anti-inflammatory drugs, your blood pressure may increase.
- if you are already taking other medicines, please read the section “Other medicines and Zirtek Plus Decongestant”.
- if you have had a cerebrovascular event (stroke) or have risk factors for experiencing such an event.
- this medicine may act as a cerebral stimulant and make insomnia, nervousness, fever, tremors and epileptic seizures worse.

Sudden abdominal pain or rectal bleeding may occur with Zirtek Plus Decongestant, due to inflammation of the colon (ischaemic colitis). If you develop these gastro-intestinal symptoms, stop taking Zirtek Plus Decongestant and contact your doctor or seek medical attention immediately (see

section 4).

Reduction of blood flow to your optic nerve may occur with Zirtek Plus Decongestant. If you develop sudden loss of vision, stop taking Zirtek Plus Decongestant and contact your doctor or seek medical attention immediately. See section 4.

Cases of posterior reversible encephalopathy syndrome (PRES) and reversible cerebral vasoconstriction syndrome (RCVS) have been reported following use of medicines containing pseudoephedrine. PRES and RCVS are rare conditions that can involve reduced blood supply to the brain. Stop using Cirrus immediately and seek immediate medical assistance if you develop symptoms that may be signs of PRES or RCVS (see section 4 "Possible side effects" for symptoms)

If you develop a severe skin reaction including signs and symptoms like fever, redness of the skin or many small pustules, stop taking Zirtek Plus Decongestant and contact your doctor or seek medical attention immediately. See section 4.

If you are a professional athlete, you should be informed that treatment with pseudoephedrine can lead to positive results in doping tests.

If you are scheduled for allergy testing, ask your doctor if you should stop taking Zirtek Plus Decongestant for several days before testing. This medicine may affect your allergy test results.

Children
Do not give this medicine to children under 12 years of age.

Other medicines and Zirtek Plus Decongestant
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

- Combination with the following medicines should be avoided: bromocriptine, cabergoline, lisuride, pergolide, dihydroergotamine, ergotamine, methylergometrine and other vasoconstricting substances for oral use or local use in the nose (phenyl-propanolamine, ephedrine, phenylephrine etc).

- Caution is advised with simultaneous administration of sedatives (tranquillisers), theophylline (anti-asthma medication), ritonavir (HIV medication), certain antidepressants (MAO inhibitors, even if you have not been taking them in the last two weeks) and tricyclic antidepressants), antihypertensives (alpha-blockers and beta-blockers, methyldopa), medicines for the circulation (dihydroergotamine), antibiotics containing linezolide, medications for the heart (cardiac glycosides such as digoxin or digitoxin).

- Some antacids may increase the effect of Zirtek Plus Decongestant, others may reduce it (kaolin).

Zirtek Plus Decongestant with food and drink
Zirtek Plus Decongestant may be taken with or without food.

Pregnancy, breast-feeding, and fertility
Zirtek Plus Decongestant is not recommended during pregnancy and breast-feeding.
If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice.

Driving and using machines
Patients intending to drive vehicles, to perform potentially hazardous activities or operating machinery should not exceed the recommended dose and take into account the individual response to Zirtek Plus Decongestant. Use caution when taking Zirtek Plus Decongestant with alcohol or other sedatives as they may cause additional reductions in alertness and impairment of performance. If you experience somnolence (drowsiness), you should refrain from driving, engaging in potentially hazardous activities or operating machinery.

Zirtek Plus Decongestant contains lactose
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

Zirtek Plus Decongestant contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take Zirtek Plus Decongestant

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 recommended dose is: 1 tablet twice daily (one in the morning and one in the evening).

Use in children and adolescents
Adolescents from 12 years of age and above: 1 tablet twice daily (one in the morning and one in the evening).
Zirtek Plus Decongestant is contraindicated for children younger than 12 years.

If you suffer from kidney or liver disease, please inform your doctor or pharmacist, who may adjust your dose.

Method of administration and duration of treatment:
Oral use. The tablet must be swallowed whole with a some liquid with or without food and must not be broken, crunched or chewed.

After the allergy-induced symptoms have been relieved, it is often recommended that treatment is continued in the pollen season with a medication that contains only an anti-allergy substance.

If symptoms have not subsided after 7 days, ask your doctor for advice.

If you take more Zirtek Plus Decongestant than you should
If you have taken or used more Zirtek Plus Decongestant than you should, contact your doctor or pharmacist immediately.

A significant overdose can cause the following symptoms: vomiting, dilated (abnormally large) pupils, disturbances of heart rhythm, high blood pressure, depression of the central nervous system (sedation, breathing difficulties, loss of consciousness, cyanosis (bluish discolouration due to oxygen

deficiency), cardiovascular collapse (circulatory failure)) or stimulation of the central nervous system (insomnia, hallucinations, tremor, seizures) which may prove fatal.

There is no specific antidote. Treatment should take place in a hospital. If the person affected does not vomit spontaneously, an attempt can be made to induce vomiting.

Read also the section for healthcare professionals.

If you forget to take Zirtek Plus Decongestant
If you forget to take a tablet, take it as soon as you remember. However, the subsequent tablets must be spaced 12 hours apart.

Do not take more than two tablets in 24 hours.

If you stop taking Zirtek Plus Decongestant
Only take this medicine if you suffer from allergy symptoms.
Rarely, itching (pruritus) may occur if you stop taking this medicine.

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.

Stop using Cirrus immediately and seek urgent medical attention if you develop symptoms, that may be signs of posterior reversible encephalopathy syndrome (PRES) and reversible cerebral vasoconstriction syndrome (RCVS). These include:

- severe headache with a sudden onset
- feeling sick
- vomiting
- confusion
- seizures
- changes in vision

The following are known side effects:

Common side effects (may affect up to 1 in 10 patients)**:** rapid heart rate, dry mouth, nausea, weakness (asthenia), dizziness, somnolence, headache, vertigo, nervousness, insomnia

Uncommon side effects (may affect up to 1 in 100 patients)**:** agitation, anxiety

Rare side effects (may affect up to 1 in 1000 patients)**:** disturbances of heart rhythm, pallor, arterial hypertension, vomiting, abnormal liver function (increase in certain enzymes), hypersensitivity reactions (including anaphylactic shock), convulsions, tremor, hallucinations, urination difficulties, dry skin, eruption, sweating, urticaria

Very rare side effects (may affect up to 1 in 10000 patients)**:** circulatory collapse (circulatory disorder), altered taste (dysgeusia), cerebrovascular event (stroke), psychosis (in isolated cases), serious allergic reaction which causes swelling of the face or throat (angioedema), fixed drug eruption

Not known frequency of side effects (frequency cannot be estimated from the available data)**:** serious conditions affecting blood vessels in the brain known as posterior reversible encephalopathy syndrome (PRES) and reversible cerebral vasoconstriction syndrome (RCVS), aggression, confusional state, depressed or low mood (depression), habit spasm (tic), exaggerated feeling of wellbeing (euphoric mood), thoughts of taking one's own life (suicidal ideation), abnormal feelings of the skin (paresthesia), inability to sit still, relax, or rest (restlessness), abnormal prolonged muscular contractions (dystonia), involuntary movements (dyskinesia), memory loss (amnesia), memory impairment, fainting (syncope), blurred vision, eye disorder - difficulty focusing (accommodation disorder), abnormal dilation of the pupil of the eye (mydriasis), eye pain, visual impairment, abnormal eye sensitivity or intolerance to visual perception of light (photophobia), eyes having uncontrolled circular movements (oculogyric crisis), reduced blood flow to the optic nerve (ischaemic optic neuropathy), difficulty in breathing (dyspnoea), erectile dysfunction, difficulty emptying the bladder (urinary retention), severe skin reactions characterised by fever and numerous small, superficial pustules, arising within large areas of redness, itching (pruritus), unpleasant sensation of faster and/or stronger/irregular beating of the heart, diarrhoea, abdominal discomfort, inflammation of the colon due to insufficient blood supply (ischaemic colitis), bed wetting (enuresis), joint pain (arthralgia), muscle pain (myalgia), swelling (oedema) and malaise.

Isolated cases of inflammation of the liver (hepatitis) have been reported when cetirizine alone is administered.

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 HPRA Pharmacovigilance, Website: www.hpra.ie.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Zirtek Plus Decongestant

Keep this medicine out of the sight and reach of children.

This medicinal product does not require any special storage conditions.

Do not use this medicine after the expiry date which is stated on the carton and blister pack after EXP. The expiry date 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 Zirtek Plus Decongestant contains

- The active substances are cetirizine dihydrochloride and pseudoephedrine hydrochloride. Each prolonged release tablet contains 5 mg cetirizine dihydrochloride and 120 mg pseudoephedrine hydrochloride.
- The other ingredients are: tablet: hypromellose, microcrystalline cellulose, colloidal anhydrous silica, magnesium stearate, lactose monohydrate, croscarmellose-sodium; coating: Opadry Y-1-7000 (= hypromellose (E464), titanium dioxide (E171), Macrogol 400).
  See section 2 “Zirtek Plus Decongestant contains lactose”.

What Zirtek Plus Decongestant looks like and contents of the pack

Zirtek Plus Decongestant is a prolonged-release film-coated tablet, i.e. the contents are released slowly in order to allow for an effective treatment over a period of approximately 12 hours.

Each round, biconvex tablet has a round logo engraved on one side.

Zirtek Plus Decongestant is available in boxes containing a blister with 6 or 14 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

For more information about the medicine please contact your doctor or pharmacist.

If you wish, you can also contact the local representative of the Marketing Authorisation Holder:
UCB Pharma (Ireland) Ltd
United Drug House,
Magna Business Park, Magna Drive,
Citywest Road,
Dublin 24

Manufacturer:
Aesica Pharmaceutical S.r.l.
Via Praglia, 15, I-10044
Pianezza (Torino)
Italy

This medicinal product is authorised in the Member States of the EEA under the following names:

Belgium: Cirrus
Cyprus: Zyrtec-D
Ireland: Zirtek Plus Decongestant
Malta: Cirrus

This leaflet was last revised in 10/2024.

The following information is intended for healthcare professionals only:

Simultaneous administration of halogenated anaesthetics such as chloroform, enflurane, isoflurane, cyclopropane, halothane can trigger or exacerbate ventricular arrhythmia.
In the event of an overdose cetirizine and pseudoephedrine are hardly eliminated at all by haemodialysis.