Zyrtec Tablets 10mg

1. NAME OF THE MEDICINAL PRODUCT

Zyrtec Tablets 10mg

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film-coated tablet contains 10 mg of cetirizine hydrochloride.

Excipients
Microcrystalline cellulose, Lactose monohydrate, Colloidal anhydrous silica, Magnesium stearate, Hydroxypropylmethylcellulose, Titanium dioxide, Macrogol 400

3. PHARMACEUTICAL FORM

White, oblong, film-coated tablet, with a bisect line and Y/Y logo

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Zyrtec Tablets 10mg are indicated in adults and paediatric patients 6 years and above:

- for the relief of nasal and ocular symptoms of seasonal and perennial allergic rhinitis.
- for the relief of symptoms of chronic idiopathic urticaria.

4.2 Posology and method of administration

Posology
10mg once daily (1 tablet).

Special population

Older people

Data do not suggest that the dose needs to be reduced in elderly subjects provided that the renal function is normal.

Patients with moderate to severe renal impairment

There are no data to document the efficacy/safety ratio in patients with renal impairment. Since cetirizine is mainly excreted via renal route, in cases no alternative treatment can be used, the dosing intervals must be individualized according to renal function. Refer to the following table and adjust the dose as indicated. To use this dosing table, an estimate of the patient's creatinine clearance (Cl_{cr}) in ml/min is needed. The Cl_{cr} (ml/min) may be estimated from serum creatinine (mg/dl) determination using the following formula:

$$Cl_{cr} = \frac{[140 - \text{age (years)}] \times \text{weight (kg)}}{72 \times \text{serum creatinine (mg/dl)}} \quad (\times 0.85 \text{ in women})$$

Dosing adjustments for adult patients with impaired renal function

Group	Creatinine clearance (ml/min)	Dosage and frequency
Normal	≥80	10mg once daily
Mild	50-79	10mg once daily
Moderate	30-49	5 mg once daily
Severe	<30	5 mg once every 2 days
End-stage renal disease - Patients undergoing dialysis	<10	Contraindicated

Patients with hepatic impairment

No dose adjustment is needed in patients with solely hepatic impairment. In patients with hepatic impairment and renal impairment, adjustment of the dose is recommended (see *Patients with moderate to severe renal impairment* above).

Paediatric population

The tablet formulation should not be used in children under 6 years of age as it does not allow the necessary dose adjustments.

Children aged 6 to 12 years: 5 mg twice daily (a half tablet twice daily).
Adolescents above 12 years: 10 mg once daily (1 tablet).

In paediatric patients suffering from renal impairment, the dose will have to be adjusted on an individual basis taking into account the renal clearance, age and body weight of the patient.

Method of administration

The tablets need to be swallowed with a glass of liquid.

4.3 Contraindications

Cetirizine is contraindicated in:

- hypersensitivity to the active substance, to any of the excipients listed in section 2, to hydroxyzine or to any piperazine derivatives
- patients with severe renal impairment with a creatinine clearance below 10 ml/min.

4.4 Special warnings and precautions for use

Alcohol
At therapeutic doses, no clinically significant interactions have been demonstrated with alcohol (for a blood alcohol level of 0.5 g/L). Nevertheless, precaution is recommended if alcohol is taken concomitantly.

Increased risk of urinary retention
Caution should be taken in patients with predisposition factors of urinary retention (e.g. spinal cord lesion, prostatic hyperplasia) as cetirizine may increase the risk of urinary retention.

Patients at risk of convulsions
Caution is recommended in epileptic patients and patients at risk of convulsions.

Allergy skin tests
Response to allergy skin tests are inhibited by antihistamines and a wash-out period (of 3 days) is required before performing them.

Excipients
Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take cetirizine film-coated tablets.

Skin reactions
Pruritus and/or urticaria may occur when cetirizine is stopped, even if those symptoms were not present before treatment initiation. In some cases, the symptoms may be intense and may require treatment to be restarted. The symptoms should resolve when the treatment is restarted.

Paediatric population
The use of the film-coated tablet formulation is not recommended in children aged less than 6 years since this formulation does not allow for appropriate dose adaptation. It is recommended to use Zyrtec Oral Solution.

4.5 Interaction with other medicinal products and other forms of interaction

Due to the pharmacokinetic, pharmacodynamic and tolerance profile of cetirizine, no interactions are expected with this antihistamine. Neither pharmacodynamic nor significant pharmacokinetic interaction was reported in drug-drug interactions studies performed, notably with pseudoephedrine or theophylline (400mg/ day).

The extent of absorption of cetirizine is not reduced with food, although the rate of absorption is decreased.

In sensitive patients, the concurrent use of alcohol or other CNS depressants may cause additional reductions in alertness and impairment of performance, although cetirizine does not potentiate the effect of alcohol (0.5 g/L blood levels).

4.6 Fertility, pregnancy and lactation

Fertility
Limited data is available on human fertility but no safety concern has been identified.
Animal data show no safety concern for human reproduction.

Pregnancy
For cetirizine prospectively collected data on pregnancy outcomes do not suggest potential for maternal or foetal/embryonic toxicity above background rates.

Animal studies do not indicate direct or indirect harmful effects with respect to pregnancy, embryonal/foetal development, parturition or postnatal development. Caution should be exercised when prescribing to pregnant women.

Lactation
Cetirizine is excreted in human milk at concentrations representing 25% to 90% of those measured in plasma, depending on sampling time after administration. Therefore, caution should be exercised when prescribing cetirizine to lactating women.

4.7 Effects on ability to drive and use machines

Objective measurements of driving ability, sleep latency and assembly line performance have not demonstrated any clinically relevant effects at the recommended dose of 10 mg. However, patients who experience somnolence should refrain from driving, engaging in potentially hazardous activities or operating machinery. They should not exceed the recommended dose and should take their response to the medicinal product into account.

4.8 Undesirable effects

Clinical Studies

Overview

Clinical studies have shown that cetirizine at the recommended dosage has minor undesirable effects on the CNS, including somnolence, fatigue, dizziness and headache. In some cases, paradoxical CNS stimulation has been reported.

Although cetirizine is a selective antagonist of peripheral H1-receptors and is relatively free of anticholinergic activity, isolated cases of micturition difficulty, eye accommodation disorders and dry mouth have been reported.

Instances of abnormal hepatic function with elevated hepatic enzymes accompanied by elevated bilirubin have been reported. Mostly this resolves upon discontinuation of the treatment with cetirizine hydrochloride.

Listing of ADRs

Double blind controlled clinical trials comparing cetirizine to placebo or other antihistamines at the recommended dosage (10 mg daily for cetirizine), of which quantified safety data are available, included more than 3200 subjects exposed to cetirizine.

From this pooling, the following adverse reactions were reported for cetirizine 10 mg in the placebo-controlled trials at rates of 1.0 % or greater:

Adverse reactions (WHO-ART)	**Cetirizine 10 mg (n = 3260)**	**Placebo (n = 3061)**
General disorders and administration site conditions		
Fatigue	1.63%	0.95%
Nervous system disorders		
Dizziness	1.10%	0.98%
Headache	7.42%	8.07%
Gastro-intestinal disorders		
Abdominal pain	0.98%	1.08%
Dry mouth	2.09%	0.82%
Nausea	1.07%	1.14%
Psychiatric disorders		
Somnolence	9.63%	5.00%
Respiratory, thoracic and mediastinal disorders		
Pharyngitis	1.29%	1.34%

Although statistically more common than under placebo, somnolence was mild to moderate in the majority of cases. Objective tests as demonstrated by other studies have demonstrated that usual daily activities are unaffected at the recommended daily dose in healthy young volunteers.

Paediatric population

Adverse reactions at rates of 1 % or greater in children aged from 6 months to 12 years, included in placebo-controlled clinical trials are:

Adverse reactions (WHO-ART)	**Cetirizine (n = 1656)**	**Placebo (n = 1294)**
Gastro-intestinal disorders		
Diarrhoea	1.0%	0.6%
Psychiatric disorders		
Somnolence	1.8%	1.4%
Respiratory, thoracic and mediastinal disorders		
Rhinitis	1.4%	1.1%
General disorders and administration site conditions		
Fatigue	1.0%	0.3%

Post-marketing experience

In addition to the adverse reactions reported during clinical studies and listed above, the following undesirable effects have been reported in post-marketing experience.
Undesirable effects are described according to MedDRA System Organ Class and by estimated frequency based on post-marketing experience.

Frequencies are defined as follows:
Very common ≥1/10
Common ≥1/100 to <1/10
Uncommon ≥1/1000 to <1/100
Rare ≥1/10000 to <1/1000
Very rare <1/10000
Not known (cannot be estimated from the available data)

- Blood and lymphatic disorders
  Very rare: thrombocytopenia

- Immune system disorders
  Rare: hypersensitivity
  Very rare: anaphylactic shock

- Metabolism and nutrition disorders
  Not known: increased appetite

- Psychiatric disorders
  Uncommon: agitation
  Rare: aggression, confusion, depression, hallucination, insomnia
  Very rare: tics
  Not known: suicidal ideation, nightmare

- Nervous system disorders
  Uncommon: paraesthesia
  Rare: convulsions

Very rare: dysgeusia, dyskinesia, dystonia, syncope, tremor
Not known: amnesia, memory impairment

- Eye disorders
  Very rare: accommodation disorder, blurred vision, oculogyration

- Ear and labyrinth disorders
  Not known: vertigo

- Cardiac disorders
  Rare: tachycardia

- Gastro-intestinal disorders
  Uncommon: diarrhoea

- Hepatobiliary disorders
  Rare: hepatic function abnormal (increased transaminases, alkaline phosphatase, γ-GT and bilirubin)
  Not known: hepatitis

- Skin and subcutaneous tissue disorders
  Uncommon: pruritus, rash
  Rare: urticaria
  Very rare: angioneurotic oedema, fixed drug eruption
  Not known: acute generalized exanthematous pustulosis

- Musculoskeletal and connective tissue disorders
  Not known: arthralgia

- Renal and urinary disorders
  Very rare: dysuria, enuresis
  Not known: urinary retention

- General disorders and administration site conditions
  Uncommon: asthenia, malaise
  Rare: oedema

- Investigations:
  Rare: weight increased

Description of selected adverse reactions

After discontinuation of cetirizine, pruritus (intense itching) and/or urticaria have been reported.

4.9 Overdose

Symptoms

Symptoms observed after an overdose of cetirizine are mainly associated with CNS effects or with effects that could suggest an anticholinergic effect.

Adverse events reported after an intake of at least 5 times the recommended daily dose are: confusion, diarrhoea, dizziness, fatigue, headache, malaise, mydriasis, pruritus, restlessness, sedation, somnolence, stupor, tachycardia, tremor, and urinary retention.

Management

There is no known specific antidote to cetirizine.

Should overdose occur, symptomatic or supportive treatment is recommended. Gastric lavage may be considered shortly after ingestion of the drug.

Cetirizine is not effectively removed by haemodialysis.

5. STORAGE CONDITIONS AND EXPIRY DATES

See outer packaging for storage and expiry date.

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Zyrtec Tablets 10mg – Patient Information Leaflet

1. What Zyrtec is and what it is used for

Cetirizine hydrochloride is the active ingredient of Zyrtec Tablets 10mg.
It is an antiallergic medication.

In adults and children aged 6 years and above, Zyrtec Tablets 10mg are 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 Zyrtec

Do not take Zyrtec

- if you have a severe kidney disease (severe renal failure with creatinine clearance below 10 ml/min);
- if you are allergic to cetirizine hydrochloride, to any of the other ingredients (listed in section 6), to hydroxyzine or to piperazine derivatives (closely related active ingredients of other medicines).

Warnings and precautions

Talk to your doctor or pharmacist before taking Zyrtec Tablets 10mg.

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 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 Zyrtec with alcohol.

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

Children

Do not give this medicine to children below the age of 6 years because the tablet formulation does not allow the necessary dose adjustments.

Other medicines and Zyrtec

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Zyrtec Tablets with food and drink

Food does not affect absorption of Zyrtec Tablets 10mg.

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.

Zyrtec 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. Therefore, you should not take Zyrtec 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 Zyrtec at the recommended dose.

You should closely observe your response to the drug after you have taken Zyrtec if you are intending to drive, engage in potentially hazardous activities or operate machinery. You should not exceed the recommended dose.

Zyrtec Tab 10mg contains lactose; if you have been told by your doctor that you have an intolerance to some sugars, please contact your doctor before taking this medicinal product.

3. How to take Zyrtec Tablets 10mg

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 tablets need to be swallowed with a glass of liquid.
The tablet can be divided into 2 equal doses.

Adults and adolescents above 12 years old:
The recommended dose is 10 mg (1 tablet) once daily.
Use in children between 6 and 12 years old:
The recommended dose is 5 mg (half tablet) twice daily.
Other form of this medicine may be more suitable for children, ask your doctor or pharmacist.

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 Zyrtec 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 Zyrtec Tablets than you should
If you think you have taken an overdose of Zyrtec Tablets, 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 Zyrtec Tablets 10mg
Do not take a double dose to make up for a forgotten dose.

If you stop taking Zyrtec Tablets 10mg

Rarely, pruritus (intense itching) and/or urticaria may be developed if you stop taking Zyrtec Tablets 10mg.

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)
- Diarrhoea, nausea, dry mouth
- Fatigue

Uncommon side effects (may affect up to 1 in 100 patients)

- Agitation
- Paraesthesia (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 are 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)

Side effects with frequency not known (frequency cannot be estimated from the available data)

- Increased appetite
- Suicide 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.

5. How to store Zyrtec Tablets 10mg

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 blister.

Also see outer packaging for storage condition.

6. Contents of the pack and other information

What Zyrtec Tablets 10mg contains

The active substance is cetirizine hydrochloride. One film-coated tablet contains 10 mg cetirizine hydrochloride.

The other ingredients are microcrystalline cellulose, lactose monohydrate, colloidal anhydrous silica, magnesium stearate, hydroxypropylmethylcellulose, titanium dioxide, macrogol 400.

What Zyrtec Tablets 10mg look like

White, oblong, film-coated tablet, with a bisect line and Y/Y logo.

Version number: HK082018 (NCDS05/eMC20180627)

治敏速 10 毫克藥片——患者須知

1. 治敏速是什麼及有何用途

Cetirizine hydrochloride 是治敏速 10 毫克藥片的活性成分。
它是一種抗過敏藥物。

對於成人和年滿 6 歲的兒童，治敏速 10 毫克藥片可用於

- 紓緩季節性和常年性過敏鼻炎在鼻腔和眼部的症狀。
- 紓緩風癮的症狀。

2. 在服用治敏速前，您需要了解哪些資訊

如有以下情況，切勿服用治敏速

- 如果您患有嚴重腎病（肌酸酐清除率低於 10 毫升/分鐘的嚴重腎衰竭）；
- 如果您對 cetirizine hydrochloride，任何其他成分（列出於第 6 部分）、hydroxyzine 或 piperazine 的衍化物（密切相關的其他藥物的活性成分）過敏

警告和注意事項

請在服用治敏速前先諮詢您的醫生或藥劑師。

如果您患有腎功能不全，請諮詢您的醫生；如有必要，您需要服用較低的劑量。您的醫生將為您決定新的服藥劑量。

如果您有排尿問題（例如脊椎、前列腺或膀胱問題），請諮詢您的醫生。

如果您患有癲癇症或有抽搐風險，您應該諮詢您的醫生。

如按照建議劑量使用，在臨床上並未有發現 cetirizine 和酒精（血中濃度 0.5 克/升，對應一杯酒的分量）之間產生顯著的交互作用。然而，現在尚未有更高劑量的 cetirizine 和酒精一同服用之安全性數據。因此，與所有抗組織胺藥一樣，建議您避免和酒精一同服用治敏速。

如果您安排好要接受過敏測試，請諮詢您的醫生，了解是否要在測試前的幾天停止服用治敏速。本藥物可能會影響您的過敏測試結果。

兒童

請勿讓不足 6 歲的兒童服用此藥片，因為此藥片不可作必要的劑量調整。

其他藥物與治敏速

如果您正在服用，最近服用過或可能會服用任何其他藥物，請告知您的醫生或藥劑師。

治敏速與食物和飲品

食物不會影響人體對治敏速 10 毫克藥片的吸收。

懷孕和哺乳

如果您已懷孕或在哺乳期中，認為自己可能懷孕或正在計劃懷孕，請在服用本藥物前諮詢您

的醫生。

孕婦應避免服用治敏速。孕婦意外服用本藥物不會對胎兒產生任何有害的效果。然而，只有在必要情況以及獲得醫療建議後，才可服用本藥物。

Cetirizine 會分泌到母乳。因此，您不應在哺乳期間服用治敏速，除非您已經諮詢過您的醫生。

駕駛和使用機器
如按照建議劑量服用，臨床研究尚未顯示治敏速會對注意力、警覺性和駕駛能力造成影響。如果您打算駕車，參與具有潛在危險性的活動或操作機器，請您密切留意自己在服用治敏速後對藥物的反應。您不應超過建議劑量。

治敏速 10 毫克藥片含乳糖；如果你的醫生曾告知你有醣類不耐症，請在服用藥前先諮詢您的醫生。

3. 如何服用治敏速 10 毫克藥片

務必按照本單張中的說明服用本藥物或遵從醫生或藥劑師的指示服用。如果您有不清楚的地方，請諮詢您的醫生或藥劑師。
本藥物應用水吞服。
本藥片可以分成 2 份相等的劑量。

成人和 12 歲以上的青少年：
建議劑量為每日 1 次，每次 10 毫克（1 片）。

6 到 12 歲之間的兒童：
建議劑量為每日 2 次，每次 5 毫克（半片）。
有更適合兒童使用的製劑，請諮詢您的醫生或藥劑師。

腎功能受損的患者
中度腎功能受損的患者的建議劑量為每日一次，每次 5 毫克。
如果您患有嚴重的腎病，請諮詢您的醫生或藥劑師。他們會相應調整劑量。
如果您的孩子患有腎病，請諮詢您的醫生或藥劑師。他們會根據孩子的需求相應調整劑量。

如果您感到治敏速的藥效太弱或太強，請諮詢您的醫生。

治療期間的長短
您的醫生會根據您疾病的類型、持續時間和病程決定你服藥期間的長短。

如果您服用了過量的治敏速藥片
如果您認為自己服用了過量的治敏速藥片，請告知您的醫生。
如有需要，您的醫生會決定採用甚麼措施。

服藥過量後，以下副作用可能會以較強烈的形式出現。不良反應如精神錯亂、腹瀉、眩暈、

困倦、頭痛、疲倦、瞳孔擴大、痕癢、煩躁、呆靜、嗜睡、昏迷、心跳異常快速、震顫和尿潴留等副作用都有被報告過。

如果您忘記服用治敏速 10 毫克藥片
請勿因忘記服藥而一次服用雙倍劑量。

如果您停止服用治敏速 10 毫克藥片
在罕見情況下，停止服用治敏速 10 毫克藥片後，可能會出現瘙癢症（劇烈痕癢）和/或風癮。

如果您對本藥物的使用有任何進一步的疑問，請諮詢您的醫生或藥劑師。

4. 可能出現的副作用
和所有藥物一樣，本藥物也會引發一些副作用，儘管並非所有人都會有這些症狀。

以下副作用是罕見或極為罕見的，但是一旦您注意到這些情況，您必須停止服藥並立即諮詢您的醫生：
- 過敏反應，包括嚴重的反應和血管性水腫（嚴重的過敏反應令面部或咽喉腫大）。

這些反應可能會在您初次服藥後很快就出現，也可能稍後才出現。

常見副作用（每 10 個人中最多有 1 人可能會受此影響）
- 嗜睡（瞌睡）
- 眩暈、頭痛
- 咽喉炎、鼻炎（兒童）
- 腹瀉、噁心、口乾
- 疲勞

不常見副作用（每 100 個人中最多有 1 人可能會受此影響）
- 焦慮
- 感覺異常（皮膚有異常感覺）
- 腹痛
- 瘙癢症（皮膚痕癢），皮疹
- 無力（極度疲勞），疲倦

罕見副作用（每 1,000 個人中最多有 1 人可能會受此影響）
- 過敏反應，部分很嚴重（極為罕見）
- 抑鬱、幻覺、攻擊性行為、精神錯亂、失眠
- 抽搐
- 心動過速（心臟跳動過快）
- 肝功能異常
- 風癮（蕁麻疹）
- 水腫（腫漲）
- 體重增加

極為罕見的副作用（每 10,000 個人中最多有 1 人可能會受此影響）

- 血小板減少症（血小板含量低）
- 抽搐（習慣性痙攣）
- 暈厥、運動障礙（不自主運動）、肌張力障礙（異常長時間肌肉收縮）、震顫、味覺障礙（味覺改變）
- 視力模糊、調節障礙（聚焦困難）、眼球旋動（眼睛不受控制的轉動）
- 血管性水腫（嚴重的過敏反應造成面部或咽喉腫大）、藥疹
- 排尿異常（遺尿、排尿疼痛和/或困難）

未知頻率的副作用（無法根據現有數據估算出頻率）
- 食欲增進
- 自殺念頭（反覆或突然出現自殺念頭），發噩夢
- 健忘，記憶力受損
- 眩暈（感到轉動或移動）
- 尿瀦留（無法完全排空膀胱）
- 停藥後出現瘙癢症（極度痕癢）和/或風癮
- 關節痛
- 皮疹包含膿液
- 肝炎

報告副作用
如果您有任何副作用，請與您的醫生或藥劑師溝通。這包括未在本單張中列出的任何可能的副作用。

5. 如何存放治敏速 10 毫克藥片
請將本藥物放在兒童無法看見並觸及的地方。
如果藥物包裝盒和吸塑包裝上印刷的到期日已過，切勿服用。
請參見外包裝上有關存放條件的指引。

6. 包裝內容和其他資訊
治敏速 10 毫克藥片的成分
活性成分為 cetirizine hydrochloride。每薄膜衣藥片含有 10 毫克的 cetirizine hydrochloride。其他成分有 microcrystalline cellulose, lactose monohydrate, colloidal anhydrous silica, magnesium stearate, hydroxypropylmethylcellulose, titanium dioxide, macrogol 400。

治敏速 10 毫克藥片的外觀
白色、橢圓形、有薄膜衣包裹的藥片。藥片上有平分線和 Y/Y 標志。

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