

**ZYRTEC-D- cetirizine hydrochloride and pseudoephedrine hydrochloride tablet, film coated, extended release**  
**Kenvue Brands LLC**

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**ZYRTEC-D**

**Drug Facts**

<b>Active ingredients (in each extended release tablet)</b>	<b>Purpose</b>
Cetirizine HCl 5 mg	Antihistamine
Pseudoephedrine HCl 120 mg	Nasal decongestant

**Uses**

- temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:
  - runny nose
  - sneezing
  - itchy, watery eyes
  - itching of the nose or throat
  - nasal congestion
- reduces swelling of nasal passages
- temporarily relieves sinus congestion and pressure
- temporarily restores freer breathing through the nose

**Warnings**

**Do not use**

- if you have ever had an allergic reaction to this product or any of its ingredients or to an antihistamine containing hydroxyzine.
- if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric, or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.

**Ask a doctor before use if you have**

- heart disease
- thyroid disease
- diabetes
- glaucoma
- high blood pressure
- trouble urinating due to an enlarged prostate gland
- liver or kidney disease. Your doctor should determine if you need a different dose.

**Ask a doctor or pharmacist before use if you are** taking tranquilizers or sedatives.

## When using this product

- **do not use more than directed**
- drowsiness may occur
- avoid alcoholic drinks
- alcohol, sedatives, and tranquilizers may increase drowsiness
- be careful when driving a motor vehicle or operating machinery

## Stop use and ask a doctor if

- an allergic reaction to this product occurs. Seek medical help right away.
- you get nervous, dizzy, or sleepless
- symptoms do not improve within 7 days or are accompanied by fever

## If pregnant or breast-feeding:

- if breast-feeding: not recommended
- if pregnant: ask a health professional before use.

**Keep out of reach of children.** In case of overdose, get medical help or contact a Poison Control Center right away. (1-800-222-1222)

## Directions

- do not break or chew tablet; swallow tablet whole

adults and children 12 years and over	take 1 tablet every 12 hours; do not take more than 2 tablets in 24 hours.
adults 65 years and over	ask a doctor
children under 12 years of age	ask a doctor
consumers with liver or kidney disease	ask a doctor

## Other information

- store between 20° to 25°C (68° to 77°F)
- **do not use if blister unit is torn or broken**

## Inactive ingredients

colloidal silicon dioxide, croscarmellose sodium, hypromellose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, polyethylene glycol, titanium dioxide

## Questions?

call **1-800-343-7805** (toll-free) or **215-273-8755** (collect)

**PRINCIPAL DISPLAY PANEL**

***Original Prescription Strength***

NDC 50580-719-24

**ZYRTEC-D**®

*Cetirizine HCl* **5 mg**/antihistamine

*Pseudoephedrine HCl* **120 mg**/ nasal decongestant

*Extended Release Tablets*

Indoor &

Outdoor

Allergies

ALLERGY

+ SINUS

NASAL CONGESTION

+ SINUS PRESSURE

**12**

***Hour***

***relief of***

- ***Sneezing***
- ***Runny Nose***
- ***Itchy, Watery Eyes***
- ***Itchy Throat or Nose***

***Actual Size***

**24**

***EXTENDED***

***RELEASE***

***TABLETS***



www.zyrtec.com  
 Made in Belgium  
 Distributed by: Kenvue Brands LLC  
 Summit, NJ 07901  
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**Drug Facts (continued)**

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■ trouble urinating due to an enlarged prostate gland

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The trade dress of this ZYRTEC® package is subject to trademark protection.  
 www.kenvuepats.com 30061092



ALLERGY + SINUS



Original Prescription Strength

NDC 50580-719-24

**ZYRTEC-D**

Cetirizine HCl 5 mg/antihistamine  
 Pseudoephedrine HCl 120 mg/nasal decongestant  
 Extended Release Tablets

Indoor & Outdoor Allergies



30061092



30061092

**ALLERGY + SINUS**



12 Hour relief of



Sneezing



Runny Nose

**NASAL CONGESTION + SINUS PRESSURE**



Itchy, Watery Eyes



Itchy Throat or Nose



Actual Size

**24 EXTENDED RELEASE TABLETS**

**ZYRTEC-D**  
 cetirizine hydrochloride and pseudoephedrine hydrochloride tablet, film coated, extended release

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:50580-719
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>CETIRIZINE HYDROCHLORIDE</b> (UNII: 64O047KTOA) (CETIRIZINE - UNII:YO7261ME24)	CETIRIZINE HYDROCHLORIDE	5 mg
<b>PSEUDOEPHEDRINE HYDROCHLORIDE</b> (UNII: 6V9V2RYJ8N) (PSEUDOEPHEDRINE - UNII:7CUC9DDI9F)	PSEUDOEPHEDRINE HYDROCHLORIDE	120 mg

### Inactive Ingredients

Ingredient Name	Strength
<b>CROSCARMELOSE SODIUM</b> (UNII: M28OL1HH48)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>HYPROMELLOSE, UNSPECIFIED</b> (UNII: 3NXW29V3WO)	
<b>LACTOSE MONOHYDRATE</b> (UNII: EWQ57Q8I5X)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	

### Product Characteristics

<b>Color</b>	white	<b>Score</b>	no score
<b>Shape</b>	ROUND	<b>Size</b>	10mm
<b>Flavor</b>		<b>Imprint Code</b>	ZYRTEC;D
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50580-719-12	2 in 1 CARTON	02/28/2023	
1		6 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:50580-719-24	4 in 1 CARTON	02/28/2023	
2		6 in 1 BLISTER PACK; Type 0: Not a Combination Product		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA021150	02/28/2023	

