# CENTER FOR DRUG EVALUATION AND RESEARCH

***APPLICATION NUMBER:***

# 022578Orig1s000

# LABELING

# **Zyrtec** 10mg ODT

6ct – 10mg

| Labeling Format Information: | |
|---|---|
| Fonts: Helvetica cond. medium, bold, bold oblique | |
| Drug Facts: | 8.5 pt |
| Header: | 8 pt |
| Subheader: | 6 pt |
| Body Text: | 6 pt |
| Drug Facts (continued): | 8 pt |
| Leading: | 6.25 pt |
| Bullets: | 5 pt |
| Barlines: | 1.5 pt |
| Hairlines: | .5 pt |
| Horizontal Scale: | 100% |
| Average Kerning: | 0 |

# **Zyrtec** 10mg ODT

12ct – 10mg

| Labeling Format Information: | |
|---|---|
| Fonts: Helvetica cond. medium, bold, bold oblique | |
| Drug Facts: | 8.5 pt |
| Header: | 8 pt |
| Subheader: | 6 pt |
| Body Text: | 6 pt |
| Drug Facts (continued): | 8 pt |
| Leading: | 6.25 pt |
| Bullets: | 5 pt |
| Barlines: | 1.5 pt |
| Hairlines: | .5 pt |
| Horizontal Scale: | 100% |
| Average Kerning: | 0 |

# **Zyrtec** 10mg ODT

24ct – 10mg

| Labeling Format Information: | |
|---|---|
| Fonts: Helvetica cond. medium, bold, bold oblique | |
| Drug Facts: | 8.5 pt |
| Header: | 8 pt |
| Subheader: | 6 pt |
| Body Text: | 6 pt |
| Drug Facts (continued): | 8 pt |
| Leading: | 6.25 pt |
| Bullets: | 5 pt |
| Barlines: | 1.5 pt |
| Hairlines: | .5 pt |
| Horizontal Scale: | 100% |
| Average Kerning: | 0 |

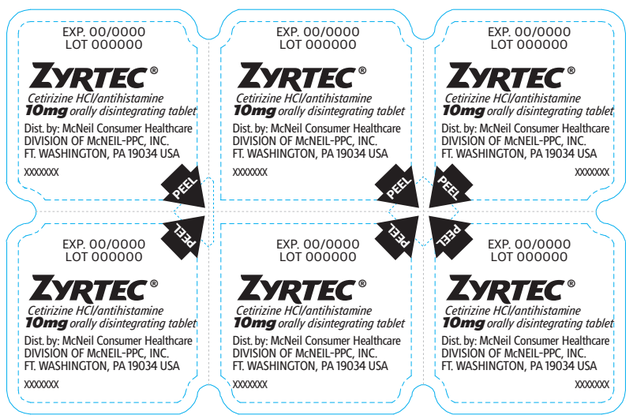
# **Zyrtec** 10mg ODT

66ct – 10mg

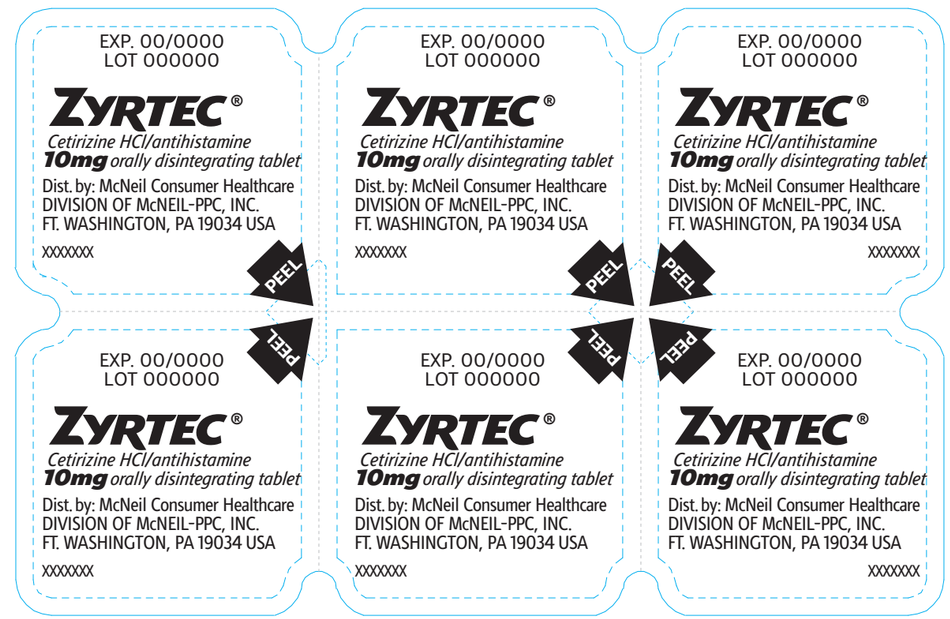
| Labeling Format Information: | |
|---|---|
| Fonts: Helvetica cond. medium, bold, bold oblique | |
| Drug Facts: | 8.5 pt |
| Header: | 8 pt |
| Subheader: | 6 pt |
| Body Text: | 6 pt |
| Drug Facts (continued): | 8 pt |
| Leading: | 6.25 pt |
| Bullets: | 5 pt |
| Barlines: | 1.5 pt |
| Hairlines: | .5 pt |
| Horizontal Scale: | 100% |
| Average Kerning: | 0 |

# **Zyrtec** 10mg ODT–Blister

100%




150%



| Application Type/Number | Submission Type/Number | Submitter Name | Product Name |
|---|---|---|---|
| NDA-22578 | ORIG-1 | MCNEIL CONSUMER HEALTHCARE DIV MCNEIL PPC INC | CETIRIZINE HCL ORALLY 10MG TABS |

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**This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.**

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/s/

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ANDREA LEONARD SEGAL
09/03/2010