





0456-0400-10

AF95USCFR404 Rev. MM/YYYY

FOREST PHARMACEUTICALS, INC.  
10000 Forest Avenue, St. Louis, Missouri 63045

Distributed by  
Forest Pharmaceuticals, Inc.  
St. Louis, MO 63045  
Manufactured by:  
Fata Farmaceutici S.p.A.  
64020, Teramo, Italy

Prior to constitution: Store at 25°C (77°F); excursions permitted to 15-30°C (59-86°F) [see USP Controlled Room Temperature].

See package insert for dosage recommendation, constitution instructions and complete directions for use.  
conditions; however, when stored as recommended, the product potency is not affected.  
The color of TEFLARO® infusion solutions range from clear, light to dark yellow depending on the concentration and storage conditions; however, when stored as recommended, the product potency is not affected.  
Further dilute the entire contents before infusing.  
Following constitution with 20 mL Sterile Water for Injection, USP, or 0.9% of sodium chloride injection (normal saline); or 5% of dextrose injection; or lactated ringers injection, the resultant solution will contain approximately 20 mg/mL.  
Single use vial. Discard unused portion.  
The constituted solution is maintained between pH 4.8 to 6.5.  
Each vial contains L-arginine, an alkalinizing agent formulated at approximately 660 mg per gram of ceftaroline fosamil.

AF95USCFR404

ACSA075F01

NDC 0456-0400-10

Rx only

10 Single-Use Vials

# (ceftaroline fosamil) for injection

**FOR INTRAVENOUS INFUSION ONLY  
CONSTITUTED SOLUTION MUST BE  
FURTHER DILUTED FOR INTRAVENOUS INFUSION**

NDC 0456-0400-10

Rx only

10 Single-Use Vials

# (ceftaroline fosamil) for injection

**FOR INTRAVENOUS INFUSION ONLY  
CONSTITUTED SOLUTION MUST BE  
FURTHER DILUTED FOR INTRAVENOUS INFUSION**

(ceftaroline fosamil) for injection

(ceftaroline fosamil) for injection

Each vial contains 400 mg ceftarone fosamil powder for intravenous infusion

Lot  
Exp date

(b) (4)

Prod. A - Teflaro Ceftaroline 400 mg MK 95  
Colors: (Black - - )  
Cutting die code: ACSA075F00  
Technical Specification code: ACSA075F01  
Size (mm): 69,5 x 67,5 x 165  
g/m<sup>2</sup>: 290 g/m<sup>2</sup>  
Thickness (mm): 0,540 mm  
Pharmacode: I X I X X I X X X  
Braille translation: not present  
Font Type: Hlevetica 7,6 pt  
BARCODE READING VERIFICATION  
0456'0400'10

(b) (4)



400 mg/vial

**Teflaro<sup>®</sup>**

**Teflaro<sup>®</sup>**

**400 mg/vial**

**Teflaro<sup>®</sup>**

**400 mg/vial**

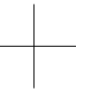
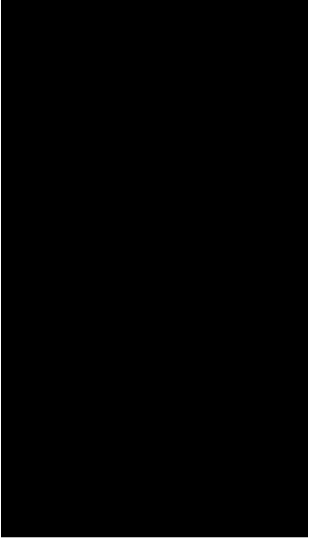
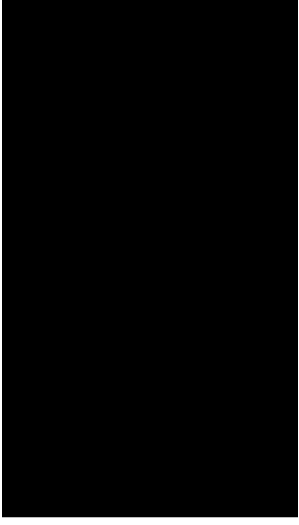
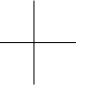
**Teflaro<sup>®</sup>**  
400 mg/vial



(b) (4)

Prod. A - Teflaro Ceftaroline 400 mg MK 95  
Colors: ( (b) (4) - )  
Cutting die code: ACSA075F00  
Technical Specification code: ACSA075F01  
Size (mm): 69,5 x 67,5 x 165  
g/m<sup>2</sup>: 290 g/m<sup>2</sup>  
Thickness (mm): 0,540 mm  
Pharmacode: I X I X X I X X X  
Braille translation: not present  
Font Type: Hlvetica 7,6 pt  
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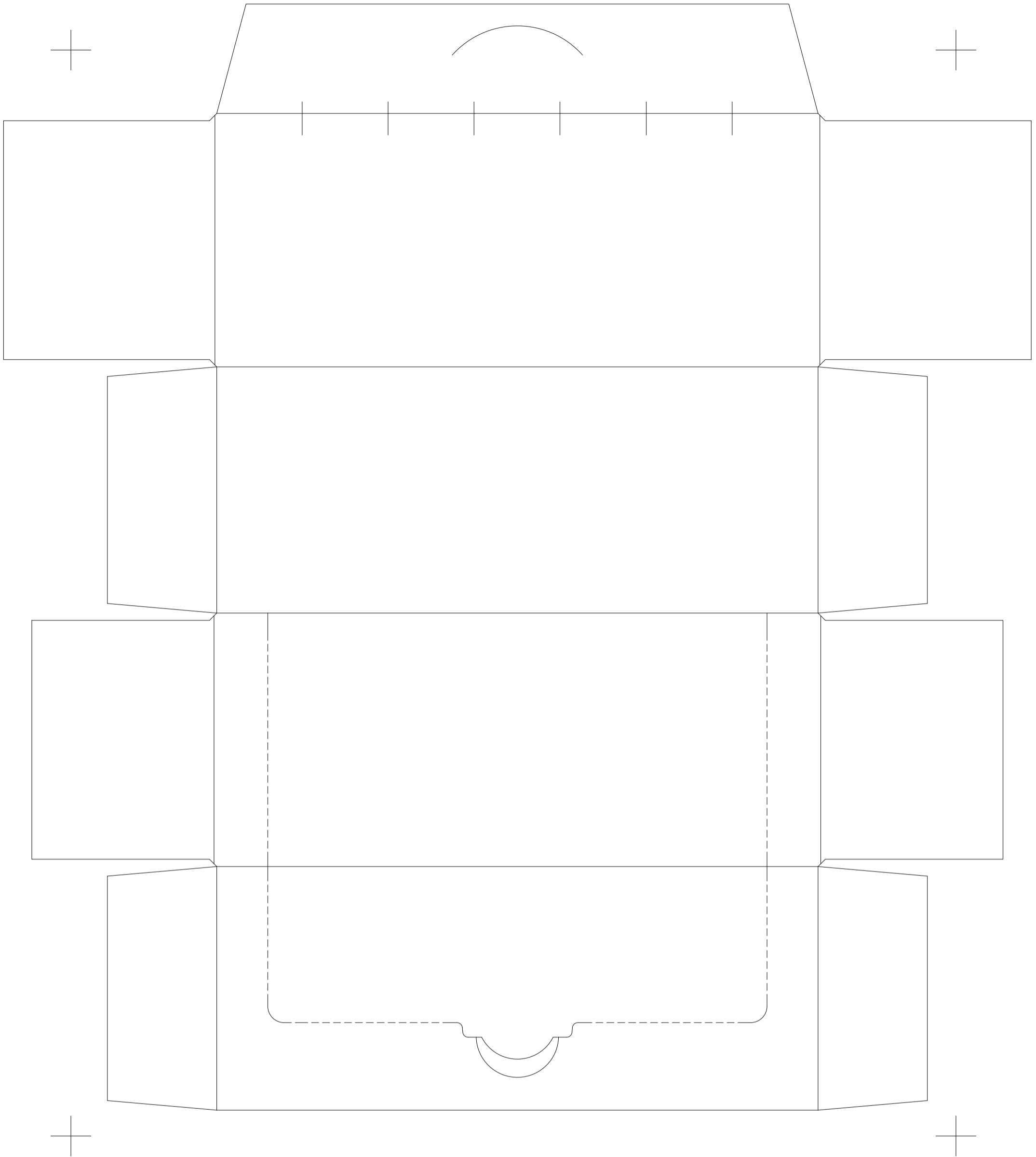
(b) (4)



(b) (4)

Prod. **A - Teflaro Ceftaroline 400 mg MK 95**  
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Colors: (       -       - VARNISH FREE AREA)  
-----  
Cutting die code: **ACSA075F00**  
Technical Specification code: **ACSA075F01**  
Size (mm): **69,5 x 67,5 x 165**  
-----  
g/m<sup>2</sup>: **290 g/m<sup>2</sup>**  
Thickness (mm): **0,540 mm**  
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Pharmacode: **I X I X X I X X X**  
Braille translation: **not present**  
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Font Type: **Hlevetica 7,6 pt**  
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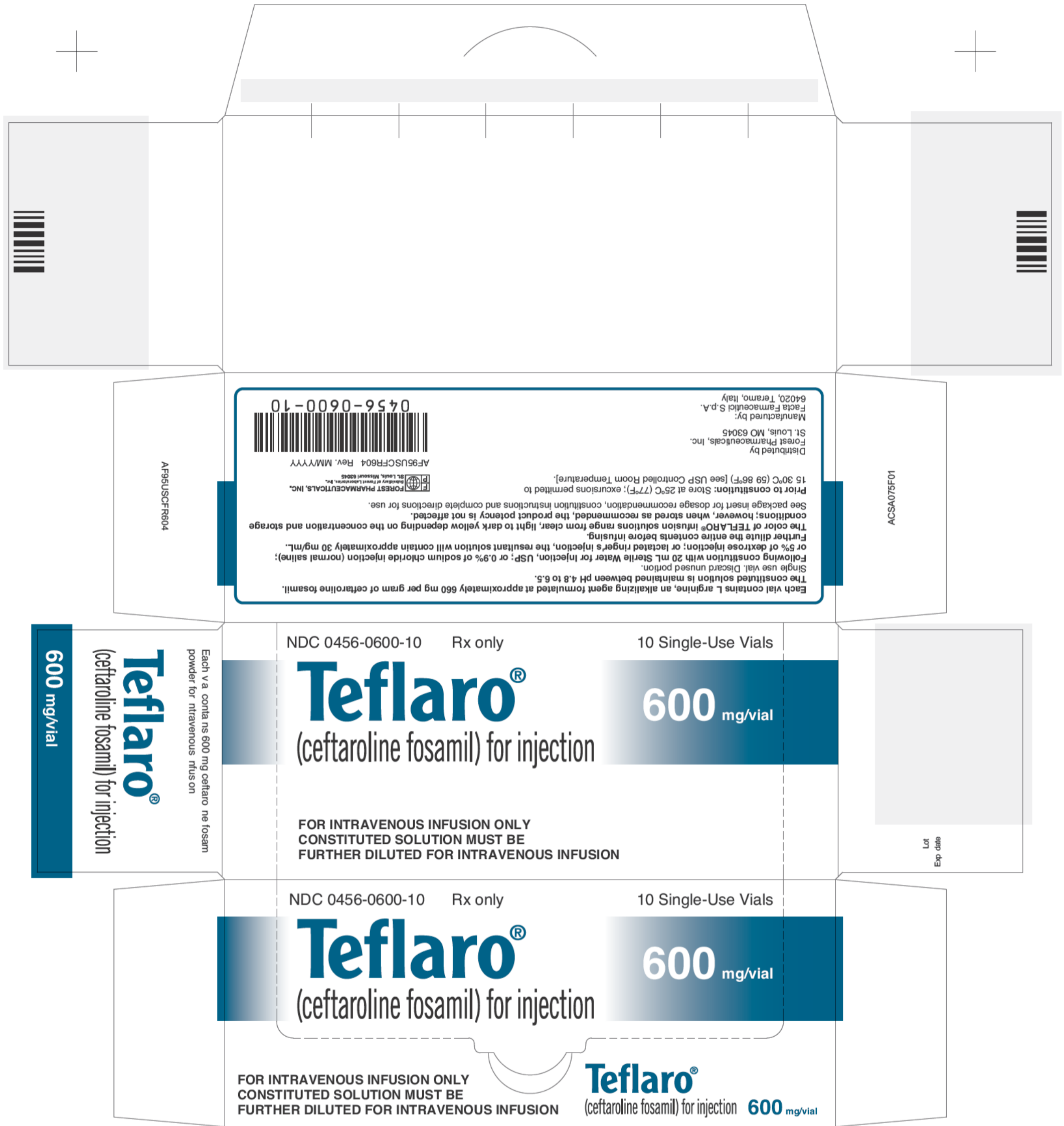
(b) (4)



(b) (4)

Prod. **A - Teflaro Ceftaroline 400 mg MK 95**  
Colors: ( - - )  
Cutting die code: **ACSA075F00**  
Technical Specification code: **ACSA075F01**  
Size (mm): **69,5 x 67,5 x 165**  
g/m<sup>2</sup>: **290 g/m<sup>2</sup>**  
Thickness (mm): **0,540 mm**  
Pharmacode: **I X I X X I X X X**  
Braille translation: **not present**  
Font Type: **Helvetica 7,6 pt**  
**BARCODE READING VERIFICATION**  
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(b) (4)



(b) (4)	<p><b>Prod. A - Teflaro Ceflaroline 600 mg MK 95</b></p> <p>Colors: (Black - (b) (4) - )</p> <p>Cutting die code: <b>ACSA075F00</b>                  Technical Specification code: <b>ACSA075F01</b>                  Size (mm): <b>69,5 x 67,50 x 165</b></p> <p>g/m<sup>2</sup>: <b>290 g/m<sup>2</sup></b>                  Thickness (mm): <b>0,540 mm</b></p> <p>Pharmacode: <b>11X X X111X</b>                  Braille translation: <b>not present</b></p> <p>Font Type: <b>Hlvetica 7,6 pt</b></p> <p><b>BARCODE READING VERIFICATION</b>  <b>0456'0600'10</b></p>	(b) (4)
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0456-0600-10

AF95USCFR604 Rev. MM/YY

FOREST PHARMACEUTICALS, INC.  
St. Louis, Missouri 63045

Distributed by  
Forest Pharmaceuticals, Inc.  
St. Louis, MO 63045  
Manufactured by:  
Facta Farmaceutici S.p.A.  
64020, Teramo, Italy

Each vial contains L-arginine, an alkalinizing agent formulated at approximately 660 mg per gram of ceftaroline fosamil.  
The constituted solution is maintained between pH 4.8 to 6.5.  
Single use vial. Discard unused portion.  
Following constitution with 20 mL Sterile Water for Injection, USP: or 0.9% of sodium chloride injection (normal saline); or 5% of dextrose injection; or lactated ringers injection, the resultant solution will contain approximately 30 mg/mL. Further dilute the entire contents before infusing.  
The color of TEFLARO® infusion solutions range from clear, light to dark yellow depending on the concentration and storage conditions; however, when stored as recommended, the product potency is not affected.  
See package insert for dosage recommendation, constitution instructions and complete directions for use.  
Prior to constitution: Store at 25°C (77°F); excursions permitted to 15-30°C (59-86°F) [see USP Controlled Room Temperature].

AF95USCFR604

ACSA075F01

NDC 0456-0600-10

Rx only

10 Single-Use Vials

# (ceftaroline fosamil) for injection

**FOR INTRAVENOUS INFUSION ONLY  
CONSTITUTED SOLUTION MUST BE  
FURTHER DILUTED FOR INTRAVENOUS INFUSION**

NDC 0456-0600-10

Rx only

10 Single-Use Vials

# (ceftaroline fosamil) for injection

**FOR INTRAVENOUS INFUSION ONLY  
CONSTITUTED SOLUTION MUST BE  
FURTHER DILUTED FOR INTRAVENOUS INFUSION** (ceftaroline fosamil) for injection

(ceftaroline fosamil) for injection

Each vial contains 600 mg ceftarone fosamil powder for intravenous infusion

Lot  
Exp date

(b) (4)

Prod. A - Teflaro Ceftaroline 600 mg MK 95  
Colors: (Black - - )  
Cutting die code: ACSA075F00  
Technical Specification code: ACSA075F01  
Size (mm): 69,5 x 67,50 x 165  
g/m<sup>2</sup>: 290 g/m<sup>2</sup>  
Thickness (mm): 0,540 mm  
Pharmacode: I I X X I I I I X  
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(b) (4)



600 mg/vial

**Teflaro<sup>®</sup>**

**Teflaro<sup>®</sup>**

**600 mg/vial**

**Teflaro<sup>®</sup>**

**600 mg/vial**

**Teflaro<sup>®</sup>**

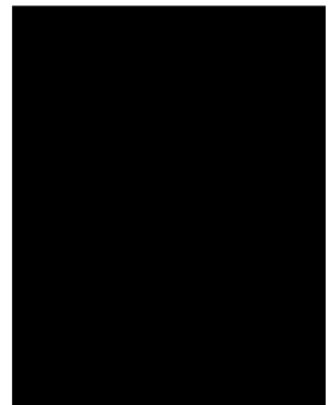
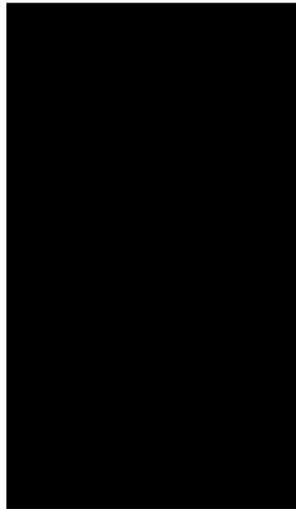
**600 mg/vial**



(b) (4)

Prod. A - Teflaro Ceftaroline 600 mg MK 95  
Colors: ( - (b) (4) - )  
Cutting die code: ACSA075F00  
Technical Specification code: ACSA075F01  
Size (mm): 69,5 x 67,50 x 165  
g/m<sup>2</sup>: 290 g/m<sup>2</sup>  
Thickness (mm): 0,540 mm  
Pharmacode: I I X X X I I I I X  
Braille translation: not present  
Font Type: Hlevetica 7,6 pt  
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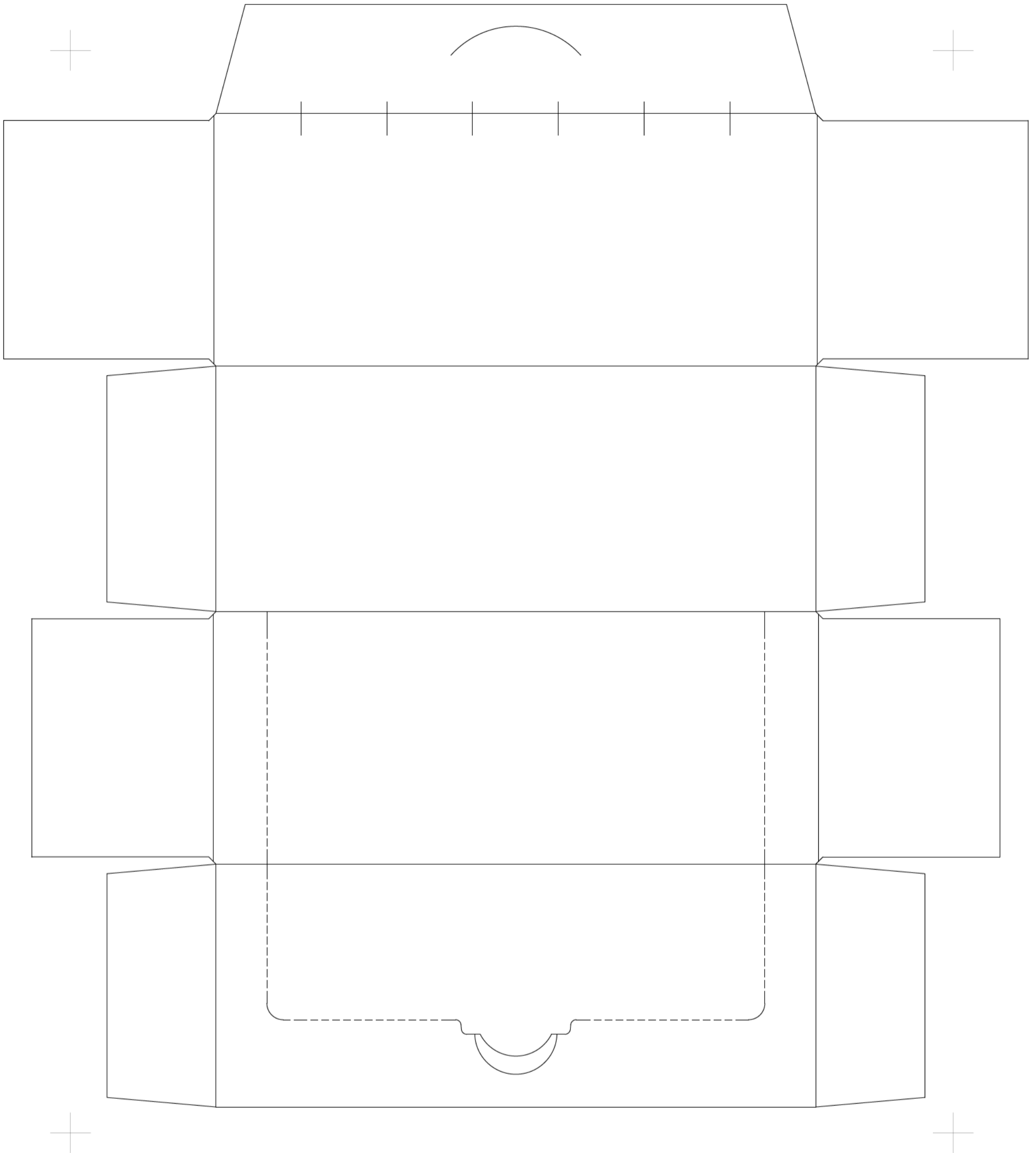
(b) (4)



(b) (4)

Prod. A - Teflaro Ceftriaxone 600 mg MK 95  
-----  
Colors: ( - - VARNISH FREE AREA)  
-----  
Cutting die code: ACSA075F00  
Technical Specification code: ACSA075F01  
Size (mm): 69,5 x 67,50 x 165  
-----  
g/m<sup>2</sup>: 290 g/m<sup>2</sup>  
Thickness (mm): 0,540 mm  
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Pharmacode: 11 X X X 111 X  
Braille translation: not present  
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Font Type: Helvetica 7,6 pt  
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**BARCODE READING VERIFICATION**  
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(b) (4)

Prod. A - Teflaro Ceftriaxone 600 mg MK 95

Colors: ( - - )

Cutting die code: ACSA075F00

Technical Specification code: ACSA075F01

Size (mm): 69,5 x 67,50 x 165

g/m<sup>2</sup>: 290 g/m<sup>2</sup>

Thickness (mm): 0,540 mm

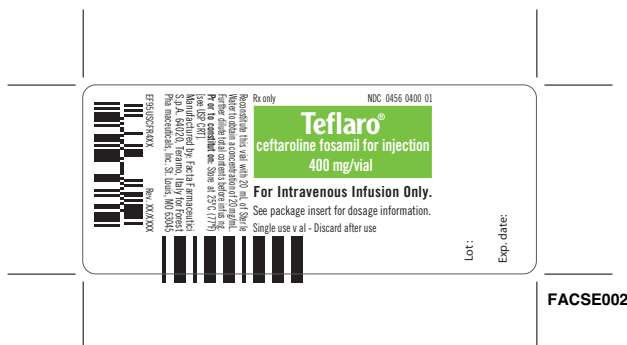
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Braille translation: not present

Font Type: Hlevetica 7,6 pt

BARCODE READING VERIFICATION  
0456'0600'10

(b) (4)



(b) (4)

Prod. **E - Teflaro Ceftazolin 400 mg MK 95**

Colors: (Black - (b) (4))

Cutting die code: **FACSE001**

Technical Specification code: **FACS002**

Size (mm): **60 x 25 mm**

g/m<sup>2</sup>: **62 g/m<sup>2</sup>**

Thickness (mm): **0,055 mm**

Pharmacode: **I X I X X I X X X**

Braille translation: **not present**

Font Type: **Trade Gothic 4 pt**

**BARCODE READING VERIFICATION**

non readable

(b) (4)

R



FACSE002

(b) (4)

Prod. **E - Teflaro Ceftaroline 600 mg MK 95**

Colors: (Black - (b) (4))

Cutting die code: **FACSE001**  
 Technical Specification code: **FACS002**  
 Size (mm): **60 x 25 mm**

g/m<sup>2</sup>: **62 g/m<sup>2</sup>**  
 Thickness (mm): **0,055 mm**

Pharmacode: **11X X X 111 X**  
 Braille translation: **not present**

Font Type: **Trade Gothic 4 pt**

**BARCODE READING VERIFICATION**

Reference ID: 3349000 non readable

(b) (4)

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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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DAVID B LEWIS

07/29/2013

Approval; signing for T. Oliver