

ATTACHED LEGEND TO ALL DIGITAL MECHANICALS
 Helvetica Condensed
 90% Horizontal Scale
STANDARD FORMAT:
Drug Facts - 10 pt Helvetica Bold Condensed Oblique
Headings - 8 pt Bold Condensed Oblique
Sub Heads - 6 pt Helvetica Bold Condensed
 Text - 6 pt Helvetica Medium Condensed
 Border - 1 pt rule, 3/64" gap all around
 Barline - 1 pt Rule
 Certified by: MS

Z-Folded



(2plcs) Not actual code
 Code bars to be changed
 to match this product

Laser Ablation
 Lot #
 Exp. Date

Drug Facts

Active ingredient (in each rectal suppository) Acetaminophen, USP 80 mg	Purposes Pain reliever/fever reducer										
Uses temporarily • reduces fever • relieves minor aches, pains, and headache											
Warnings Liver warning: This product contains acetaminophen. Severe liver damage may occur if your child takes: • more than 4 doses in 24 hours, which is the maximum daily amount for ages 6 to 11 months • more than 5 doses in 24 hours, which is the maximum daily amount for ages 12 to 36 months • with other drugs containing acetaminophen Allergy alert: acetaminophen may cause severe skin reactions. Symptoms may include: • skin reddening • blisters • rash If a skin reaction occurs, stop use and seek medical help right away. For rectal use only. Do not use • if you are allergic to acetaminophen. • with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist. Ask a doctor before use if • the child has liver disease. • the child is taking the blood thinning drug warfarin. Stop use and ask a doctor if • fever lasts more than 3 days (72 hours), or recurs. • pain lasts more than 3 days or gets worse. • new symptoms occur. • redness or swelling is present in the painful area. These may be signs of a serious condition.	Drug Facts (continued) Keep out of reach of children. If swallowed or in case of overdose, get medical help or contact a Poison Control Center right away. Quick medical attention is critical in case of overdose for adults and for children even if you do not notice any signs or symptoms. Directions • this product does not contain directions or warnings for adult use • do not use more than directed • remove wrapper • carefully insert suppository well up into the rectum <table border="1"> <tr> <th colspan="2">Dosing Chart</th> </tr> <tr> <th>Age</th> <th>Dose</th> </tr> <tr> <td>under 6 months</td> <td>Do not use unless directed by a doctor</td> </tr> <tr> <td>6 to 11 months</td> <td>Use 1 suppository every 6 hours (maximum of 4 doses in 24 hours)</td> </tr> <tr> <td>12 to 36 months</td> <td>Use 1 suppository every 4 to 6 hours (maximum of 5 doses in 24 hours)</td> </tr> </table> Other information • store at 2°-27°C (35°-80°F) • do not use if imprinted suppository wrapper is opened or damaged Inactive ingredients glycerol monostearate, hydrogenated vegetable oil, polyoxyethylene stearate, polysorbate 80 Questions? call 1-866-923-4914	Dosing Chart		Age	Dose	under 6 months	Do not use unless directed by a doctor	6 to 11 months	Use 1 suppository every 6 hours (maximum of 4 doses in 24 hours)	12 to 36 months	Use 1 suppository every 4 to 6 hours (maximum of 5 doses in 24 hours)
Dosing Chart											
Age	Dose										
under 6 months	Do not use unless directed by a doctor										
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Dist. by: Taro Pharmaceuticals U.S.A., Inc.
 Hawthorne, NY 10532
 Made in USA
 GW 710010
 Do not use if imprinted wrapper is opened or damaged.

5.187

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100% Horizontal Scale

Drug Facts - 14 pt Helvetica Bld Condensed Oblique

Headings - 9 pt Bold Condensed Oblique

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Text - 7 pt Helvetica Medium Condensed

Border - 2.5 pt rule, 3/64" gap all around

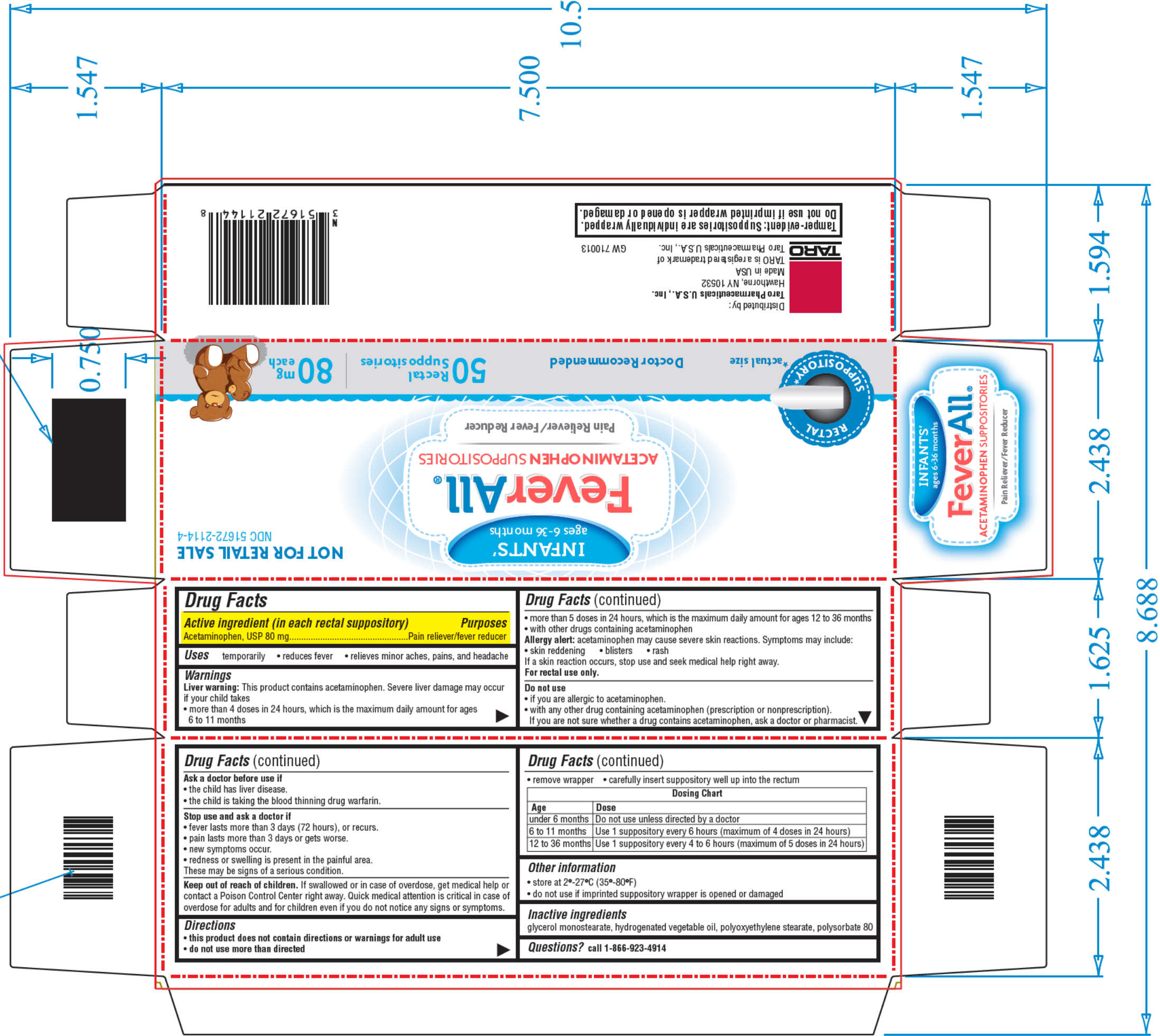
Baseline - .75 pt Rule

Certified by: MS

Gear Side
Web Direction

Laser Ablation
Lot #
Exp. Date

5 2 locations



.10272A2
 Overall 5th PNL CTN
 1.500" x 1.000" x 1.648"
 5pt C1S SBS
 1-17-2014

Z-Folded

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(b) (4)

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Certified by: MS



L10272A2

Feverall 5th PNL CTN
2.500' x 1.000" x 1.648"
15pt C1S SBS
11-17-2014

(b) (4)

Z-Folded



Laser Ablation
Lot #
Exp. Date

(2plcs) Not actual code
Code bars to be changed
to match this product

ATTACHED LEGEND TO ALL
DIGITAL MECHANICALS

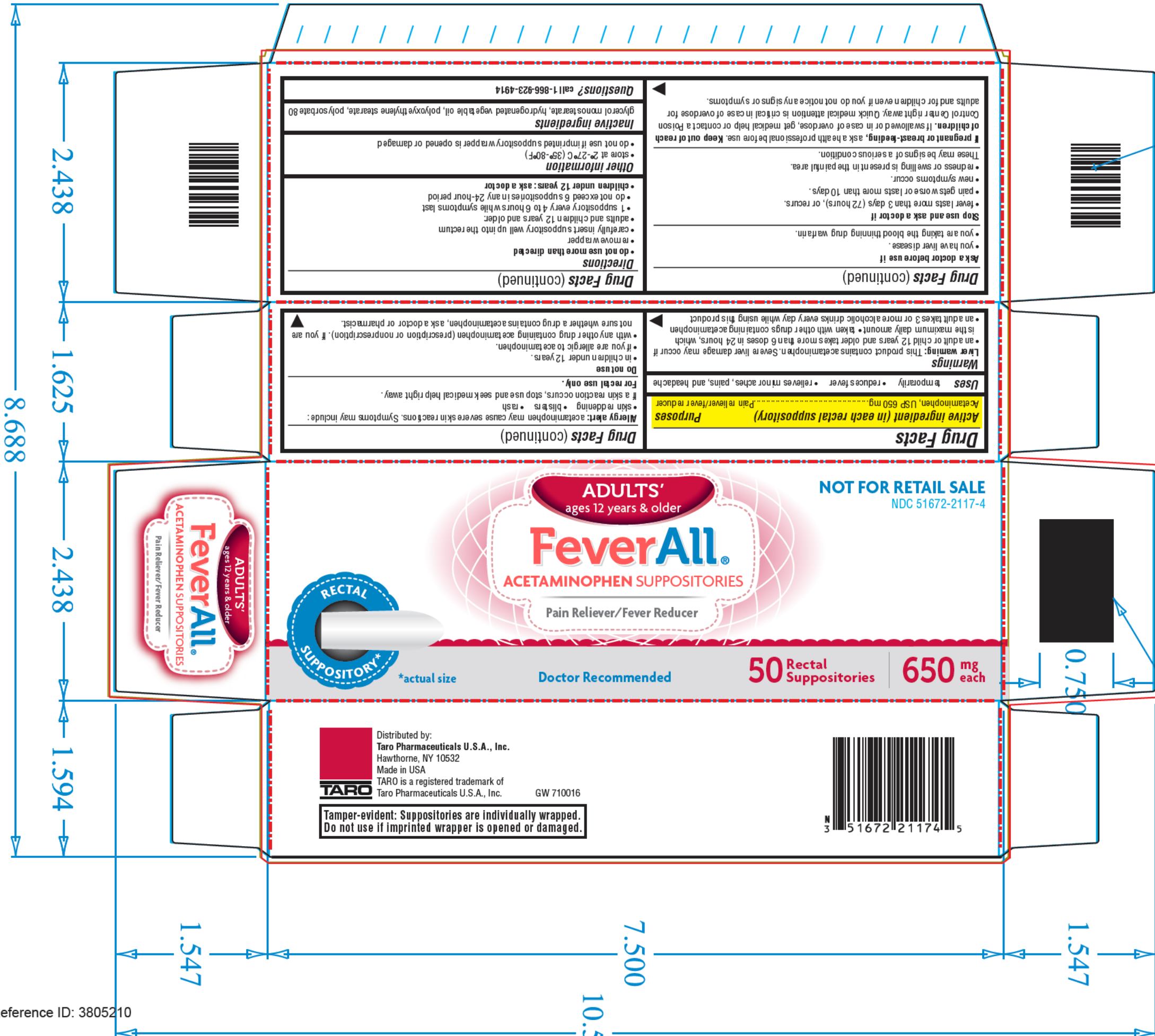
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(b) (4)



f5 2 locations

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Web Direction

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Taro Pharmaceuticals U.S.A., Inc.

SUPPOSITORY SIDE BY SIDE COMPARISON

CURRENT DRUG LABELING

80 mg

PROPOSED DRUG LABELING



1. Changed color scheme and design (b) (4)
2. Bar code and numbers revised from Actavis to Taro's.
3. Updated Distributor statement from Actavis to Taro's.



Taro Pharmaceuticals U.S.A., Inc.

CURRENT DRUG LABELING

120 mg

PROPOSED DRUG LABELING



1. Changed color scheme and design. (b) (4)
2. Bar code number revised from Actavis to Taro's.
3. Updated Distributor statement from Actavis to Taro's.



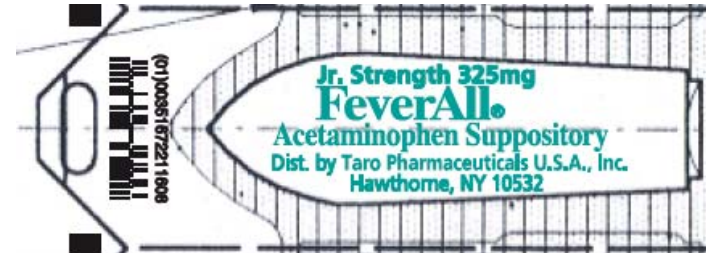
Taro Pharmaceuticals U.S.A., Inc.

NDA #018337
FeverAll® (Acetaminophen Rectal Suppositories) 80 mg, 120 mg, 325 mg and 650 mg
CBE-0 Labeling Supplement

CURRENT DRUG LABELING

325 mg

PROPOSED DRUG LABELING



1. Changed color scheme and design. (b) (4)
2. Added Jr. Strength before 325mg.
3. Bar code number revised from Actavis to Taro's.
4. Updated Distributor statement from Actavis to Taro's.



Taro Pharmaceuticals U.S.A., Inc.

NDA #018337
FeverAll® (Acetaminophen Rectal Suppositories) 80 mg, 120 mg, 325 mg and 650 mg
CBE-0 Labeling Supplement

CURRENT DRUG LABELING

650 mg

PROPOSED DRUG LABELING



1. No change to colors.
2. Bar code number revised from Actavis to Taro's.
3. Updated Distributor statement from Actavis to Taro's.

Acetaminophen Suppositories
Pain reliever/fever reducer
FeverAll[®]

DIRECTIONS: When practical, cleanse area around rectum with mild soap and warm water and rinse thoroughly. Gently dry by patting or blotting with toilet tissue or a soft cloth before using FeverAll[®].



1. Remove wrapper before inserting suppository as follows: hold suppository upright and carefully separate wrapper at pointed end to open.
2. Carefully peel wrapper down both sides evenly, exposing suppository.
3. Avoid excess handling, as suppository is designed to melt at body temperature. Suppositories should not need to be refrigerated if stored below 80°F (27°C).
4. Place child flat on back or on side with anal opening exposed.
5. Insert suppository gently, well into rectum. Use fingertip to complete insertion.

Questions? call 1-866-923-4914

FeverAll[®]
Acetaminophen Suppositories
Pain reliever/fever reducer

Dist by: Taro Pharmaceuticals U.S.A., Inc.
Hawthorne, NY 10532
Made in USA

FPO

(b) (4)

**ATTACHED LEGEND TO ALL
DIGITAL MECHANICALS**

STANDARD FORMAT:
Myriad Pro
100% Horizontal Scale

Heads - 10 pt Myriad Pro bold

Text - 10 pt Myriad Pro regular

Certified by: MS

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

/s/

KAREN M MAHONEY
08/12/2015