CENTER FOR DRUG EVALUATION AND RESEARCH

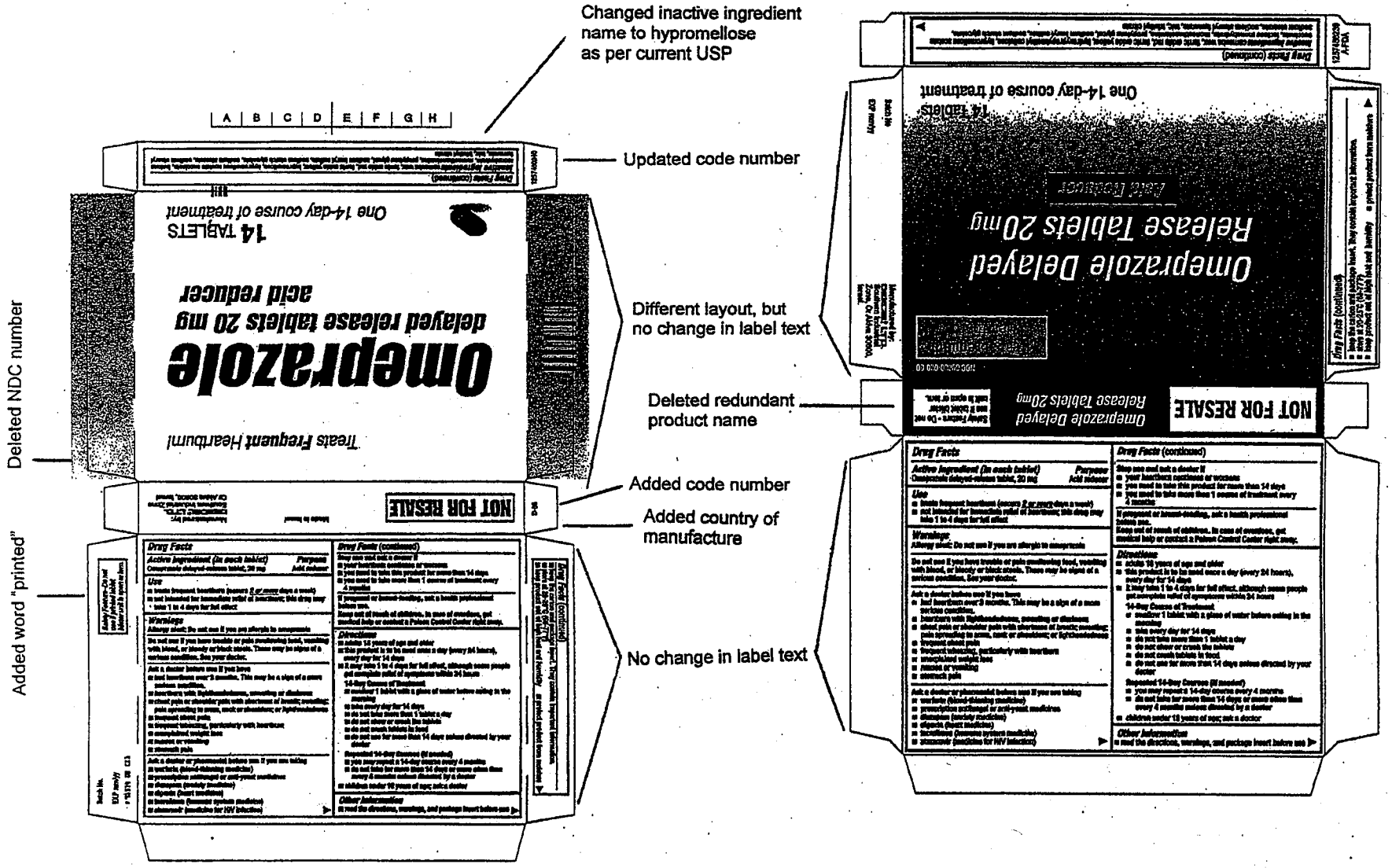
APPLICATION NUMBER:

22-032

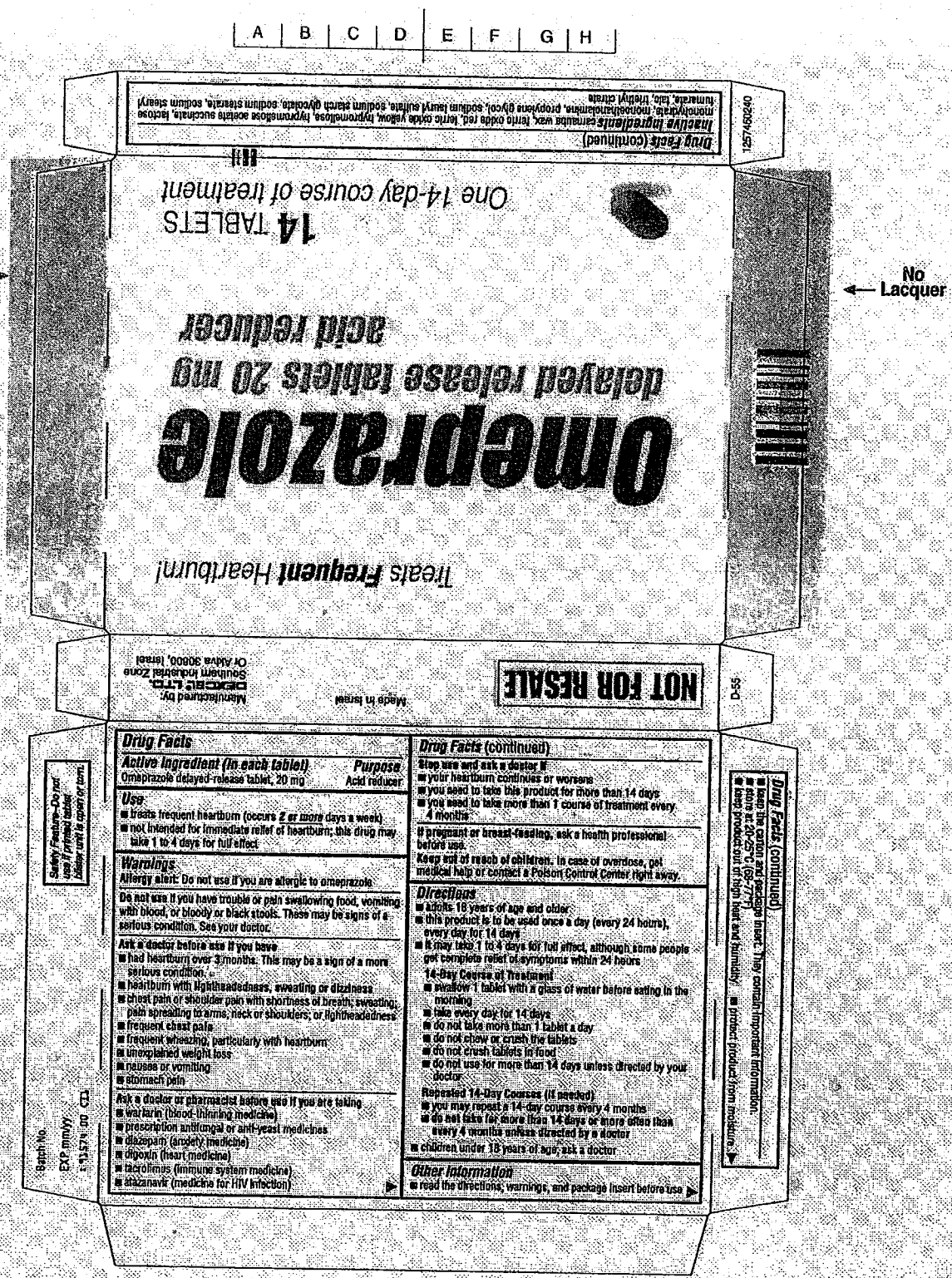
LABELING

UPDATED 14-COUNT INNER CARTON LABEL

14-COUNT INNER CARTON LABEL FROM THE JUNE 14, 2007 TENTATIVE APPROVAL LETTER



16-S-07



10-5-07

Batch No.
EXP mm/yy
1257460 CD

Safety Feature–Do not use if printed tablet blister unit is open or torn.

Drug Facts

Active Ingredient (in each tablet)
Omeprazole delayed-release tablet, 20 mg

Purpose
Acid reducer

Use
- treats frequent heartburn (occurs 2 or more days a week)
- not intended for immediate relief of heartburn; this drug may take 1 to 4 days for full effect

Warnings
Allergy alert: Do not use if you are allergic to omeprazole

Do not use if you have trouble or pain swallowing food, vomiting with blood, or bloody or black stools. These may be signs of a serious condition. See your doctor.

Ask a doctor before use if you have
- had heartburn over 3 months. This may be a sign of a more serious condition.
- heartburn with lightheadedness, sweating or dizziness
- chest pain or shoulder pain with shortness of breath; sweating; pain spreading to arms, neck or shoulders; or lightheadedness
- frequent chest pain
- frequent wheezing, particularly with heartburn
- unexplained weight loss
- nausea or vomiting
- stomach pain

Ask a doctor or pharmacist before use if you are taking
- warfarin (blood-thinning medicine)
- prescription antifungal or anti-yeast medicines
- diazepam (anxiety medicine)
- digoxin (heart medicine)
- tacrolimus (immune system medicine)
- atazanavir (medicine for HIV infection)

Drug Facts (continued)

Stop use and ask a doctor if
- your heartburn continues or worsens
- you need to take this product for more than 14 days
- you need to take more than 1 course of treatment every 4 months

If pregnant or breast-feeding, 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.

Directions
- adults 18 years of age and older
- this product is to be used once a day (every 24 hours), every day for 14 days
- it may take 1 to 4 days for full effect, although some people get complete relief of symptoms within 24 hours

14-Day Course of Treatment
- swallow 1 tablet with a glass of water before eating in the morning
- take every day for 14 days
- do not take more than 1 tablet a day
- do not chew or crush the tablets
- do not crush tablets in food
- do not use for more than 14 days unless directed by your doctor

Repeated 14-Day Courses (if needed)
- you may repeat a 14-day course every 4 months
- do not take for more than 14 days or more often than every 4 months unless directed by a doctor
- children under 18 years of age, ask a doctor

Other Information
- read the directions, warnings, and package insert before use

Drug Facts (continued)
- keep the carton and package insert. They contain important information.
- store at 20-25°C (68-77°F)
- keep product out of high heat and humidity
- protect product from moisture

D-55

NOT FOR RESALE

Made in Israel

Manufactured by:
DEXCEL LTD.
Southern Industrial Zone
Or Akiva 30800, Israel

Treats **Frequent** Heartburn!

Omeprazole

delayed release tablets 20 mg

acid reducer

14 TABLETS

One 14-day course of treatment

No Lacquer

No Lacquer

Drug Facts (continued)

Inactive Ingredients carnauba wax, ferric oxide red, ferric oxide yellow, hypromellose, hypromellose acetate succinate, lactose monohydrate, monoethanolamine, propylene glycol, sodium lauryl sulfate, sodium starch glycolate, sodium stearate, sodium stearyl fumarate, talc, triethyl citrate

1257460240

A B C D E F G H

10-5-07

UPDATED PACKAGE INSERT

Omeprazole Delayed Release Tablets 20 mg

Acid Reducer

Please read all of this package insert before taking Omeprazole Delayed Release Tablets 20 mg. Save this to read, as you need.

How Omeprazole Delayed Release Tablets 20 mg Works For Your Frequent Heartburn

Omeprazole Delayed Release Tablets 20 mg works differently from other heartburn products, such as antacids and other acid reducers. Omeprazole Delayed Release Tablets 20 mg stops acid production at the source – the acid pump that produces stomach acid. Omeprazole Delayed Release Tablets 20 mg is to be used once a day (every 24 hours), every day for 14 days.

What to Expect When Using Omeprazole Delayed Release Tablets 20 mg

Omeprazole Delayed Release Tablets 20 mg is a different type of medicine from antacids and other acid reducers. Omeprazole Delayed Release Tablets 20 mg may take 1 to 4 days for full effect, although some people get complete relief of symptoms within 24 hours. Make sure you take the entire 14 days of dosing to treat your frequent heartburn.

Safety Record

For years, doctors have prescribed Omeprazole to treat acid-related conditions in millions of people safely.

Who Should Take Omeprazole Delayed Release Tablets 20 mg

This product is for adults (18 years and older) with frequent heartburn – when you have heartburn 2 or more days a week.

- Omeprazole Delayed Release Tablets 20 mg is not intended for those who have heartburn infrequently, one episode of heartburn a week or less, or for those who want immediate relief of heartburn.

How to Take Omeprazole Delayed Release Tablets 20 mg

14-Day Course of Treatment

- Swallow 1 tablet with a glass of water before eating in the morning.
- Take every day for 14 days.
- Do not take more than 1 tablet a day.
- Do not chew or crush the tablets.
- Do not crush tablets in food.
- Do not use for more than 14 days unless directed by your doctor.

It is important not to chew or crush these tablets, or crush the tablets in food. This decreases how well Omeprazole Delayed Release Tablets 20 mg works.

When to Take Omeprazole Delayed Release Tablets 20 mg Again

You may repeat a 14-day course of therapy every 4 months.

A B C D E F G H

No change in labeling text

PACKAGE INSERT FROM THE JUNE 4, 2007 AMENDMENT

Omeprazole Delayed Release Tablets 20 mg

Acid Reducer

Please read all of this package insert before taking Omeprazole Delayed Release Tablets 20 mg. Save this to read, as you need.

How Omeprazole Delayed Release Tablets 20 mg Works For Your Frequent Heartburn

Omeprazole Delayed Release Tablets 20 mg works differently from other heartburn products, such as antacids and other acid reducers. Omeprazole Delayed Release Tablets 20 mg stops acid production at the source – the acid pump that produces stomach acid. Omeprazole Delayed Release Tablets 20 mg is to be used once a day (every 24 hours), every day for 14 days.

What to Expect When Using Omeprazole Delayed Release Tablets 20 mg

Omeprazole Delayed Release Tablets 20 mg is a different type of medicine from antacids and other acid reducers. Omeprazole Delayed Release Tablets 20 mg may take 1 to 4 days for full effect, although some people get complete relief of symptoms within 24 hours. Make sure you take the entire 14 days of dosing to treat your frequent heartburn.

Safety Record

For years, doctors have prescribed Omeprazole to treat acid-related conditions in millions of people safely.

Who Should Take Omeprazole Delayed Release Tablets 20 mg

This product is for adults (18 years and older) with frequent heartburn – when you have heartburn 2 or more days a week.

- Omeprazole Delayed Release Tablets 20 mg is not intended for those who have heartburn infrequently, one episode of heartburn a week or less, or for those who want immediate relief of heartburn.

How to Take Omeprazole Delayed Release Tablets 20 mg

14-Day Course of Treatment

- Swallow 1 tablet with a glass of water before eating in the morning.
- Take every day for 14 days.
- Do not take more than 1 tablet a day.
- Do not chew or crush the tablets.
- Do not crush tablets in food.
- Do not use for more than 14 days unless directed by your doctor.

It is important not to chew or crush these tablets, or crush the tablets in food. This decreases how well Omeprazole Delayed Release Tablets 20 mg works.

When to Take Omeprazole Delayed Release Tablets 20 mg Again

You may repeat a 14-day course of therapy every 4 months.

A B C D E F G H

10-5-09

UPDATED PACKAGE INSERT

When to Talk to Your Doctor
Do not take for more than 14 days or more often than every 4 months unless directed by a doctor.

Warnings and When to ask Your Doctor

Allergy alert: Do not use if you are allergic to omeprazole

Do not use if you have trouble or pain swallowing food, vomiting with blood, or bloody or black stools. These may be signs of a serious condition. See your doctor.

Ask a doctor before use if you have
- had heartburn over 3 months. This may be a sign of a more serious condition.
- heartburn with lightheadedness, sweating or dizziness
- chest pain or shoulder pain with shortness of breath; sweating; pain spreading to arms, neck or shoulders; or lightheadedness
- frequent chest pain
- frequent wheezing, particularly with heartburn
- unexplained weight loss
- nausea or vomiting
- stomach pain

Ask a doctor or pharmacist before use if you are taking
- warfarin (blood-thinning medicine)
- prescription antifungal or anti-yeast medicines
- diazepam (anxiety medicine)
- digoxin (heart medicine)
- tacrolimus (immune system medicine)
- atazanavir (medicine for HIV infection)

Stop use and ask a doctor if
- your heartburn continues or worsens
- you need to take this product for more than 14 days
- you need to take more than 1 course of treatment every 4 months

If pregnant or breast-feeding, 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.

Tips for Managing Heartburn
- Do not lie flat or bend over soon after eating.
- Do not eat late at night or just before bedtime.
- Certain foods or drinks are more likely to cause heartburn, such as rich, spicy, fatty and fried foods, chocolate, caffeine, alcohol and even some fruits and vegetables.
- Eat slowly and do not eat big meals.
- If you are overweight, lose weight.
- If you smoke, quit smoking.
- Raise the head of your bed.
- Wear loose-fitting clothing around your stomach.

How are Omeprazole Delayed Release Tablets 20 mg Sold

Omeprazole Delayed Release Tablets 20 mg is available in 14 tablet, 28 tablet and 42 tablet sizes. These sizes contain one, two and three 14-day courses of treatment, respectively. Do not use for more than 14 days in a row unless directed by your doctor. For the 28 count (two 14-day courses) and the 42 count (three 14-day courses), you may repeat a 14-day course every 4 months.

Manufactured by:
[redacted]
Beit Shemesh Industrial Zone
Or Akiva 30600, Israel

Made in Israel

81500 00 J1
1257450111

No change in labeling text

Added manufacturer name / address

Added country of manufacture

Added code numbers

PACKAGE INSERT FROM THE JUNE 4, 2007 AMENDMENT

When to Talk to Your Doctor
Do not take for more than 14 days or more often than every 4 months unless directed by a doctor.

Warnings and When to ask Your Doctor

Allergy alert: Do not use if you are allergic to omeprazole

Do not use if you have trouble or pain swallowing food, vomiting with blood, or bloody or black stools. These may be signs of a serious condition. See your doctor.

Ask a doctor before use if you have
- had heartburn over 3 months. This may be a sign of a more serious condition.
- heartburn with lightheadedness, sweating or dizziness
- chest pain or shoulder pain with shortness of breath; sweating; pain spreading to arms, neck or shoulders; or lightheadedness
- frequent chest pain
- frequent wheezing, particularly with heartburn
- unexplained weight loss
- nausea or vomiting
- stomach pain

Ask a doctor or pharmacist before use if you are taking
- warfarin (blood-thinning medicine)
- prescription antifungal or anti-yeast medicines
- diazepam (anxiety medicine)
- digoxin (heart medicine)
- tacrolimus (immune system medicine)
- atazanavir (medicine for HIV infection)

Stop use and ask a doctor if
- your heartburn continues or worsens
- you need to take this product for more than 14 days
- you need to take more than 1 course of treatment every 4 months

If pregnant or breast-feeding, 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.

Tips for Managing Heartburn
- Do not lie flat or bend over soon after eating.
- Do not eat late at night or just before bedtime.
- Certain foods or drinks are more likely to cause heartburn, such as rich, spicy, fatty and fried foods, chocolate, caffeine, alcohol and even some fruits and vegetables.
- Eat slowly and do not eat big meals.
- If you are overweight, lose weight.
- If you smoke, quit smoking.
- Raise the head of your bed.
- Wear loose-fitting clothing around your stomach.

How is Omeprazole Delayed Release Tablets 20 mg Sold

Omeprazole Delayed Release Tablets 20 mg is available in 14 tablet, 28 tablet and 42 tablet sizes. These sizes contain one, two and three 14-day courses of treatment, respectively. Do not use for more than 14 days in a row unless directed by your doctor. For the 28 count (two 14-day courses) and the 42 count (three 14-day courses), you may repeat a 14-day course every 4 months.

11-28-07

UPDATED 14-COUNT OUTER CARTON LABEL

No change in label text

Relocated, but no change in label text

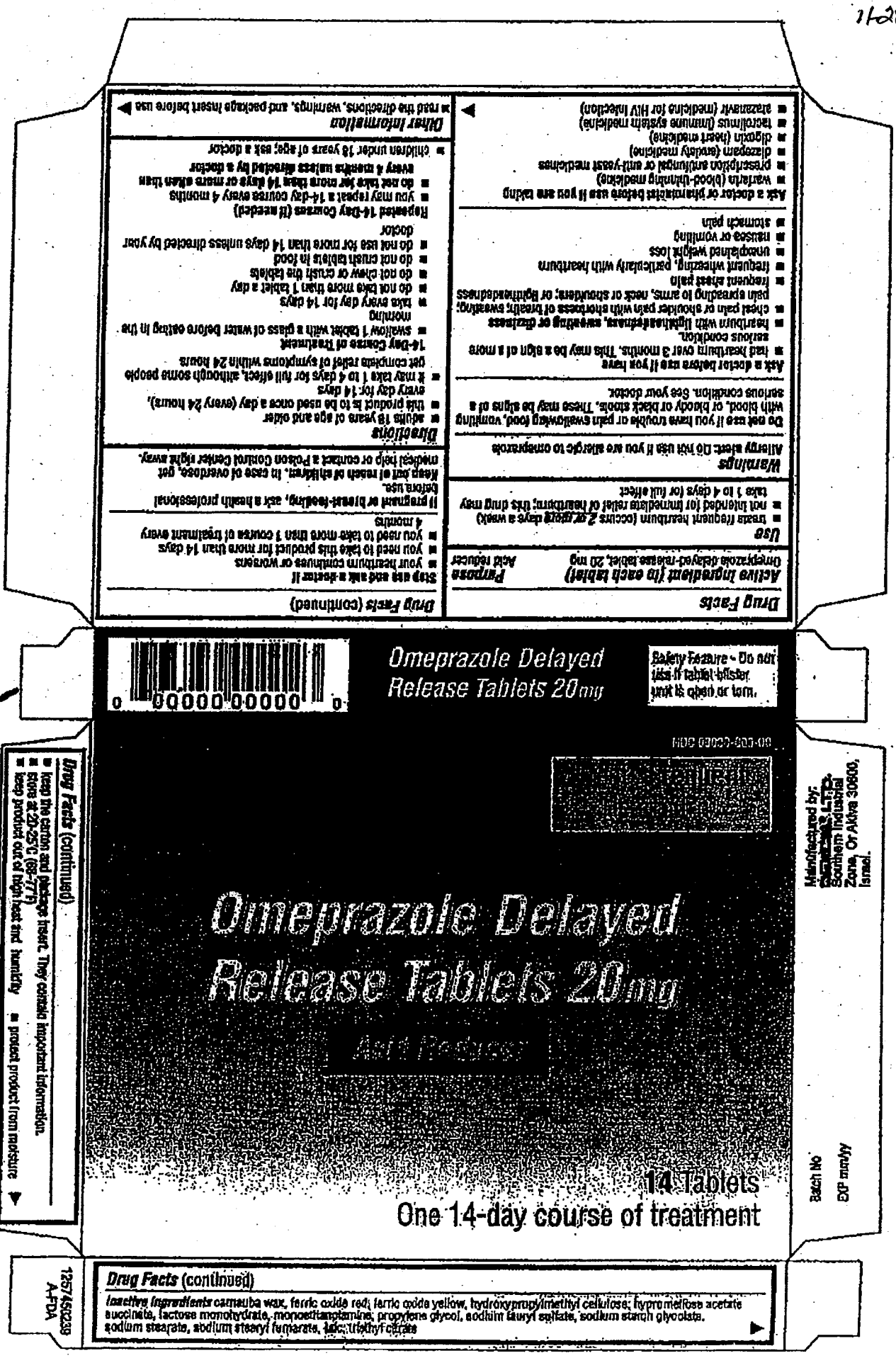
Added word "printed" to Safety Feature box, country of manufacture and code number

Deleted redundant product name

Different layout, but no change in label text. Added depiction of tablet.

Changed inactive ingredient name to hypromellose as per USP. Updated code number.

1428-07



Omeprazole Delayed Release Tablets 20mg

Safety Feature - Do not take if tablet blister unit is open or torn.

Omeprazole Delayed Release Tablets 20mg

Acid Reducer

14 Tablets

One 14-day course of treatment

Manufactured by: Dexcel Pharma Ltd. Southern Industrial Zone, Or Akiva 30600, Israel.

Batch No

EXP mm/yy

Drug Facts (continued)

Inactive ingredients carnauba wax, ferric oxide red, ferric oxide yellow, hydroxypropylmethyl cellulose, hypromellose acetate succinate, lactose monohydrate, monoethanolamine, propylene glycol, sodium lauryl sulfate, sodium starch glycolate, sodium stearate, sodium stearyl fumarate, talc, triethyl citrate

1257450239 A-FDA

Drug Facts (continued)

- keep the carton and package insert. They contain important information.
- store at 20-25°C (68-77°F)
- keep product out of high heat and humidity
- protect product from moisture

Drug Facts

Active ingredient (in each tablet)

Omeprazole delayed-release tablet, 20 mg

Purpose

Acid reducer

Use

- treats frequent heartburn (occurs 2 or more days a week)
- not intended for immediate relief of heartburn; this drug may take 1 to 4 days for full effect

Warnings

Allergy alert: Do not use if you are allergic to omeprazole

Do not use if you have trouble or pain swallowing food, vomiting with blood, or black stools. These may be signs of a serious condition. See your doctor.

Ask a doctor before use if you have

- had heartburn over 3 months. This may be a sign of a more serious condition.
- heartburn with lightheadedness, sweating or dizziness
- chest pain or shoulder pain with shortness of breath; sweating; pain spreading to arms, neck or shoulders; or lightheadedness
- frequent chest pain
- frequent wheezing, particularly with heartburn
- unexplained weight loss
- nausea or vomiting
- stomach pain

Ask a doctor or pharmacist before use if you are taking

- warfarin (blood-thinning medicine)
- prescription antifungal or anti-yeast medicines
- diazepam (anxiety medicine)
- digoxin (heart medicine)
- tacrolimus (immune system medicine)
- atazanavir (medicine for HIV infection)

Drug Facts (continued)

Stop use and ask a doctor if

- your heartburn continues or worsens
- you need to take this product for more than 14 days
- you need to take more than 1 course of treatment every 4 months

If pregnant or breast-feeding, 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.

Directions

- adults 18 years of age and older
- this product is to be used once a day (every 24 hours), every day for 14 days
- it may take 1 to 4 days for full effect, although some people get complete relief of symptoms within 24 hours

14-Day Course of Treatment

- swallow 1 tablet with a glass of water before eating in the morning
- take every day for 14 days
- do not take more than 1 tablet a day
- do not chew or crush the tablets
- do not crush tablets in food
- do not use for more than 14 days unless directed by your doctor

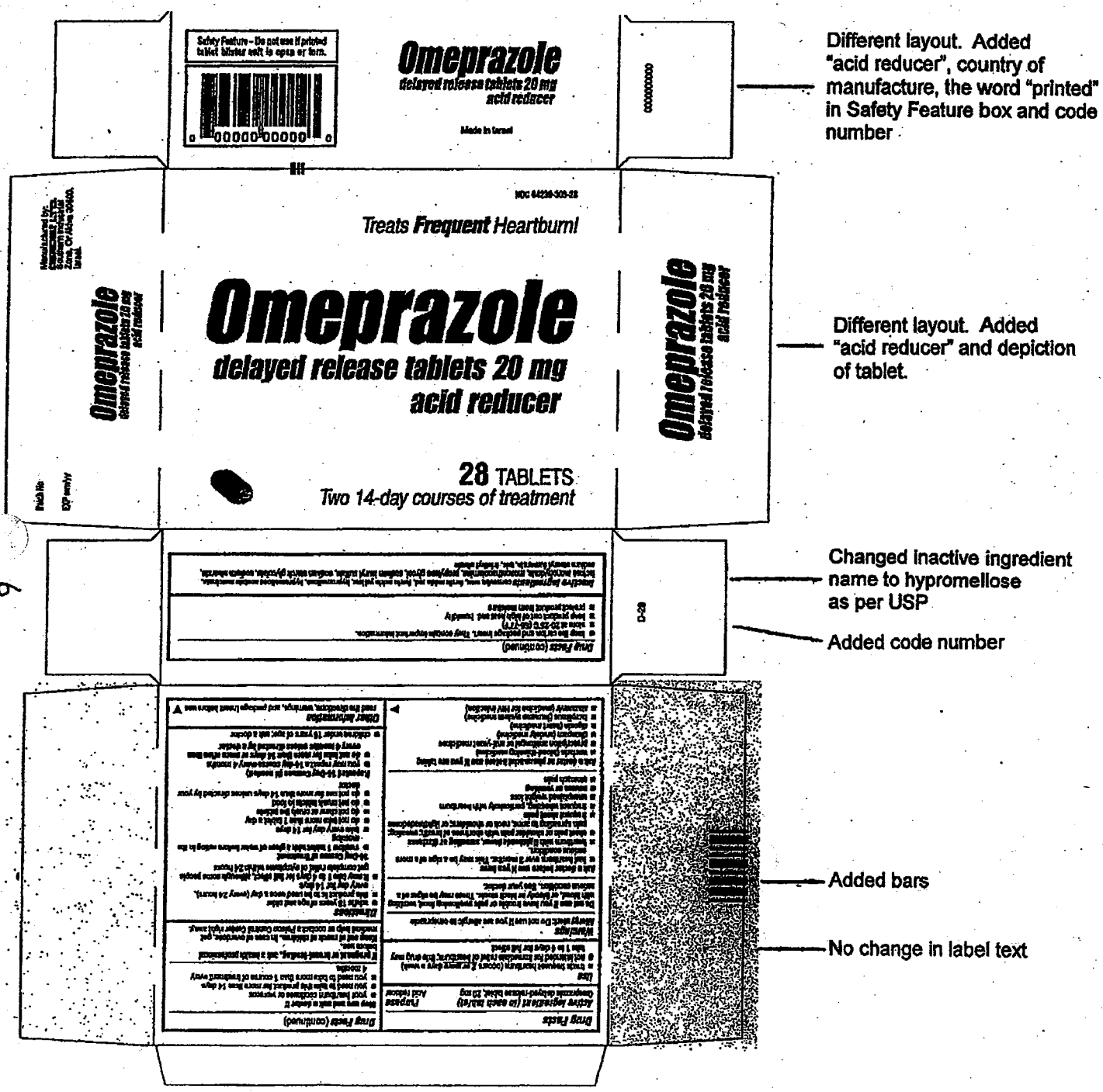
Repeated 14-Day Courses (if needed)

- you may repeat a 14-day course every 4 months
- do not take for more than 14 days or more often than every 4 months unless directed by a doctor
- children under 18 years of age: ask a doctor

Other information

- read the directions, warnings, and package insert before use

11-28-07



Different layout. Added "acid reducer", country of manufacture, the word "printed" in Safety Feature box and code number

Different layout. Added "acid reducer" and depiction of tablet.

Changed inactive ingredient name to hypromellose as per USP

Added code number

Added bars

No change in label text

Drug Facts

Active Ingredient (in each tablet)
Omeprazole delayed-release tablet, 20 mg

Purpose
Acid reducer

Use
- treats frequent heartburn (occurs 2 or more days a week)
- not intended for immediate relief of heartburn; this drug may take 1 to 4 days for full effect

Warnings
Allergy alert: Do not use if you are allergic to omeprazole

Do not use if you have trouble or pain swallowing food, vomiting with blood, or bloody or black stools. These may be signs of a serious condition. See your doctor.

Ask a doctor before use if you have
- bad heartburn over 3 months. This may be a sign of a more serious condition.
- heartburn with lightheadedness, sweating or dizziness
- chest pain or shoulder pain with shortness of breath; sweating; pain spreading to arms, neck or shoulders; or lightheadedness
- frequent chest pain
- frequent wheezing, particularly with heartburn
- unexplained weight loss
- nausea or vomiting
- stomach pain

Ask a doctor or pharmacist before use if you are taking
- warfarin (blood-thinning medicine)
- prescription antifungal or anti-yeast medicines
- diazepam (anxiety medicine)
- digoxin (heart medicine)
- tacrolimus (immune system medicine)
- atazanavir (medicine for HIV infection) ▶

Drug Facts (continued)

Stop use and ask a doctor if
- your heartburn continues or worsens
- you need to take this product for more than 14 days
- you need to take more than 1 course of treatment every 4 months

If pregnant or breast-feeding, 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.

Directions
- adults 18 years of age and older
- this product is to be used once a day (every 24 hours), every day for 14 days
- it may take 1 to 4 days for full effect, although some people get complete relief of symptoms within 24 hours

14-Day Course of Treatment
- swallow 1 tablet with a glass of water before eating in the morning
- take every day for 14 days
- do not take more than 1 tablet a day
- do not chew or crush the tablets
- do not crush tablets in food
- do not use for more than 14 days unless directed by your doctor

Repeated 14-Day Courses (if needed)
- you may repeat a 14-day course every 4 months
- do not take for more than 14 days or more often than every 4 months unless directed by a doctor
- children under 15 years of age; ask a doctor

Other Information
- read the directions, warnings, and package insert before use ▼

Drug Facts (continued)

- keep the carton and package insert. They contain important information.
- store at 20-25°C (68-77°F)
- keep product out of high heat and humidity
- protect product from moisture

Inactive Ingredients carnauba wax, ferric oxide red, ferric oxide yellow, hydroxypropylmethyl cellulose, hypromellose acetate succinate, lactose monohydrate, monoethanolamine, propylene glycol, sodium lauryl sulfate, sodium starch glycolate, sodium stearate, sodium stearyl fumarate, talc, tristkyl citrate

Omeprazole Delayed Release Tablets 20mg

28 Tablets
Two 14-day courses of treatment

Omeprazole Delayed Release Tablets 20mg

Omeprazole Delayed Release Tablets 20mg

Manufactured by: [illegible] LTD. Southern Industrial Zone, Or Akiva 30600, Israel.

Batch No
EXP mm/yy

Safety Feature
Do not use if tablet blister unit is open or torn.

Omeprazole Delayed Release Tablets 20mg

0 00000 00000 0

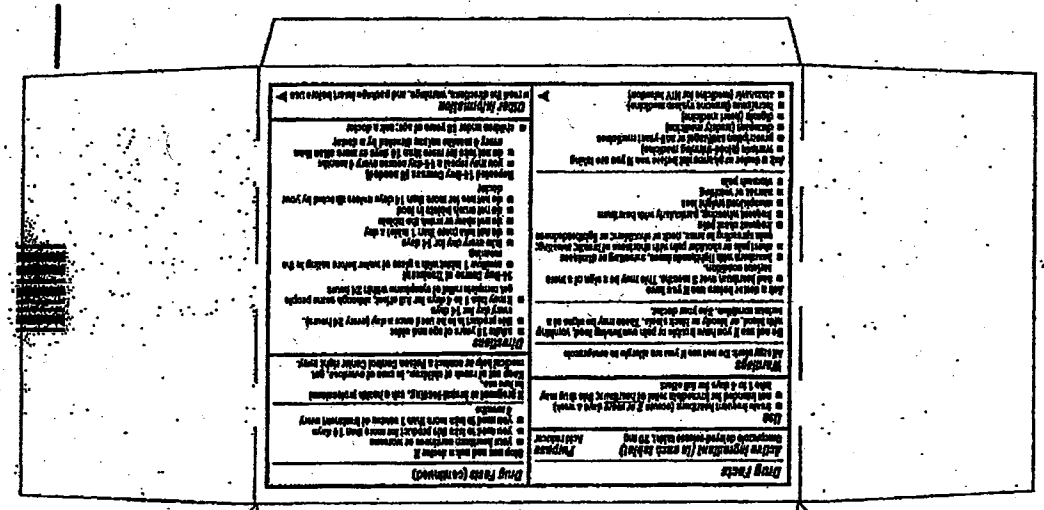
1257450239
A-FDA

11-28-69

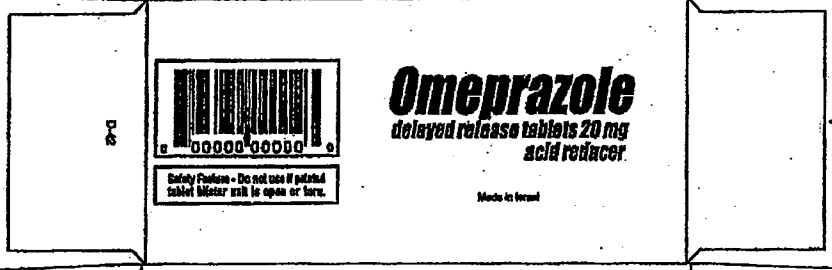
11-28-07

Added bars

UPDATED 42-COUNT OUTER CARTON LABEL



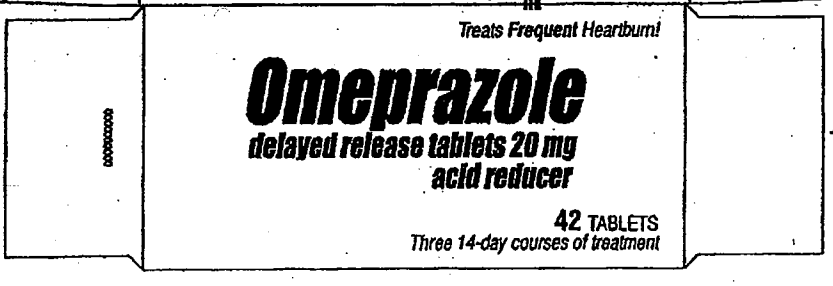
No change in label text



Different layout. Added "acid reducer", country of manufacture, the word "printed" in Safety Feature box and code number

Different layout. Added "acid reducer" and depiction of tablet.

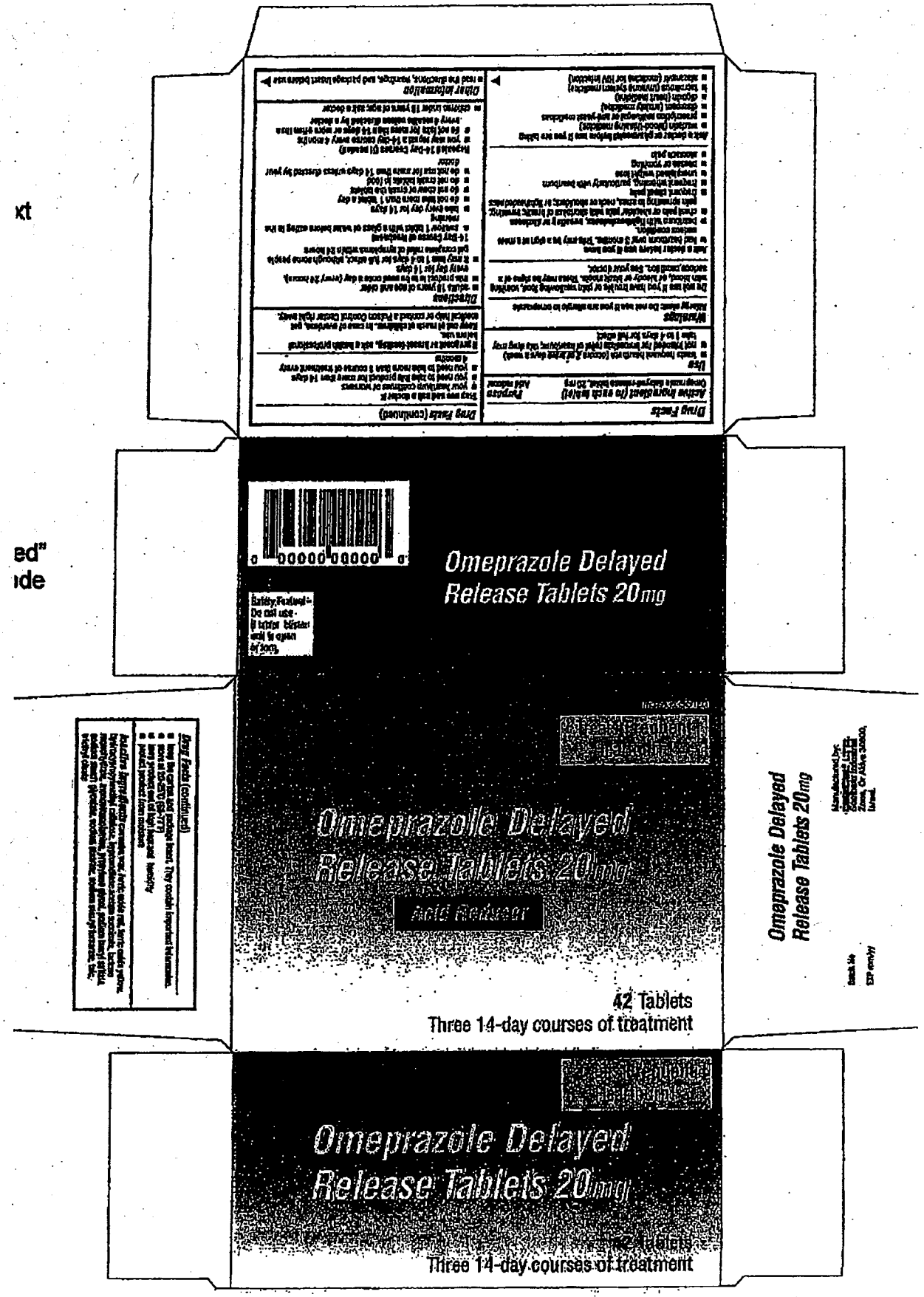
Changed inactive ingredient name to hypromellose as per USP

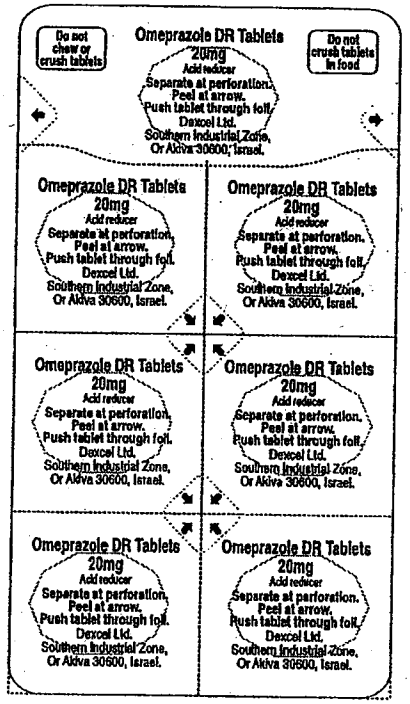


Different layout. Added "acid reducer" and code number.

42-COUNT OUTER CARTON LABEL FROM THE JUNE 14, 2007 TENTATIVE APPROVAL LETTER

11-28-07




Do not chew or crush tablets
Omeprazole DR Tablets
20mg
Acid reducer
Separate at perforation.
Peel at arrow.
Push tablet through foil.
Dexcel Ltd.
Southern Industrial Zone,
Or Akiva 30600, Israel.
Do not crush tablets in food
Omeprazole DR Tablets
20mg
Acid reducer
Separate at perforation.
Peel at arrow.
Push tablet through foil.
Dexcel Ltd.
Southern Industrial Zone,
Or Akiva 30600, Israel.
Omeprazole DR Tablets
20mg
Acid reducer
Separate at perforation.
Peel at arrow.
Push tablet through foil.
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