THE BAYARD FIRM
ATTORNEYS

222 DELAWARE AVENUE, SUITE 900
P.O. BOX 25130
WILMINGTON, DE 19899
ZIP CODE FOR DELIVERIES: 19801

MERITAS LAW FIRMS WORLDWIDE
www.bayardfirm.com

302-655-5000
(FAX) 302-658-6395

WRITER'S DIRECT ACCESS

(302) 429-4242
astitzer@bayardfirm.com

ELECTRONICALLY FILED

June 18, 2007

The Honorable Sue L. Robinson
United States District Court
844 King Street
Wilmington, DE 19801

Re: *AstraZeneca AB, et al. v. Dexcel, Ltd., et al.*,
C.A. No. 06-358 (SLR)

Dear Judge Robinson:

I represent the Dexcel defendants ("Dexcel") in this matter. At the status conference held on February 1, 2007, the Court stated that it would like to see Dexcel's "approvable" letter from the FDA (February 1, 2007 transcript at 28:5-8). In response, Dexcel forwarded the "approvable" letter to the Court on February 23, 2007. On June 14, 2007, Dexcel received another letter from the FDA, this time granting tentative approval to Dexcel's omeprazole tablet product NDA 22-032.

Dexcel has produced to plaintiffs the June 14, 2007 letter granting tentative approval to NDA 22-032. Pursuant to the Court's prior request and as a follow up to Dexcel's February 23 letter to the Court, we enclose herewith a copy of the letter granting tentative approval.

Respectfully submitted,

Ashley B. Stitzer (#3891)

Enclosure
cc: All counsel as shown on attached certificate

EXHIBIT A

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 22-032

Lachman Consultant Services, Inc
Attention: John D. Franolic, Ph.D.
Manager
US Agent for Dexcel Pharma Technologies Limited
1600 Stewart Ave
Westbury, NY 11590

Dear Dr. Franolic:

Please refer to your new drug application (NDA) dated February 8, 2006, received February 10, 2006, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act ("the Act") for omeprazole 20 mg delayed-release tablets.

We acknowledge receipt of your submissions dated December 18, 2006; April 4 and 16, and June 4, 2007.

Your submission of December 18, 2006, constituted a complete response to our December 8, 2006, action letter.

This NDA provides for the nonprescription use of omeprazole 20 mg delayed release tablets for the treatment of frequent heartburn.

We have completed our review of this application, as amended. It is **tentatively approved** under 21 CFR 314.105(a) for use as recommended in the agreed-upon enclosed labeling (the 14-, 28-, 42-count carton labels with Drug Facts, the 14-count inner carton label with Drug Facts, and the package insert submitted June 4, 2007, and the blister card backing submitted December 18, 2006). This determination is contingent upon information available to us at this time (i.e., information in your application and the status of current good manufacturing practices of the facilities used in the manufacturing and testing of the drug product) and is therefore subject to change on the basis of any new information that may come to our attention.

The listed drugs referenced in your application, Prilosec and Prilosec OTC of AstraZeneca, are subject to periods of patent protection. The following patents and expiration dates are currently listed in the agency's publication titled Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book"):

U.S. Patent Number	Expiration Date
6,150,380	November 10, 2018
4,786,505*PED	October 20, 2007
4,853,230*PED	October 20, 2007

5,690,960	November 25, 2014
5,753,265	June 7, 2015
5,817,338	October 6, 2015
5,900,424	May 4, 2016
6,403,616	November 15, 2019
6,428,810	November 3, 2019
6147103	April 9, 2019
6166213	October 9, 2018
6166213*PED	April 9, 2019
6191148	October 9, 2018
6191148*PED	April 9, 2019

Your application contains certifications to each of the patents under section 505(b)(2)(A)(iv) of the Act stating that the patents are invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of, this drug product under this application ("Paragraph IV certifications"). Section 505(c)(3)(C) of the Act provides that approval of a new drug application submitted pursuant to section 505(b)(2) of the Act shall be made effective immediately, unless an action is brought for infringement of one or more of the patents that were the subject of the paragraph IV certifications. This action must be taken prior to the expiration of forty-five days from the date the notice provided under section 505(b)(3) is received by the patent owner/approved application holder. You notified us that Dexcel Pharma Technologies Limited ("Dexcel") complied with the requirements of section 505(b)(3) of the Act. In addition, you have notified the Agency that the patent owner and/or approved application holder has initiated a patent infringement suit against Dexcel with respect to patent 4,853,230, patent 4,786,505, and patent 6,150,380 in the United States District Court for the District of Delaware (AstraZeneca AB, Aktiebolaget Hässle, KBI-E, Inc., KBI, Inc. and AstraZeneca LP vs. Dexcel, Ltd., Dexxon, Ltd., Dexcel Pharma Technologies, Ltd. and Dexcel Pharma Technologies [Civil Action Case No. 06-358]).[1]

Therefore, final approval cannot be granted until:

1. a. expiration of the 30-month period provided for in Section 505(c)(3)(C) beginning on the date of receipt of the 45-day notice required under Section 505(b)(3), unless the court has extended or reduced the period because of the failure of either party to reasonably cooperate in expediting the action, or

   b. the date the court decides[2] that the patent(s) is/are invalid or not infringed as described in section 505(c)(3)(C)(i), (ii), (iii,) or (iv) of the Act, or,

   c. the listed patent(s) has/have expired, and

2. we are assured there is no new information that would affect whether final approval should be granted.

---

[1] We note that Dexcel failed to timely advise the FDA that it was sued in response to its notice of Paragraph IV certification. We remind you that the Agency's regulations require that a "505(b)(2) applicant *shall* notify FDA *immediately* of the filing of any legal action filed within 45 days of receipt of the notice of [paragraph IV] certification" (21 CFR 314.107(f)(2))(emphasis added).

[2] This decision may be either a decision of the district court or the court of appeals, whichever court is the first to decide that the patent is invalid or not infringed.

At least 60 days prior to the date when approval can be granted, or when requested, you should submit an amendment to this application identifying changes, if any, in the conditions under which your product was tentatively approved. This information should include updated labeling, chemistry, manufacturing and controls data, and a safety update.

Failure to submit this amendment will prompt a review of the application that may result in rescission of the tentative approval letter.

Any significant change in the conditions outlined in this NDA requires our review before final approval may be granted.

Before we issue a final approval letter, this NDA is not deemed approved.

This drug product may not be marketed and may be considered misbranded without final agency approval under Section 505 of the Act. The introduction or delivery for introduction into interstate commerce of this drug product before the final approval date is prohibited under section 301 of the Act.

If you choose to use a proprietary name for this product, the name and its use in the labels must conform to the specifications under 21 CFR 201.10 and 201.15. We recommend that you submit any proprietary name to the Agency for our review prior to its implementation.

All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred. Per our letter dated December 8, 2006, we are waiving the pediatric study requirement for this application.

If you have any questions, call Keith Olin, Regulatory Project Manager, at (301) 796-0962.

Sincerely,

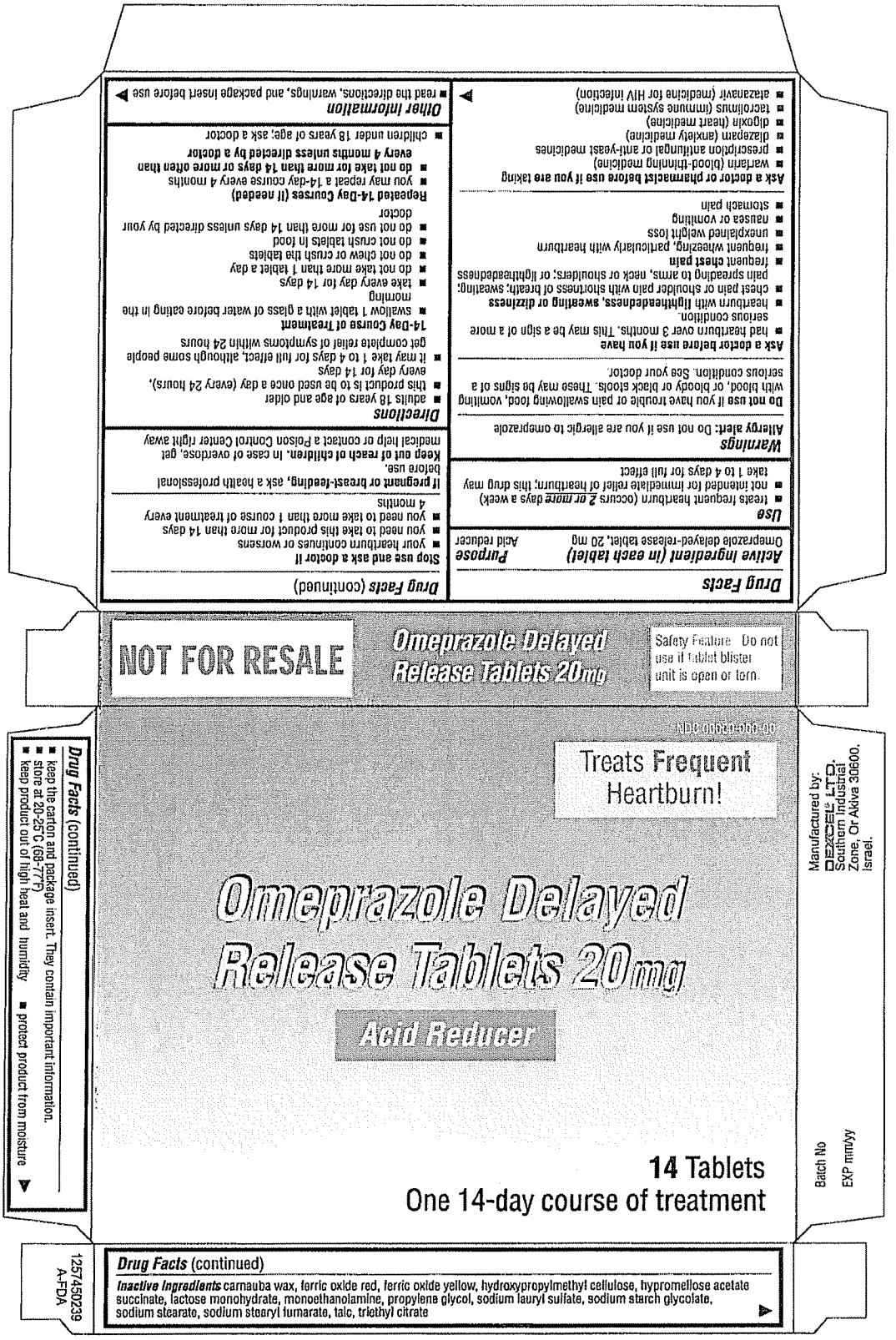
{See appended electronic signature page}

Andrea Leonard-Segal, MD
Director
Division of Nonprescription Clinical Evaluation
Office of Nonprescription Products
Center of Drug Evaluation and Research

Sincerely,

{See appended electronic signature page}

Joyce Korvick, MD
Acting Director
Division of Gastroenterology Products
Office of Drug Evaluation III
Center of Drug Evaluation and Research



Drug Facts

Active Ingredient (in each tablet) — **Purpose**

Omeprazole delayed-release tablet, 20 mg — 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 ▶

NOT FOR RESALE

Omeprazole Delayed Release Tablets 20mg

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

NDC 00000-0000-00

Treats Frequent Heartburn!

Omeprazole Delayed Release Tablets 20mg

Acid Reducer

14 Tablets

One 14-day course of treatment

Manufactured by:
DEXCEL LTD.
Southern Industrial Zone, Or Akiva 30600, Israel.

Batch No

EXP mm/yy

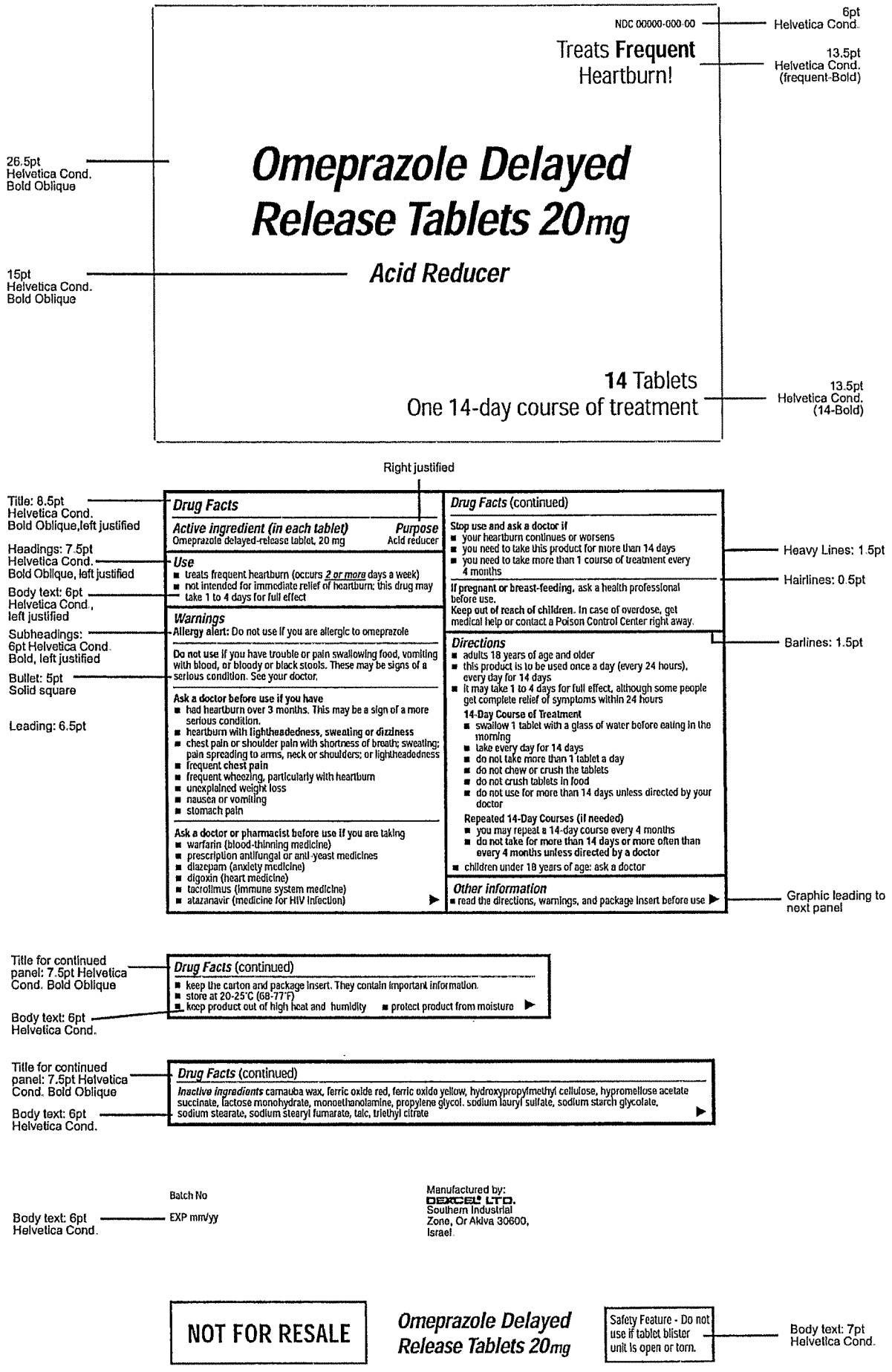
Drug Facts (continued)

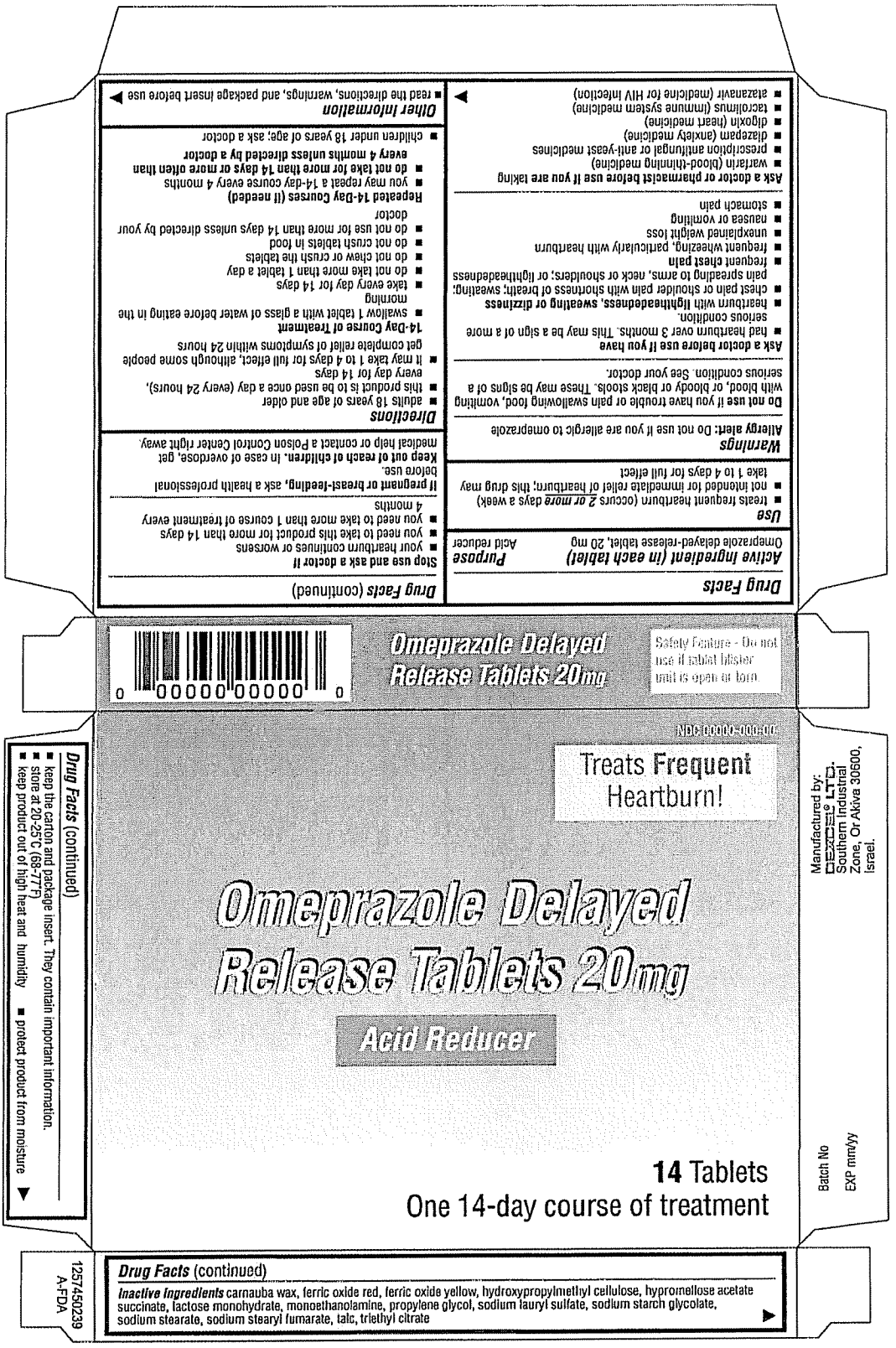
- keep the carton and package insert. They contain important information.
- store at 20-25°C (68-77°F)
- keep product out of high heat and humidity
- protect product from moisture

▼

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, triethyl citrate ▶

125745023
A-FDA


NDC 00000-000-00
6pt Helvetica Cond.
Treats Frequent Heartburn!
13.5pt Helvetica Cond. (frequent-Bold)
26.5pt Helvetica Cond. Bold Oblique
Omeprazole Delayed Release Tablets 20mg
15pt Helvetica Cond. Bold Oblique
Acid Reducer
14 Tablets
One 14-day course of treatment
13.5pt Helvetica Cond. (14-Bold)
Right justified
Title: 8.5pt Helvetica Cond. Bold Oblique,left justified
Drug Facts
Active ingredient (in each tablet)
Omeprazole delayed-release tablet, 20 mg
Purpose
Acid reducer
Headings: 7.5pt Helvetica Cond. Bold Oblique, left justified
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
Body text: 6pt Helvetica Cond., left justified
Warnings
Allergy alert: Do not use if you are allergic to omeprazole
Subheadings: 6pt Helvetica Cond. Bold, left justified
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
Bullet: 5pt Solid square
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)
Leading: 6.5pt
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
Heavy Lines: 1.5pt
Hairlines: 0.5pt
Barlines: 1.5pt
Graphic leading to next panel
Title for continued panel: 7.5pt Helvetica Cond. Bold Oblique
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
Body text: 6pt Helvetica Cond.
Title for continued panel: 7.5pt Helvetica Cond. Bold Oblique
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
Body text: 6pt Helvetica Cond.
Batch No
EXP mm/yy
Body text: 6pt Helvetica Cond.
Manufactured by:
DEXCEL LTD.
Southern Industrial Zone, Or Akiva 30600, Israel
NOT FOR RESALE
Omeprazole Delayed Release Tablets 20mg
Safety Feature - Do not use if tablet blister unit is open or torn.
Body text: 7pt Helvetica Cond.



Drug Facts

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

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

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

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

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

Omeprazole Delayed Release Tablets 20mg

Safety Feature - Do not use if tablet blister unit is open at birth

NDC 00000-000-00

Treats Frequent Heartburn!

Omeprazole Delayed Release Tablets 20mg

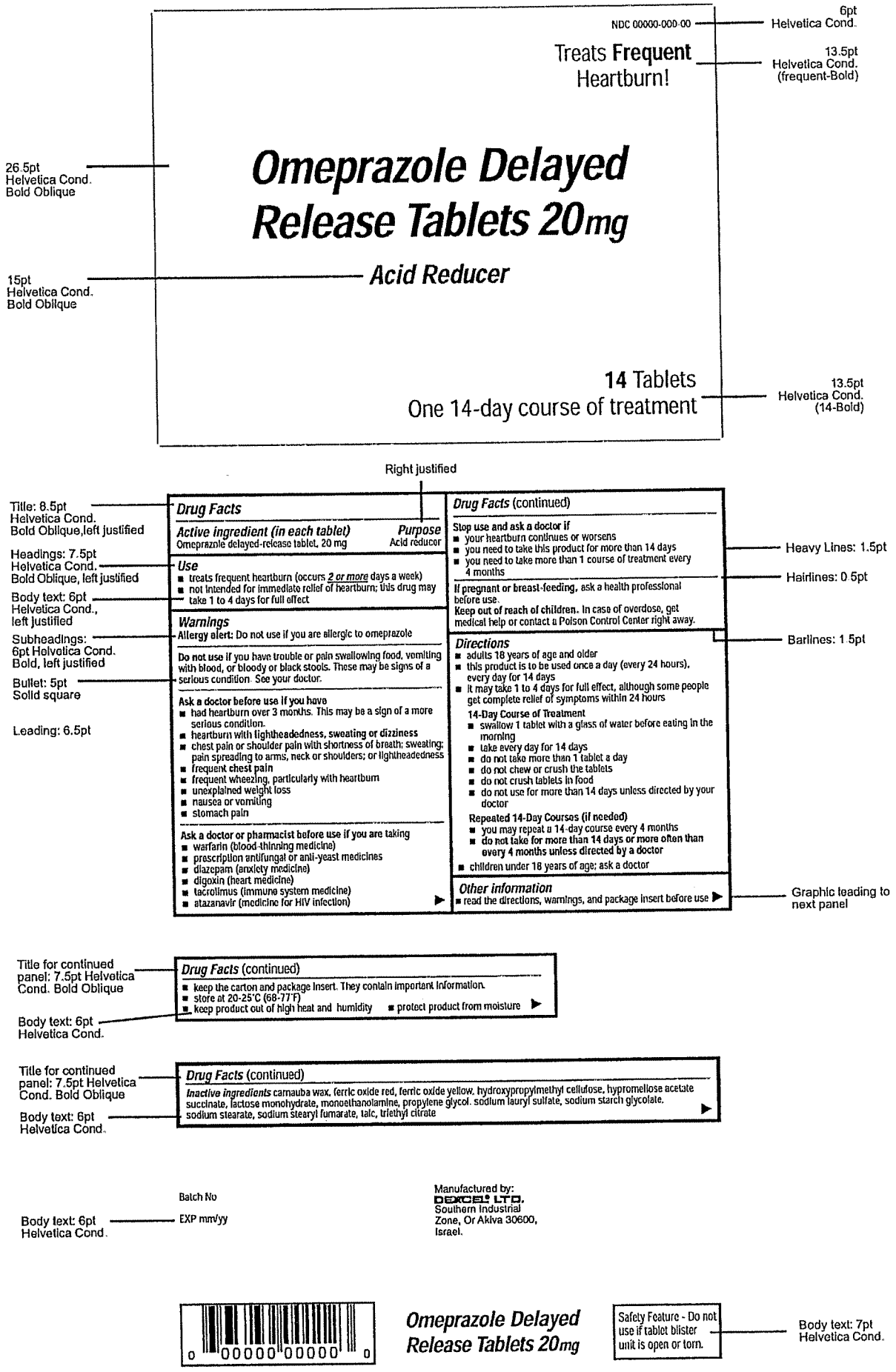
Acid Reducer

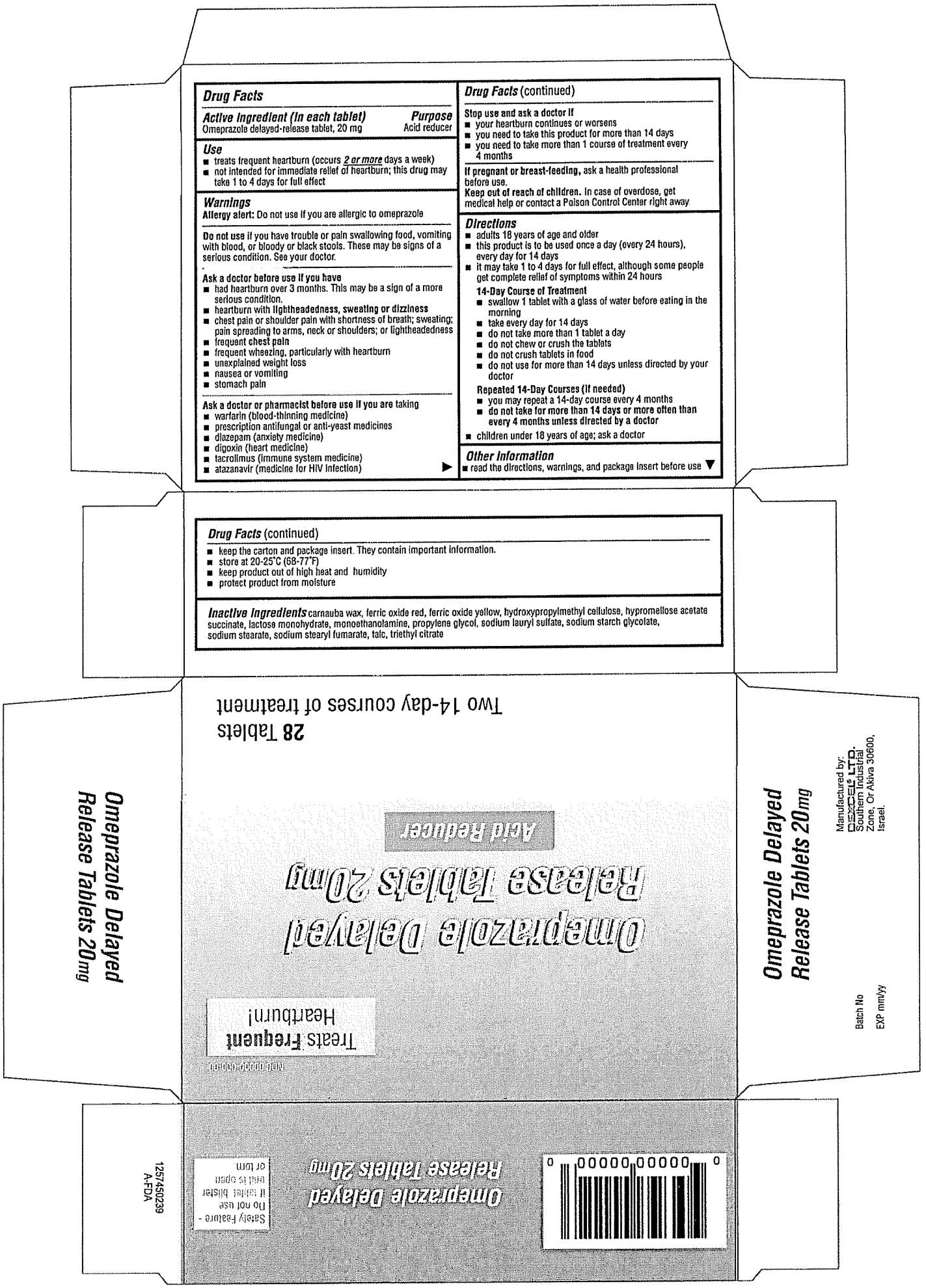
14 Tablets
One 14-day course of treatment

Manufactured by:
DEXCEL LTD.
Southern Industrial Zone, Or Akiva 30600, Israel.

Batch No
EXP mm/yy

1257450239
A-FDA


NDC 00000-000-00
6pt Helvetica Cond.
Treats Frequent Heartburn!
13.5pt Helvetica Cond. (frequent-Bold)
26.5pt Helvetica Cond. Bold Oblique
Omeprazole Delayed Release Tablets 20mg
15pt Helvetica Cond. Bold Oblique
Acid Reducer
14 Tablets
One 14-day course of treatment
13.5pt Helvetica Cond. (14-Bold)
Right justified
Title: 8.5pt Helvetica Cond. Bold Oblique,left justified
Drug Facts
Active ingredient (in each tablet)
Omeprazole delayed-release tablet, 20 mg
Purpose
Acid reducer
Headings: 7.5pt Helvetica Cond. Bold Oblique, left justified
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
Body text: 6pt Helvetica Cond., left justified
Warnings
Allergy alert: Do not use if you are allergic to omeprazole
Subheadings: 6pt Helvetica Cond. Bold, left justified
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.
Bullet: 5pt Solid square
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
Leading: 6.5pt
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.
Heavy Lines: 1.5pt
Hairlines: 0.5pt
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
Barlines: 1.5pt
Other information
read the directions, warnings, and package insert before use
Graphic leading to next panel
Title for continued panel: 7.5pt Helvetica Cond. Bold Oblique
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
Body text: 6pt Helvetica Cond.
Title for continued panel: 7.5pt Helvetica Cond. Bold Oblique
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
Body text: 6pt Helvetica Cond.
Batch No
EXP mm/yy
Body text: 6pt Helvetica Cond.
Manufactured by:
DEXCEL LTD.
Southern Industrial Zone, Or Akiva 30600, Israel.
0 00000 00000 0
Omeprazole Delayed Release Tablets 20mg
Safety Feature - Do not use if tablet blister unit is open or torn.
Body text: 7pt Helvetica Cond.



Drug Facts

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

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

Omeprazole Delayed Release Tablets 20mg

28 Tablets
Two 14-day courses of treatment

Omeprazole Delayed Release Tablets 20mg

Acid Reducer

Omeprazole Delayed Release Tablets 20mg

Treats Frequent Heartburn!

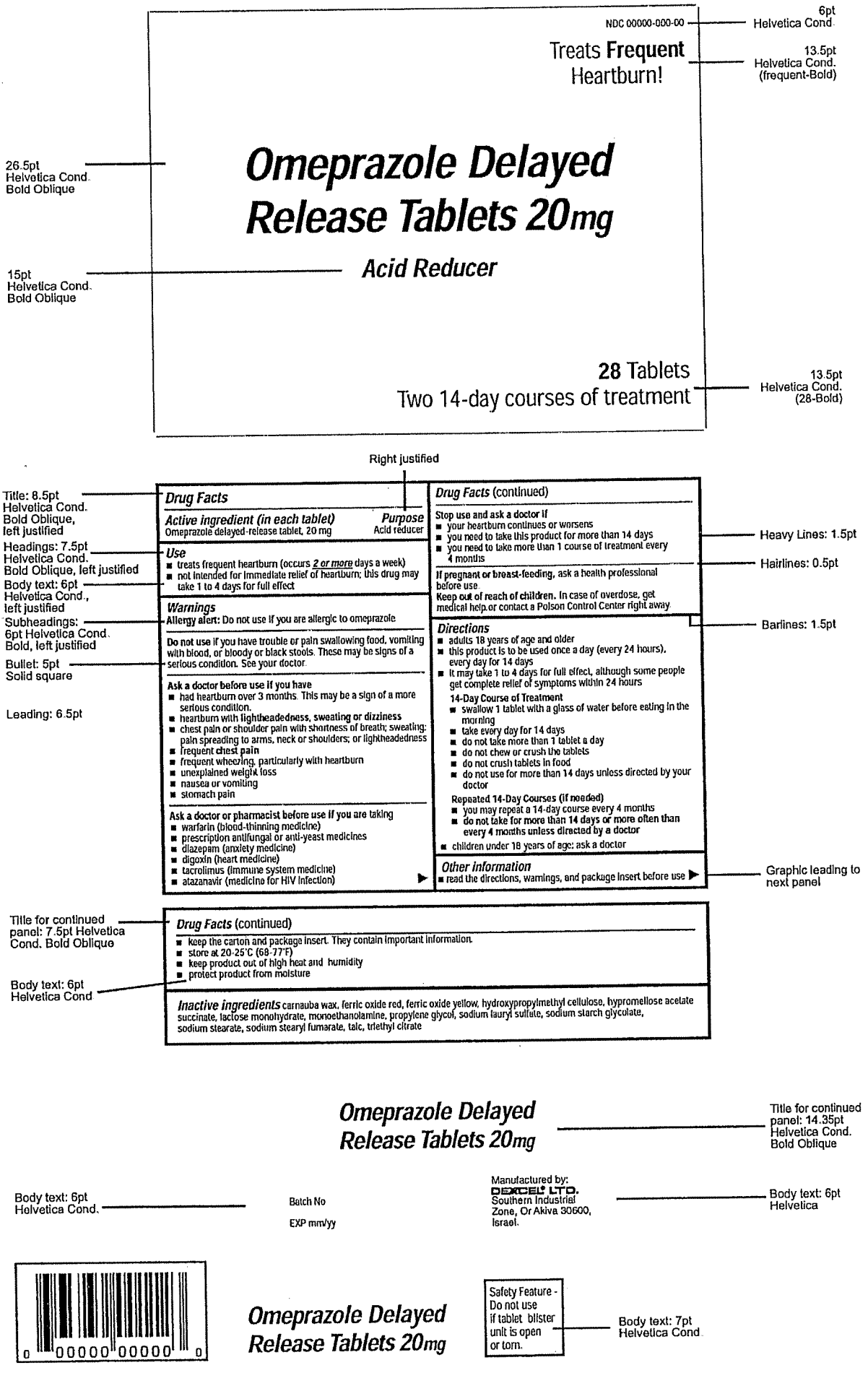
Manufactured by:
DEXCEL® LTD.
Southern Industrial Zone, Or Akiva 30600, Israel.

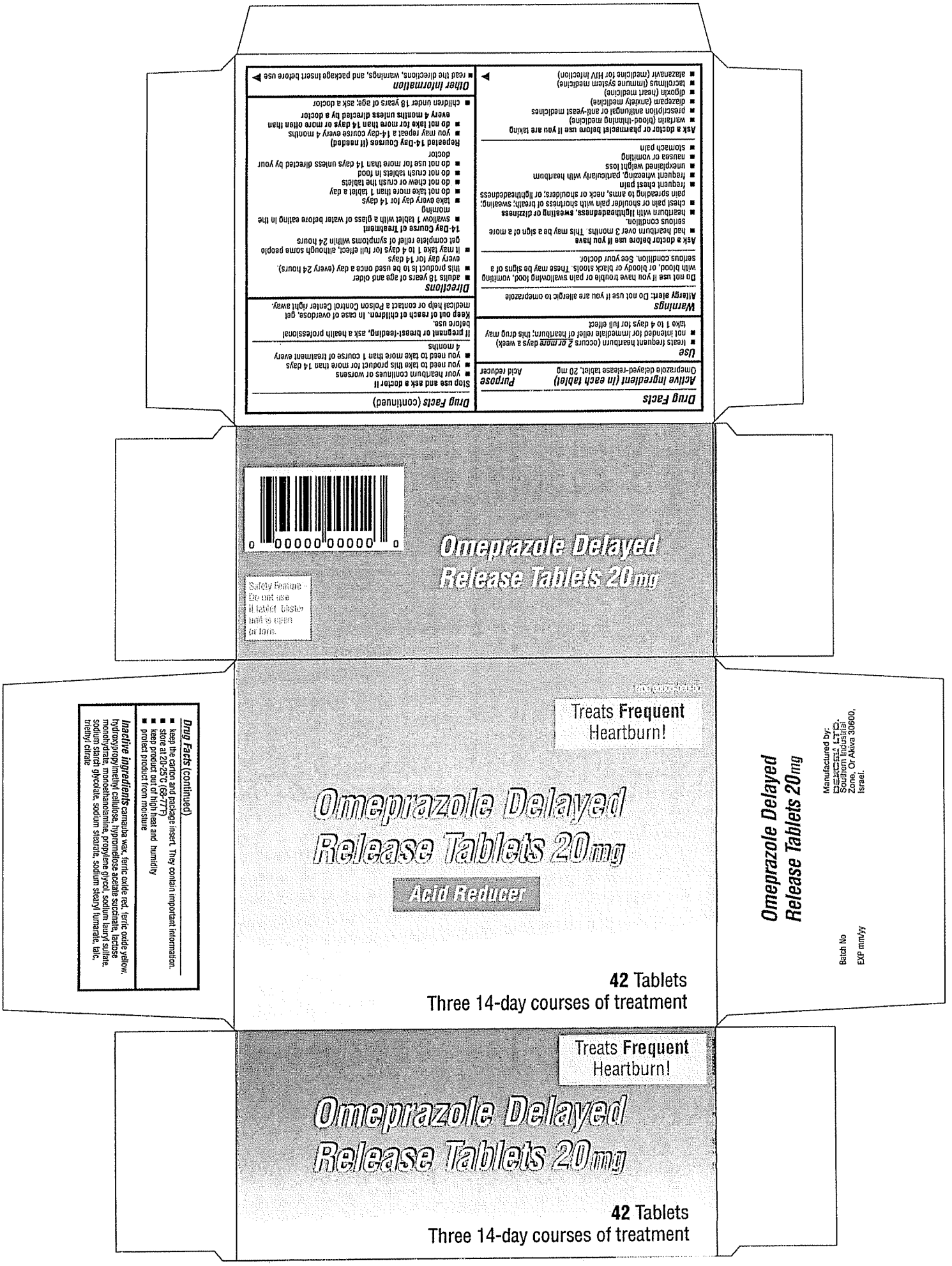
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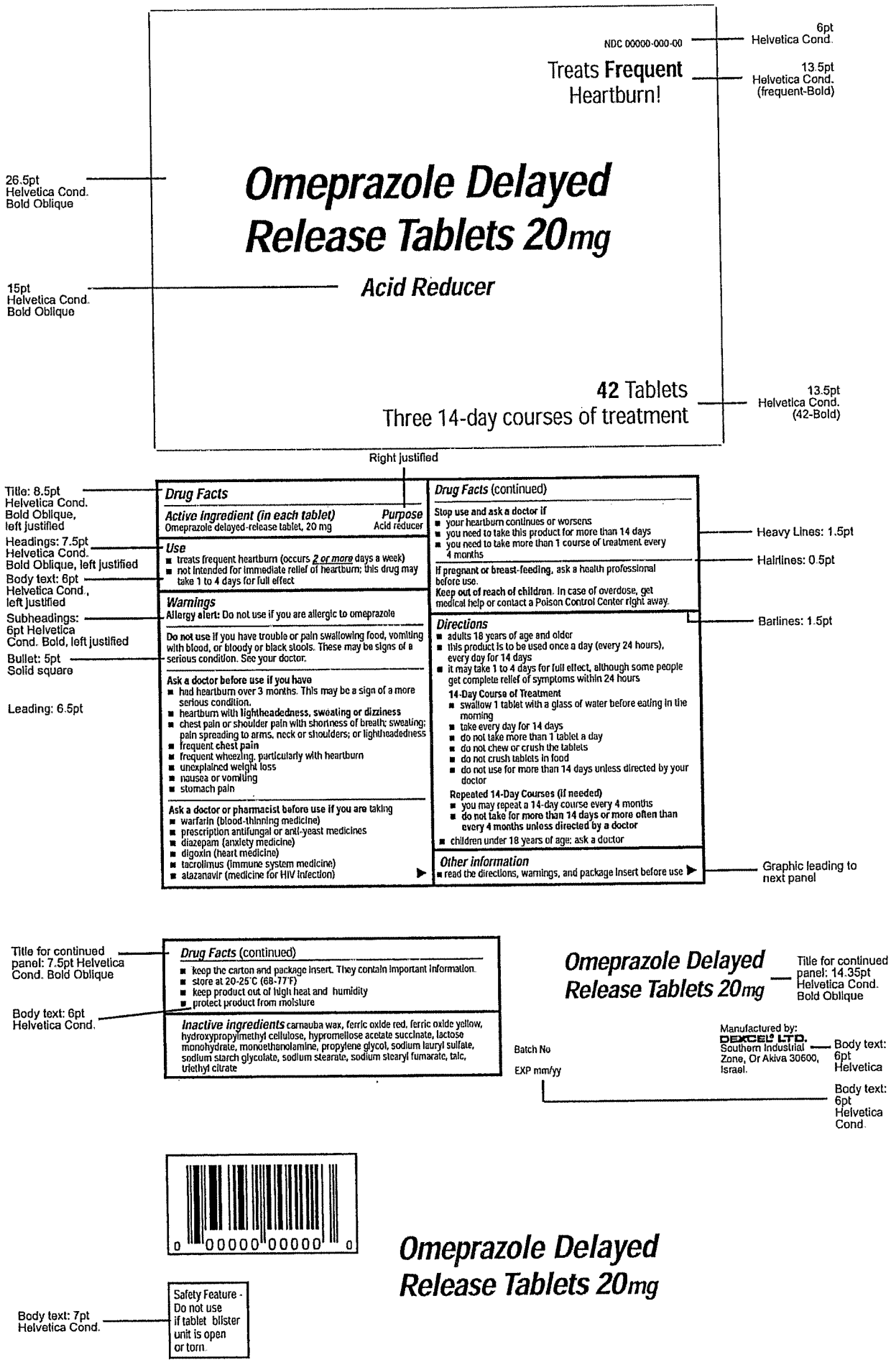
Omeprazole Delayed Release Tablets 20mg

Safety Feature - Do not use if tablet blister seal is open or torn

1257450239
A-FDA


NDC 00000-000-00
6pt Helvetica Cond.
Treats Frequent Heartburn!
13.5pt Helvetica Cond. (frequent-Bold)
26.5pt Helvetica Cond. Bold Oblique
Omeprazole Delayed Release Tablets 20mg
15pt Helvetica Cond. Bold Oblique
Acid Reducer
28 Tablets
Two 14-day courses of treatment
13.5pt Helvetica Cond. (28-Bold)
Right justified
Title: 8.5pt Helvetica Cond. Bold Oblique, left justified
Drug Facts
Active ingredient (in each tablet)
Omeprazole delayed-release tablet, 20 mg
Purpose
Acid reducer
Headings: 7.5pt Helvetica Cond. Bold Oblique, left justified
Use
Body text: 6pt Helvetica Cond., left justified
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
Subheadings: 6pt Helvetica Cond. Bold, left justified
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.
Bullet: 5pt Solid square
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)
Leading: 6.5pt
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
Heavy Lines: 1.5pt
Hairlines: 0.5pt
Barlines: 1.5pt
Graphic leading to next panel
Title for continued panel: 7.5pt Helvetica Cond. Bold Oblique
Drug Facts (continued)
Body text: 6pt Helvetica Cond
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, triethyl citrate
Omeprazole Delayed Release Tablets 20mg
Title for continued panel: 14.35pt Helvetica Cond. Bold Oblique
Body text: 6pt Helvetica Cond.
Batch No
EXP mm/yy
Manufactured by:
DEXCEL LTD.
Southern Industrial Zone, Or Akiva 30600, Israel.
Body text: 6pt Helvetica
0 00000 00000 0
Omeprazole Delayed Release Tablets 20mg
Safety Feature - Do not use if tablet blister unit is open or torn.
Body text: 7pt Helvetica Cond.


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/ 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).
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
Omeprazole Delayed Release Tablets 20mg
Safety Feature - Do not use if tablet blister unit is open or torn.
Treats Frequent Heartburn!
Omeprazole Delayed Release Tablets 20mg
Acid Reducer
42 Tablets
Three 14-day courses of treatment
Omeprazole Delayed Release Tablets 20mg
Manufactured by:
DEXCEL LTD.
Southern Industrial Zone, Or Akiva 30600, Israel.
Batch No
EXP mm/yy
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, triethyl citrate


NDC 00000-000-00
6pt Helvetica Cond.
Treats Frequent Heartburn!
13.5pt Helvetica Cond. (frequent-Bold)
26.5pt Helvetica Cond. Bold Oblique
Omeprazole Delayed Release Tablets 20mg
15pt Helvetica Cond. Bold Oblique
Acid Reducer
42 Tablets
Three 14-day courses of treatment
13.5pt Helvetica Cond. (42-Bold)
Right justified
Title: 8.5pt Helvetica Cond. Bold Oblique, left justified
Drug Facts
Active Ingredient (in each tablet)
Omeprazole delayed-release tablet, 20 mg
Purpose
Acid reducer
Headings: 7.5pt Helvetica Cond. Bold Oblique, left justified
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
Body text: 6pt Helvetica Cond., left justified
Warnings
Allergy alert: Do not use if you are allergic to omeprazole
Subheadings: 6pt Helvetica Cond. Bold, left justified
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.
Bullet: 5pt Solid square
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)
Leading: 6.5pt
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.
Heavy Lines: 1.5pt
Hairlines: 0.5pt
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
Barlines: 1.5pt
Other information
read the directions, warnings, and package insert before use
Graphic leading to next panel
Title for continued panel: 7.5pt Helvetica Cond. Bold Oblique
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
Body text: 6pt Helvetica Cond.
Inactive ingredients carnauba wax, ferric oxide red, ferric oxide yellow, hydroxypropylmethyl cellulose, hypromellose acetate succinate, lactose monohydrate, monoethenolamine, propylene glycol, sodium lauryl sulfate, sodium starch glycolate, sodium stearate, sodium stearyl fumarate, talc, triethyl citrate
Omeprazole Delayed Release Tablets 20mg
Title for continued panel: 14.35pt Helvetica Cond. Bold Oblique
Manufactured by:
DEXCEL LTD.
Southern Industrial Zone, Or Akiva 30600, Israel.
Body text: 6pt Helvetica
Batch No
EXP mm/yy
Body text: 6pt Helvetica Cond.
0 00000 00000 0
Omeprazole Delayed Release Tablets 20mg
Body text: 7pt Helvetica Cond.
Safety Feature - Do not use if tablet blister unit is open or torn.

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.

Headings: 9pt Helvetica Cond. Bold, left justified

Body text: 9pt Helvetica Cond., left justified

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

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.




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.
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.
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.
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.
Dexcel Ltd.
Southern Industrial Zone,
Or Akiva 30600, Israel.

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

/s/

Andrea Segal
6/14/2007 03:06:26 PM

Joyce Korvick
6/14/2007 03:58:26 PM

CERTIFICATE OF SERVICE

The undersigned counsel certifies that, on June 18, 2007, she electronically filed the foregoing document with the Clerk of the Court using CM/ECF, which will send automatic notification of the filing to the following:

Jack B. Blumenfeld, Esq.
Karen Jacobs Louden, Esq.
Morris, Nichols, Arsht & Tunnell LLP
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19801

The undersigned counsel further certifies that, on June 18, 2007, copies of the foregoing document were sent by email and hand to the above local counsel and by email and first class mail to the following non-registered participant:

Errol B. Taylor, Esq.
Robert J. Koch, Esq.
Jay I. Alexander, Esq.
Enrique D. Longton, Esq.
Milbank, Tweed, Hadley & McCloy LLP
1850 K Street NW
Washington, DC 20006

/s/ Ashley B. Stitzer (as3891)
Ashley B. Stitzer