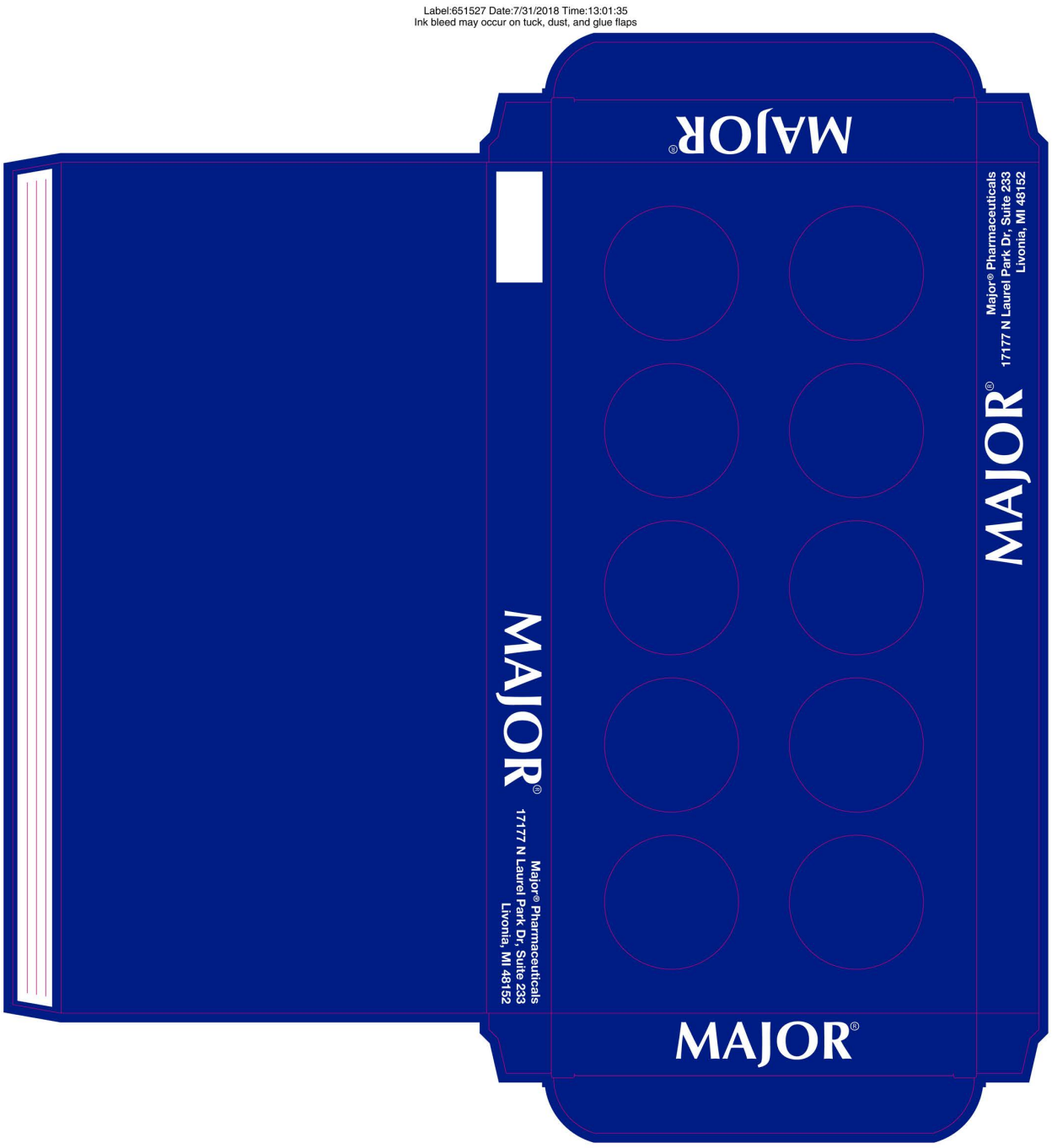
ACETAMINOPHEN ORAL SOLUTION- acetaminophen oral solution solution
DIPHENHYDRAMINE HYDROCHLORIDE- diphenhydramine hydrochloride liquid
MILK OF MAGNESIA- magnesium hydroxide suspension
Major Pharmaceuticals

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Major Pharmaceuticals
Unit dose OTC Monograph drugs
Diphenhydramine HCl, APAP and Milk of Mag (conc and non-conc)

Acetaminophen Oral Solution 160 mg/ 5 mL Unit Dose Cup
Major Pharmaceutical


NDC 0904-6738-70
Acetaminophen
Oral Solution, USP
160 mg / 5 mL
Delivers 5 mL
MAJOR®
See insert
For Institutional Use Only
MAJOR® PHARMACEUTICALS
Livonia, MI 48152
Sugar Free • Dye Free • Alcohol Free



NDC 0904-6738-70

Acetaminophen

Oral Solution, USP

160 mg / 5 mL

Delivers 5 mL

See Insert

For Institutional Use Only

MAJOR PHARMACEUTICALS

Livonia, MI 48152

Sugar Free - Dye Free - Alcohol Free

Acetaminophen 160 mg / 5 mL Unit Dose Cup
Major Pharmaceuticals

Directions

Do not use more than directed Shake well before use

Age (yr)	Dose (mL)
adults	• take 20 mL (640 mg) every 4 to 6 hours • not to exceed 6 doses in a 24-hour period • do not use more than 10 days unless directed by a doctor
under 18 years of age	• ask a doctor

Acetaminophen 160 mg / 5 mL
Major Pharmaceuticals

Keep out of reach of children.

Overdose warning: taking more than the recommended dose (overdose) may cause liver damage. In case of overdose, get medical help or contact Poison Control Center (1-800-222-1222) right away. Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Acetaminophen 160 mg / 5 mL
Major Pharmaceuticals

Do not use

- with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.

- if you are allergic to acetaminophen or any other inactive ingredients in this product

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Ask a doctor before use if the user

- has liver disease - is pregnant or breast-feeding

Ask a doctor or pharmacist before use if you are taking the blood thinning drug warfarin

---

Stop use and ask a doctor if

- pain gets worse or lasts more than 10 days - new symptoms occur

- fever gets worse or lasts more than 3 days - redness or swelling is present

These could be signs of a serious condition

Acetaminophen 160 mg / 5 mL

Major Pharmaceuticals

Inactive ingredients cherry flavor, citric acid, glycerin, methylcellulose, microcrystalline cellulose, propyl paraben, propylene glycol, purified water, sodium benzoate, sorbitol, sucralose, xantham gum

Acetaminophen 160 mg / 5 mL
Major Pharmaceuticals

Uses temporarily relieves minor aches and pains due to:

- minor pain of arthritis
- muscular aches
- backache
- premenstrual and menstrual cramps
- the common cold
- headache
- toothache
- temporarily reduces fever

Acetaminophen 160 mg / 5 mL
Major Pharmaceuticals

Active ingredient (in each 5 mL cup) Purpose Acetaminophen USP 160 mg…….. ……..Pain reliever / fever reducer

Acetaminophen 160 mg / 5 mL
Major Pharmaceuticals

Pain reliever / fever reducer

Acetaminophen 160 mg / 5 mL
Major Pharmaceuticals

Other information

- store at 20°-25°C (68°-77°F). Avoid excessive heat 40°C (104°F)

- protect from excessive moisture - do not use if lid seal is open or damaged

- sugar free, dye free, alcohol free - see bottom of cup for lot number and expiration date

Acetaminophen 160 mg / 5 mL
Major Pharmaceuticals

Product Insert

Acetaminophen Oral Solution, USP

NDC 0904-6738-70
For institutional use only
10 x 5 mL Cups

Drug Facts

Active ingredient (in each 5 mL cup)	***Purpose***
Acetaminophen USP 160 mg	Pain reliever / fever reducer

Uses temporarily relieves minor aches and pains due to: ■ minor pain of arthritis
■ muscular aches ■ backache ■ premenstrual and menstrual cramps
■ the common cold ■ headache ■ toothache ■ temporarily reduces fever

Warnings

Liver warning: This product contains acetaminophen. Severe liver damage may occur if
■ adults take more than 6 doses in 24 hours which is the maximum daily amount
■ taken with other drugs containing acetaminophen
■ adult has 3 or more alcoholic drinks every day while using this product

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

Do not use
■ with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.
■ if you are allergic to acetaminophen or any other inactive ingredients in this product

Ask a doctor before use if the user
■ has liver disease ■ is pregnant or breast-feeding

Ask a doctor or pharmacist before use if you are taking the blood thinning drug warfarin

Stop use and ask a doctor if
■ pain gets worse or lasts more than 10 days ■ new symptoms occur
■ fever gets worse or lasts more than 3 days ■ redness or swelling is present
These could be signs of a serious condition

Keep out of reach of children.
Overdose warning: taking more than the recommended dose (overdose) may cause liver damage. In case of overdose, get medical help or contact Poison Control Center (1-800-222-1222) right away. Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Directions

■ Do not use more than directed ■ Shake well before use

Age (yr)	Dose (mL)
adults	■ take 20 mL (640 mg) every 4 to 6 hours ■ not to exceed 6 doses in a 24-hour period ■ do not use more than 10 days unless directed by a doctor
under 18 years of age	■ ask a doctor

Other information

■ store at 20°-25°C (68°-77°F). Avoid excessive heat 40°C (104°F)
■ protect from excessive moisture ■ do not use if lid seal is open or damaged
■ sugar free, dye free, alcohol free ■ see bottom of cup for lot number and expiration date

Inactive ingredients cherry flavor, citric acid, glycerin, methylcellulose, microcrystalline cellulose, propyl paraben, propylene glycol, purified water, sodium benzoate, sorbitol, sucralose, xantham gum

Questions or comments?
Call 1-800-616-2471

MAJOR®

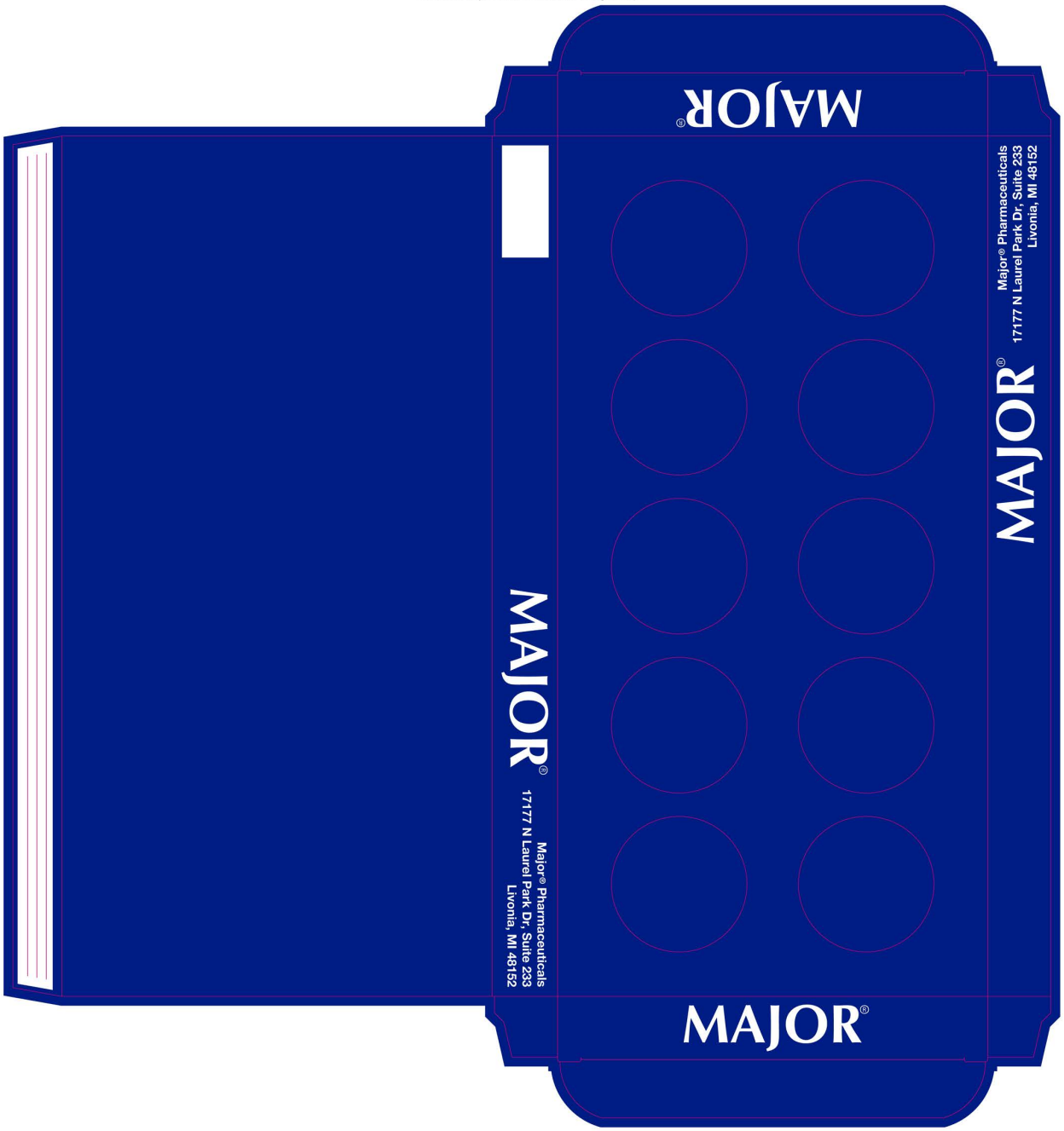
Re-order
No. 700898

MAJOR® PHARMACEUTICALS
17177 N Laurel Park Dr., Suite 233
Livonia, MI 48152

M-154
C05011 R2
Rev. 01/19

Diphenhydramine HCl 12.5 mg/ 5 mL Cups

Label:651527 Date:7/31/2018 Time:13:01:35
Ink bleed may occur on tuck, dust, and glue flaps



NDC 0904-6740-70

Diphenhydramine HCl

Oral Solution, USP

12.5 mg/5 mL

Antihistamine - Delivers 5 mL

See Insert

For Instituional Use Only

MAJOR PHARMACEUTICALS

Livonia, MI 64152

Sugar Free - Dye Free - Alcohol Free

Diphenhydramine HCl 12.5 mg/5 mL
Major Pharmaceuticals - Institutional Use Only

Directions

• Use the following dosage guidelines when using this product

Age (yr)	Dose (mL)
adults and children 12 years and over	take 10 mL every 4 to 6 hours; not more than 60 mL in 24 hours
children 6 years to under 12 years	take 5 mL every 4 to 6 hours; not more than 30 mL in 24 hours
children under 6 years	ask a doctor

Diphenhydramine HCl 12.5 mg/5 mL
Major Pharmaceuticals - For Institutional Use Only

Warnings

Do not use

in neonates or premature infants

if pregnant or breast-feeding

if hypersensitive to diphenhydramine HCl and other similar antihistamines

with any other product containing diphenhydramine, even one used on skin

to make a child sleepy

Ask a doctor before use if you have

glaucoma a breathing problem such as emphysema or chronic bronchitis

a sodium restricted diet trouble urinating due to an enlarged prostate gland

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Ask a doctor or pharmacist before use if

taking tranquilizers or sedatives

When using this product

marked drowsiness may occur avoid alcoholic drinks

alcohol, sedatives, and tranquilizers may increase drowsiness

be careful when driving a motor vehicle or operating machinery

excitability may occur, especially in children

Diphenhydramine HCl 12.5 mg/5 mL
Major Pharmaceuticals - for Institutional Use Only

Inactive ingredients cherry flavor, citric acid, glycerin, monoammonium glycyrrhizinate, poloxamer 407, purified water, sodium benzoate, sodium chloride, sodium citrate, sucralose

Diphenhydramine HCl 12.5 mg/5 mL
Major Pharmaceuticals - For Institutional Use Only

Uses temporarily relieves these symptoms due to hay fever or other upper respiratory allergies: • runny nose • sneezing • itchy, watery eyes • itchy throat

Diphenydramine HCl 12.5 mg/ 5 mL
Major Pharmaceutical - For Institutional Use Only

Keep out of reach of children.

In case of overdose, get medical help or contact a Poison Control Center right away. (1-800-222-1222)

Diphenhydramine HCl 12.5 mg/ 5 mL
Major Pharmaceuticals - For Intitutional Use Only

Antihistamine

Diphenhydramine HCl 12.5 mg/ 5 mL
Major Pharmaceuticals - For Institutional Use Only

Active ingredient (in each 5 mL cup) Purpose Diphenhydramine HCl USP 12.5 mg.. ……Antihistamine

Diphenhydramine HCl 12.5 mg/5 mL
Major Pharmaceuticals - For Institutional Use Only

Other information

- each 5 mL contains: sodium 15 mg
- store at 20-25°C (68-77°F)
- protect from excessive moisture
- do not use if lid seal is open or damaged
- sugar free, dye free, alcohol free
- see bottom of cup for lot number and expiration date

Diphenhydramine HCl 12.5 mg/ 5 mL
Major Pharmaceuticals - IFU - For Institutional use Only

Product Insert

Diphenhydramine HCl Oral Solution, USP

NDC 0904-6740-70
10 x 5 mL Unit Dose Cups

Drug Facts

Active ingredient (in each 5 mL cup) — **Purpose**
Diphenhydramine HCl USP 12.5 mg ..... Antihistamine

Uses temporarily relieves these symptoms due to hay fever or other upper respiratory allergies: ■ runny nose ■ sneezing ■ itchy, watery eyes ■ itchy throat

Warnings

Do not use
- in neonates or premature infants
- if pregnant or breast-feeding
- if hypersensitive to diphenhydramine HCl and other similar antihistamines
- with any other product containing diphenhydramine, even one used on skin
- to make a child sleepy

Ask a doctor before use if you have
- glaucoma
- a breathing problem such as emphysema or chronic bronchitis
- a sodium restricted diet
- trouble urinating due to an enlarged prostate gland

Ask a doctor or pharmacist before use if
- taking tranquilizers or sedatives

When using this product
- marked drowsiness may occur
- avoid alcoholic drinks
- alcohol, sedatives, and tranquilizers may increase drowsiness
- be careful when driving a motor vehicle or operating machinery
- excitability may occur, especially in children

Keep out of reach of children.
In case of overdose, get medical help or contact a Poison Control Center right away. (1-800-222-1222)

Directions
- Use the following dosage guidelines when using this product

Age (yr)	Dose (mL)
adults and children 12 years and over	take 10 mL every 4 to 6 hours; not more than 60 mL in 24 hours
children 6 years to under 12 years	take 5 mL every 4 to 6 hours; not more than 30 mL in 24 hours
children under 6 years	ask a doctor

Other information
- each 5 mL contains: sodium 15 mg
- store at 20-25°C (68-77°F)
- protect from excessive moisture
- do not use if lid seal is open or damaged
- sugar free, dye free, alcohol free
- see bottom of cup for lot number and expiration date

Inactive ingredients cherry flavor, citric acid, glycerin, monoammonium glycyrrhizinate, poloxamer 407, purified water, sodium benzoate, sodium chloride, sodium citrate, sucralose

Questions or comments?
Call 1-800-616-2471

MAJOR®

MAJOR® PHARMACEUTICALS
17177 N Laurel Park Dr., Suite 233
Livonia, MI 48152

Re-order
No. 700900

M-154
C05006 R2
Rev. 08/18

Product Insert

Diphenhydramine HCl Oral Solution, USP

NDC 0904-6740-70

10 x 5 mL Unit Dose Cups

Active ingredient (in each 5 mL cup) Purpose Diphenhydramine HCl USP 12.5 mg.. ……Antihistamine

Uses temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:

- runny nose
- sneezing
- itchy, watery eyes
- itchy throat

Warnings

Do not use

- in neonates or premature infants
- if pregnant or breast-feeding
- if hypersensitive to diphenhydramine HCl and other similar antihistamines
- with any other product containing diphenhydramine, even one used on skin
- to make a child sleepy

Ask a doctor before use if you have

- glaucoma
- a breathing problem such as emphysema or chronic bronchitis
- a sodium restricted diet
- trouble urinating due to an enlarged prostate gland

Ask a doctor or pharmacist before use if

- taking tranquilizers or sedatives

When using this product

- marked drowsiness may occur
- avoid alcoholic drinks
- alcohol, sedatives, and tranquilizers may increase drowsiness
- be careful when driving a motor vehicle or operating machinery
- excitability may occur, especially in children

Keep out of reach of children.

In case of overdose, get medical help or contact a Poison Control Center right away. (1-800-222-1222)

Other information

- each 5 mL contains: sodium 15 mg
- store at 20-25°C (68-77°F)
- protect from excessive moisture
- do not use if lid seal is open or damaged
- sugar free, dye free, alcohol free
- see bottom of cup for lot number and expiration date

Inactive ingredients cherry flavor, citric acid, glycerin, monoammonium glycyrrhizinate, poloxamer 407, purified water, sodium benzoate, sodium chloride, sodium citrate, sucralose

Directions

Use the following dosage guidelines when using this product

Age (yr) Dose (mL)

adults and children 12 years and over take 10 mL every 4 to 6 hours; not more than 60 mL in 24 hours

children 6 years to under 12 years take 5 mL every 4 to 6 hours; not more than 30 mL in 24 hours

children under 6 years ask a doctor

Questions or comments?

Call 1-800-616-2471

Re-order No. 700900

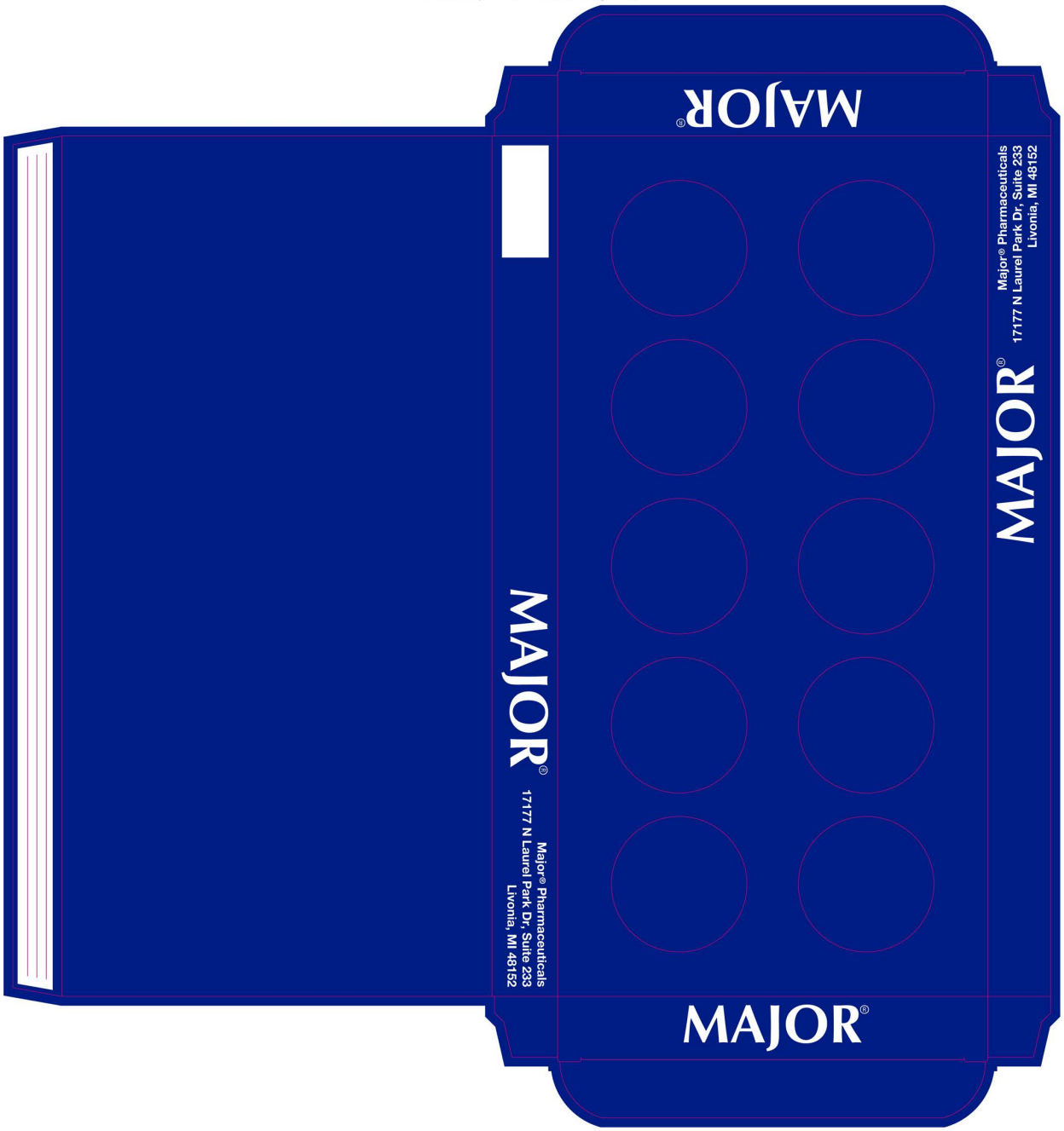
MAJOR® PHARMACEUTICALS

17177 N Laurel Park Dr., Suite 233

Livonia, MI 48152

Diphenhydramine HCl 25 mg / 10 mL Cups

Label:651527 Date:7/31/2018 Time:13:01:35
Ink bleed may occur on tuck, dust, and glue flaps



NDC 0904-6741-72

Diphenhydramine HCl

Oral Solution, USP

25 mg/10 mL

Antihistamine - Delivers 10 mL

See Insert

For Instituional Use Only

MAJOR PHARMACEUTICALS

Livonia, MI 64152

Sugar Free - Dye Free - Alcohol Free

Diphenhydramine HCl 25 mg/ 10 mL
Major Pharmaceuticals - for Instutional use Only

Directions

Use the following dosage guidelines when using this product

Age (yr) Dose (mL)

adults and children 12 years and over take 10 mL every 4 to 6 hours; not more than 60 mL in 24 hours

children 6 years to under 12 years ask a doctor

Diphenhydramine HCl 10 mg/ 10 mL
Major Pharmaceuticals - For Institutional Use Only

Warnings

Do not use

• in neonates or premature infants

• if pregnant or breast-feeding

• if hypersensitive to diphenhydramine HCl and other similar antihistamines

• with any other product containing diphenhydramine, even one used on skin

• to make a child sleepy

Ask a doctor before use if you have

• glaucoma • a breathing problem such as emphysema or chronic bronchitis

• a sodium restricted diet • trouble urinating due to an enlarged prostate gland

---

Ask a doctor or pharmacist before use if

• taking tranquilizers or sedatives

When using this product

• marked drowsiness may occur • avoid alcoholic drinks

• alcohol, sedatives, and tranquilizers may increase drowsiness

• be careful when driving a motor vehicle or operating machinery

• excitability may occur, especially in children

Diphenhydramine HCl 25 mg/ 10 mL
Major Pharmaceuticals - For Institutional Use Only

Inactive ingredients cherry flavor, citric acid, glycerin, monoammonium glycyrrhizinate, poloxamer 407, purified water, sodium benzoate, sodium chloride, sodium citrate, sucralose

Diphenhydramine HCl 10 mg / 10 mL
Major Pharmaceuticals - For Institutional Use Only

Uses temporarily relieves these symptoms due to hay fever or other upper respiratory allergies: • runny nose • sneezing • itchy, watery eyes • itchy throat

Diphenhydramine HCl 25 mg/ 10 mL
Major Pharmaceuticals - For Institutional use Only

Keep out of reach of children.

In case of overdose, get medical help or contact a Poison Control Center right away. (1-800-222-1222)

Diphenhydramine HCl 25 mg/ 10 mL
Major Pharmaceuticals - For Institutional Use Only

Antihistamine

Diphenhydramine HCl 25 mg/ 10 mL
Major Pharmaceuticals - For Institutional Use Only

Active ingredient (in each 10 mL cup) Purpose Diphenhydramine HCl USP 25 mg..
……Antihistamine

Diphenhydramine HCl 25 mg/ 10 mL
Major Pharmaceuticals - For Institutional Use Only

• each 10 mL contains: sodium 30 mg

- store at 20-25°C (68-77°F)
- protect from excessive moisture
- do not use if lid seal is open or damaged
- sugar free, dye free, alcohol free
- see bottom of cup for lot number and expiration date

Diphenhydramine HCl 25 mg/ 10 mL
Major Pharmaceuticals - IFU - For Institutional Use Only

Product Insert

Diphenhydramine HCl Oral Solution, USP

NDC 0904-6741-72
10 x 10 mL Unit Dose Cups

Drug Facts

Active ingredient (in each 10 mL cup) — **Purpose**
Diphenhydramine HCl USP 25 mg ..... Antihistamine

Uses temporarily relieves these symptoms due to hay fever or other upper respiratory allergies: ■ runny nose ■ sneezing ■ itchy, watery eyes ■ itchy throat

Warnings

Do not use
- in neonates or premature infants
- if pregnant or breast-feeding
- if hypersensitive to diphenhydramine HCl and other similar antihistamines
- with any other product containing diphenhydramine, even one used on skin
- to make a child sleepy

Ask a doctor before use if you have
- glaucoma
- a breathing problem such as emphysema or chronic bronchitis
- a sodium restricted diet
- trouble urinating due to an enlarged prostate gland

Ask a doctor or pharmacist before use if
- taking tranquilizers or sedatives

When using this product
- marked drowsiness may occur
- avoid alcoholic drinks
- alcohol, sedatives, and tranquilizers may increase drowsiness
- be careful when driving a motor vehicle or operating machinery
- excitability may occur, especially in children

Keep out of reach of children.
In case of overdose, get medical help or contact a Poison Control Center right away. (1-800-222-1222)

Directions
- Use the following dosage guidelines when using this product

Age (yr)	Dose (mL)
adults and children 12 years and over	take 10 mL every 4 to 6 hours; not more than 60 mL in 24 hours
children 6 years to under 12 years	ask a doctor

Other information
- each 10 mL contains: sodium 30 mg
- store at 20-25°C (68-77°F)
- protect from excessive moisture
- do not use if lid seal is open or damaged
- sugar free, dye free, alcohol free
- see bottom of cup for lot number and expiration date

Inactive ingredients cherry flavor, citric acid, glycerin, monoammonium glycyrrhizinate, poloxamer 407, purified water, sodium benzoate, sodium chloride, sodium citrate, sucralose

Questions or comments?
Call 1-800-616-2471

MAJOR®

MAJOR® PHARMACEUTICALS
17177 N Laurel Park Dr., Suite 233
Livonia, MI 48152

Re-order
No. 700901

M-154
C05007 R1
Rev. 08/18

roduct Insert

Diphenhydramine HCl Oral Solution, USP

NDC 0904-6741-72

10 x 10 mL Unit Dose Cups

Active ingredient (in each 10 mL cup) Purpose Diphenhydramine HCl USP 25 mg.. ……Antihistamine

Uses temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:

- runny nose
- sneezing
- itchy, watery eyes
- itchy throat

Warnings

Do not use

- in neonates or premature infants
- if pregnant or breast-feeding
- if hypersensitive to diphenhydramine HCl and other similar antihistamines
- with any other product containing diphenhydramine, even one used on skin
- to make a child sleepy

Ask a doctor before use if you have

- glaucoma
- a breathing problem such as emphysema or chronic bronchitis
- a sodium restricted diet
- trouble urinating due to an enlarged prostate gland

Ask a doctor or pharmacist before use if

- taking tranquilizers or sedatives

When using this product

- marked drowsiness may occur
- avoid alcoholic drinks
- alcohol, sedatives, and tranquilizers may increase drowsiness
- be careful when driving a motor vehicle or operating machinery
- excitability may occur, especially in children

Keep out of reach of children.

In case of overdose, get medical help or contact a Poison Control Center right away. (1-800-222-1222)

Directions

Use the following dosage guidelines when using this product

Age (yr) Dose (mL)

adults and children 12 years and over take 10 mL every 4 to 6 hours; not more than 60 mL in 24 hours

children 6 years to under 12 years ask a doctor

Other information

- each 10 mL contains: sodium 30 mg
- store at 20-25°C (68-77°F)
- protect from excessive moisture
- do not use if lid seal is open or damaged
- sugar free, dye free, alcohol free

- see bottom of cup for lot number and expiration date

Inactive ingredients cherry flavor, citric acid, glycerin, monoammonium glycyrrhizinate, poloxamer 407, purified water, sodium benzoate, sodium chloride, sodium citrate, sucralose

Questions or comments?

Call 1-800-616-2471

Re-order

No. 700901

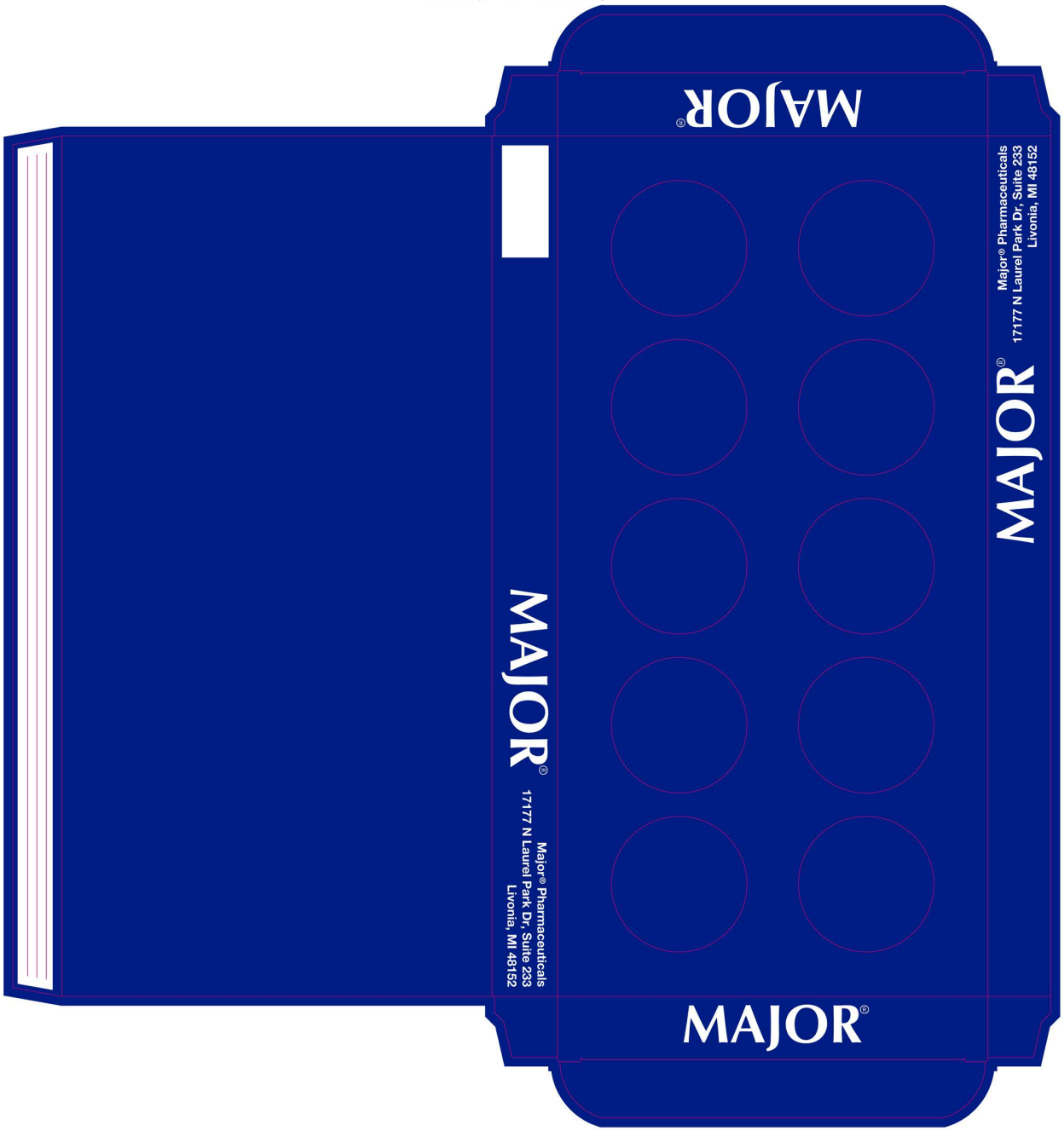
MAJOR® PHARMACEUTICALS

17177 N Laurel Park Dr., Suite 233

Livonia, MI 48152

Acetaminophen 325 mg / 10.15 mL
Major Pharmaceuticals

Label:651527 Date:7/31/2018 Time:13:01:35
Ink bleed may occur on tuck, dust, and glue flaps



NDC 0904-6739-71

Acetaminophen

Oral Solution, USP

325 mg / 10.15 mL

Delivers 10.15 mL

See Insert

For Institutional Use Only

MAJOR PHARMACEUTICALS

Livonia, MI 48152

Sugar Free - Dye Free - Alcohol Free

Acetaminophen 325 mg / 10.15 mL
Major Pharmaceuticals

Directions

Do not use more than directed Shake well before use

Age (yr)	**Dose (mL)**
adults	take 20.3 mL (650 mg) every 4 to 6 hours not to exceed 6 doses in a 24-hour period do not use more than 10 days unless directed by a doctor
under 18 years of age	ask a doctor

Acetaminophen 325 mg / 5 mL
Major Pharmaceuticals

Do not use

- with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.

- if you are allergic to acetaminophen or any other inactive ingredients in this product

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Ask a doctor before use if the user

- has liver disease - is pregnant or breast-feeding

Ask a doctor or pharmacist before use if you are taking the blood thinning drug warfarin

---

Stop use and ask a doctor if

- pain gets worse or lasts more than 10 days - new symptoms occur

- fever gets worse or lasts more than 3 days - redness or swelling is present

These could be signs of a serious condition

Acetaminophen 325 mg / 10.15 mL

Major Pharmaceuticals

Inactive ingredients cherry flavor, citric acid, glycerin, methylcellulose, microcrystalline cellulose, propyl paraben, propylene glycol, purified water, sodium benzoate, sorbitol, sucralose, xantham gum

Acetaminophen 325 mg / 10.15 mL
Major Pharmaceuticals

Active ingredient (in each 10.15 mL cup) Purpose Acetaminophen USP 325 mg…….. ……..Pain reliever / fever reducer

Acetaminophen 325 mg / 10.15 mL
Major Pharmaceuticals

Uses temporarily relieves minor aches and pains due to:

- minor pain of arthritis
- muscular aches
- backache
- premenstrual and menstrual cramps
- the common cold
- headache
- toothache
- temporarily reduces fever

Acetaminophen 325 mg / 10.15 mL
Major Pharmaceuticals

Keep out of reach of children.

Overdose warning: taking more than the recommended dose (overdose) may cause liver damage. In case of overdose, get medical help or contact Poison Control Center (1-800-222-1222) right away. Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Acetaminophen 325 mg / 10.15 mL
Major Pharmaceuticals

Pain reliever / fever reducer

Acetaminophen 325 mg / 10.15 mL
Major Pharmaceuticals

Other information

- store at 20°-25°C (68°-77°F). Avoid excessive heat 40°C (104°F)
- protect from excessive moisture
- do not use if lid seal is open or damaged
- sugar free, dye free, alcohol free
- see bottom of cup for lot number and expiration date

Acetaminophen 325 mg / 10.15 mL
Major Pharmaceutcals - IFU

Product Insert

Acetaminophen Oral Solution, USP

NDC 0904-6739-71
For institutional use only
10 x 10.15 mL Cups

Drug Facts

Active ingredient (in each 10.15 mL cup) — **Purpose**
Acetaminophen USP 325 mg — Pain reliever / fever reducer

Uses temporarily relieves minor aches and pains due to: ■ minor pain of arthritis ■ muscular aches ■ backache ■ premenstrual and menstrual cramps ■ the common cold ■ headache ■ toothache ■ temporarily reduces fever

Warnings

Liver warning: This product contains acetaminophen. Severe liver damage may occur if
■ adults take more than 6 doses in 24 hours which is the maximum daily amount
■ taken with other drugs containing acetaminophen
■ adult has 3 or more alcoholic drinks every day while using this product

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

Do not use
■ with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.
■ if you are allergic to acetaminophen or any other inactive ingredients in this product

Ask a doctor before use if the user
■ has liver disease ■ is pregnant or breast-feeding

Ask a doctor or pharmacist before use if you are taking the blood thinning drug warfarin

Stop use and ask a doctor if
■ pain gets worse or lasts more than 10 days ■ new symptoms occur
■ fever gets worse or lasts more than 3 days ■ redness or swelling is present
These could be signs of a serious condition

Keep out of reach of children.
Overdose warning: taking more than the recommended dose (overdose) may cause liver damage. In case of overdose, get medical help or contact Poison Control Center (1-800-222-1222) right away. Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Directions
■ Do not use more than directed ■ Shake well before use

Age (yr)	Dose (mL)
adults	■ take 20.3 mL (650 mg) every 4 to 6 hours ■ not to exceed 6 doses in a 24-hour period ■ do not use more than 10 days unless directed by a doctor
under 18 years of age	■ ask a doctor

Other information
■ store at 20°-25°C (68°-77°F). Avoid excessive heat 40°C (104°F)
■ protect from excessive moisture ■ do not use if lid seal is open or damaged
■ sugar free, dye free, alcohol free ■ see bottom of cup for lot number and expiration date

Inactive ingredients cherry flavor, citric acid, glycerin, methylcellulose, microcrystalline cellulose, propyl paraben, propylene glycol, purified water, sodium benzoate, sorbitol, sucralose, xantham gum

Questions or comments?
Call 1-800-616-2471

Re-order
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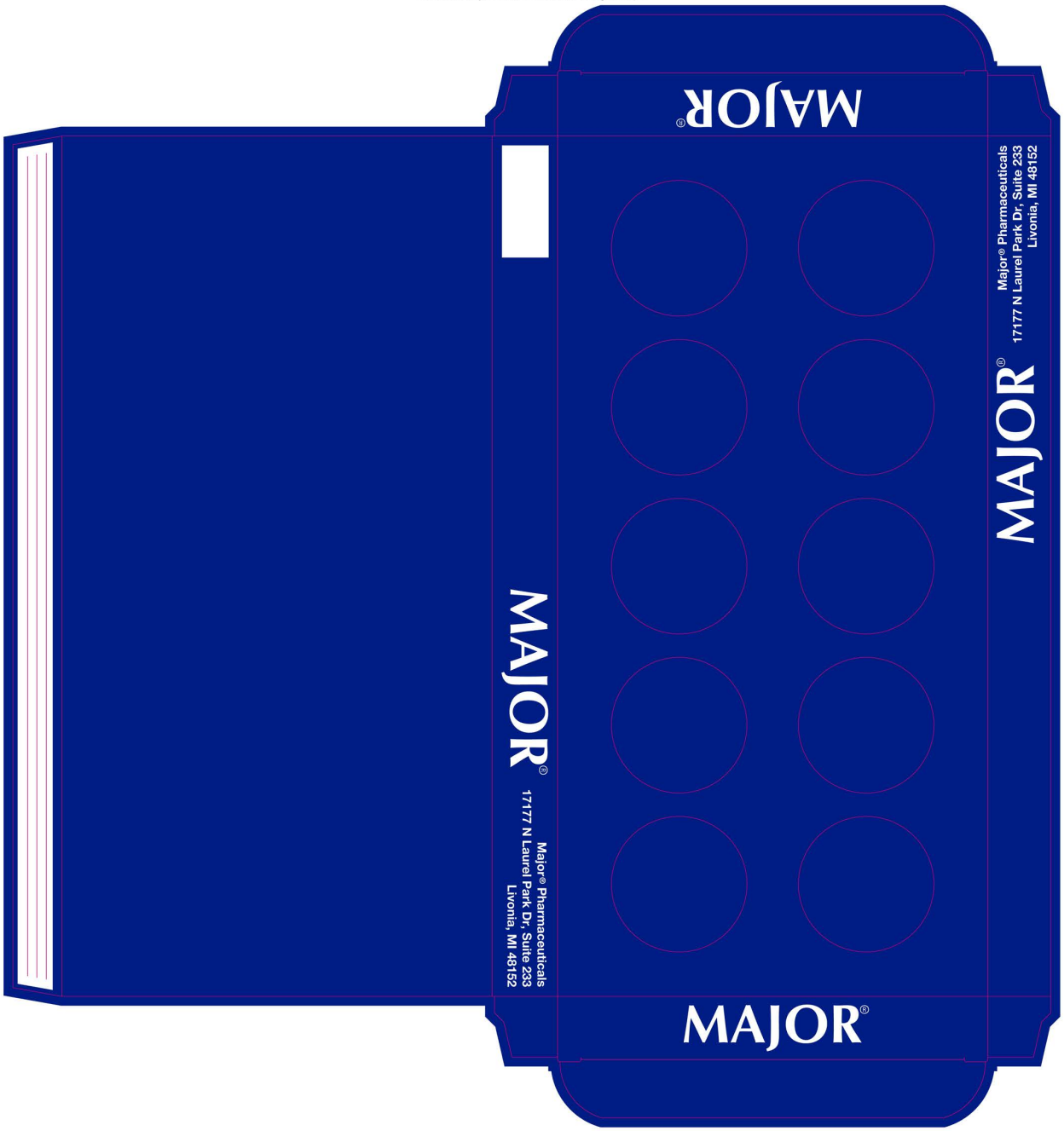
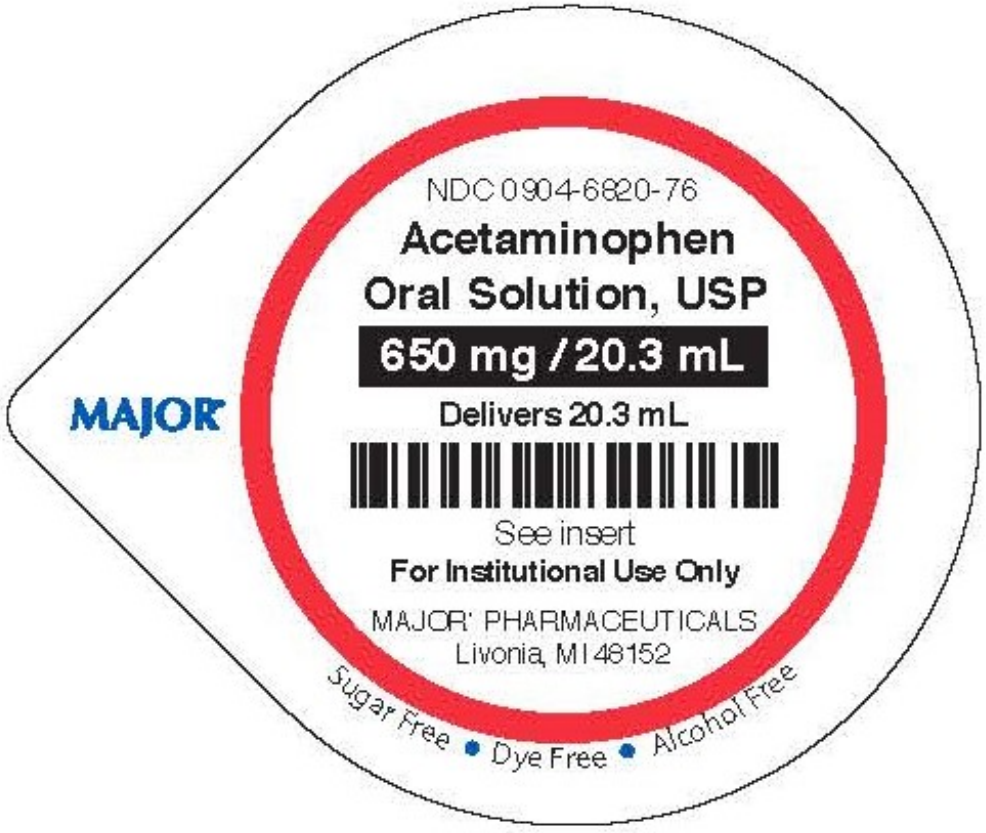
M-154
C05012 R2
Rev. 01/19

Acetaminophen 650 mg / 20.3 mL

Major Pharmaceuticals

Label:651527 Date:7/31/2018 Time:13:01:35
Ink bleed may occur on tuck, dust, and glue flaps





NDC 0904-6820-76

Acetaminophen

Oral Solution, USP

650 mg / 20.3 mL

Delivers 20.3 mL

See Insert

For Institutional Use Only

MAJOR PHARMACEUTICALS

Livonia, MI 48152

Sugar Free - Dye Free - Alcohol Free

Acetaminophen 650 mg / 20.3 mL
Major Pharmaceuticals

Directions

Do not use more than directed Shake well before use

Age (yr)	Dose (mL)
adults	take 20.3 mL (650 mg) every 4 to 6 hours not to exceed 6 doses in a 24-hour period do not use more than 10 days unless directed by a doctor
under 18 years of age	ask a doctor

Acetaminophen 650 mg / 20.3 mL
Major Pharmaceuticals

Warnings

Liver warning: This product contains acetaminophen. Severe liver damage may occur if
- adults take more than 6 doses in 24 hours which is the maximum daily amount
- taken with other drugs containing acetaminophen
- adult has 3 or more alcoholic drinks every day while using this product

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

---

Do not use
- with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.
- if you are allergic to acetaminophen or any other inactive ingredients in this product

---

Ask a doctor before use if the user
- has liver disease
- is pregnant or breast-feeding

Ask a doctor or pharmacist before use if you are taking the blood thinning drug warfarin

---

Stop use and ask a doctor if
- pain gets worse or lasts more than 10 days
- new symptoms occur
- fever gets worse or lasts more than 3 days
- redness or swelling is present

These could be signs of a serious condition

Acetaminophen 650 mg / 20.3 mL
Major Pharmaceuticals

Inactive ingredients cherry flavor, citric acid, glycerin, methylcellulose, microcrystalline cellulose, propyl paraben, propylene glycol, purified water, sodium benzoate, sorbitol, sucralose, xantham gum

Acetaminophen 650 mg / 20.3 mL
Major Pharmaceuticals

Uses temporarily relieves minor aches and pains due to:

- minor pain of arthritis
- muscular aches
- backache
- premenstrual and menstrual cramps
- the common cold
- headache
- toothache
- temporarily reduces fever

Acetaminophen 650 mg / 20.3 mL
Major Pharmaceuticals

Keep out of reach of children.

Overdose warning: taking more than the recommended dose (overdose) may cause liver damage. In case of overdose, get medical help or contact Poison Control Center (1-800-222-1222) right away. Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Acetaminophen 650 mg / 20.3 mL
Major Pharmaceuticals - IFU

Product Insert

Acetaminophen Oral Solution, USP

NDC 0904-6820-76

For institutional use only

10 x 20.3 mL Cups

Drug Facts

Active ingredient (in each 20.3 mL cup) — **Purpose**

Acetaminophen USP 650 mg ..... Pain reliever / fever reducer

Uses temporarily relieves minor aches and pains due to: ■ minor pain of arthritis ■ muscular aches ■ backache ■ premenstrual and menstrual cramps ■ the common cold ■ headache ■ toothache ■ temporarily reduces fever

Warnings

Liver warning: This product contains acetaminophen. Severe liver damage may occur if
- adults take more than 6 doses in 24 hours which is the maximum daily amount
- taken with other drugs containing acetaminophen
- adult has 3 or more alcoholic drinks every day while using this product

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

Do not use
- with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.
- if you are allergic to acetaminophen or any other inactive ingredients in this product

Ask a doctor before use if the user
- has liver disease ■ is pregnant or breast-feeding

Ask a doctor or pharmacist before use if you are taking the blood thinning drug warfarin

Stop use and ask a doctor if
- pain gets worse or lasts more than 10 days ■ new symptoms occur
- fever gets worse or lasts more than 3 days ■ redness or swelling is present

These could be signs of a serious condition

Keep out of reach of children.

Overdose warning: taking more than the recommended dose (overdose) may cause liver damage. In case of overdose, get medical help or contact Poison Control Center (1-800-222-1222) right away. Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Directions

■ Do not use more than directed ■ Shake well before use

Age (yr)	Dose (mL)
adults	■ take 20.3 mL (650 mg) every 4 to 6 hours ■ not to exceed 6 doses in a 24-hour period ■ do not use more than 10 days unless directed by a doctor
under 18 years of age	■ ask a doctor

Other information
- store at 20°-25°C (68°-77°F). Avoid excessive heat 40°C (104°F)
- protect from excessive moisture ■ do not use if lid seal is open or damaged
- sugar free, dye free, alcohol free ■ see bottom of cup for lot number and expiration date

Inactive ingredients cherry flavor, citric acid, glycerin, methylcellulose, microcrystalline cellulose, propyl paraben, propylene glycol, purified water, sodium benzoate, sorbitol, sucralose, xantham gum

Questions or comments?

Call 1-800-616-2471

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M-154
C05013 R2
Rev. 01/19

Acetaminophen 650 mg / 20.3 mL
Major Pharmaceuticals

Pain reliever / fever reducer

Acetaminophen 650 mg / 20.3 mL
Major Pharmaceuticals

Active ingredient (in each 20.3 mL cup) Purpose Acetaminophen USP 650 mg…….. …….……..Pain reliever / fever reducer

Acetaminophen 650 mg / 20.3 mL
Major Pharmaceuticals

Other information

- store at 20°-25°C (68°-77°F). Avoid excessive heat 40°C (104°F)
- protect from excessive moisture
- do not use if lid seal is open or damaged
- sugar free, dye free, alcohol free
- see bottom of cup for lot number and expiration date

Milk of Magnesia Concentrated 10 mL
Major Pharmaceutical OTC Monograph

NDC 0904-6840-72

Milk of Magnesia Concentrate

2400 mg/10 mL

Magnesium Hydroxide 2400 mg.

Saline Laxative

Shake Well

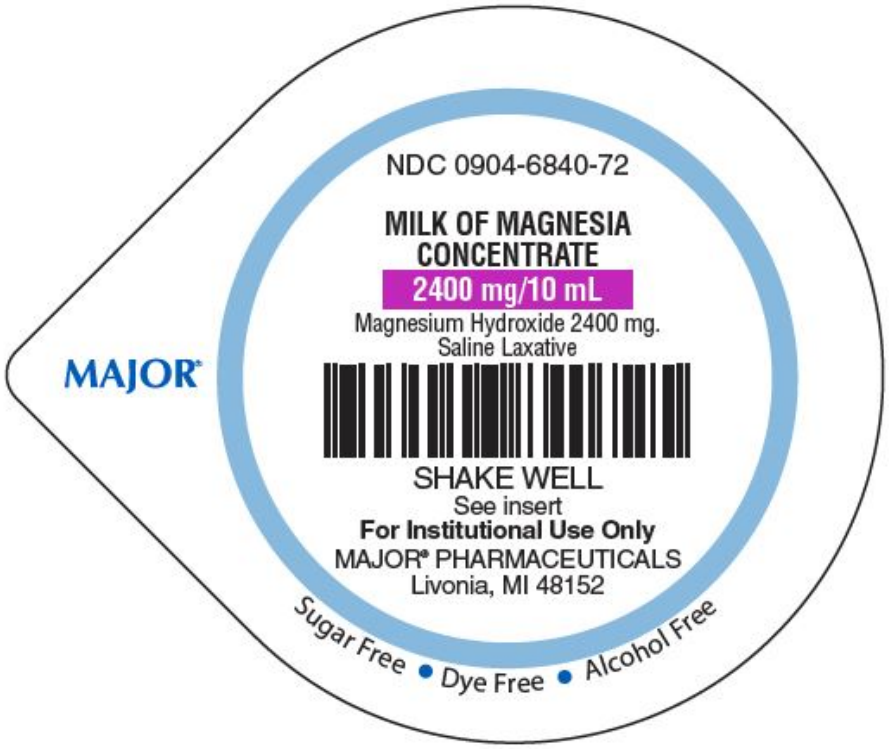
See Insert

For Instituional Use Only

MAJOR PHARMACEUTICALS

Livonia, MI 64152

Sugar Free - Dye Free - Alcohol Free



Milk of Magnesia Concentrated 2400 mg/ 10 mL

Directions

- do not exceed the maximum recommended daily dose in a 24 hour period
- shake well before use
- dose may be taken once a day preferably at bedtime, in divided doses, or as directed by a doctor
- drink a full glass (8 oz) of liquid with each dose

Age (yr)	**Dose (mL)**
adults and children 12 years and over	10 mL, not more than 20 mL in 24 hours
children under 12 years	ask a doctor

Milk of Magnesia Concentrated 2400 mg / 10 mL

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away. (1-800-222-1222)

Milk of Magnesia concentrated 2400 mg / 10 mL

Warnings

Ask a doctor before use if you have

- kidney disease
- a magnesium-restricted diet
- stomach pain, nausea, or vomiting
- a sudden change in bowel habits that lasts more than 2 weeks

---

Ask a doctor or pharmacist before use if you are taking any other drug. Take this product two or more hours before or after other drugs. Laxatives may affect how other drugs work.

Stop use and ask a doctor if

- you have rectal bleeding or no bowel movements after using this product. These could be signs of a serious condition.
- you need to use a laxative for more than 1 week

If pregnant or breast-feeding, ask a health professional before use.

Milk of Magnesia concentrated 2400 mg / 10 mL

Inactive ingredients citric acid, glycerin, microcrystalline cellulose, methyl cellulose, purified water, saccharin sodium, sodium citrate, spearmint oil, xantham gum

Milk of Magnesia Concentrated 2400 mg / 10 mL

Uses

- relieves occasional constipation (irregularity)
- generally produces bowel movement in ½ to 6 hours

Milk of Magnesia Concentrated 2400 mL / 10 mL

Active ingredient (in each 10 mL cup) Magnesium hydroxide USP 2400 mg

Milk of Magnesia concentrated 2400 mg / 10 mL

Saline laxative

Milk of Magnesia Concentrated 2400 mg / 10 mL

Other information

- each 10 mL contains: calcium 40 mg, sodium 35 mg, and magnesium 1000 mg
- store at 20-25°C (68-77°F)
- protect from excessive moisture
- do not use if lid seal is open or damaged
- sugar free, dye free, alcohol free
- see bottom of cup for lot number and expiration date

Milk of Magnesia Concentrated 2400 mg / 10 mL

Product Insert

Milk of Magnesia Concentrate

NDC 0904-6840-72

10 x 10 mL Unit Dose Cups

Drug Facts

Active ingredient (in each 10 mL cup) — **Purpose**

Magnesium hydroxide USP 2400 mg ..... Saline laxative

Uses

- relieves occasional constipation (irregularity)
- generally produces bowel movement in ½ to 6 hours

Warnings

Ask a doctor before use if you have

- kidney disease
- a magnesium-restricted diet
- stomach pain, nausea, or vomiting
- a sudden change in bowel habits that lasts more than 2 weeks

Ask a doctor or pharmacist before use if you are taking any other drug. Take this product two or more hours before or after other drugs. Laxatives may affect how other drugs work.

Stop use and ask a doctor if

- you have rectal bleeding or no bowel movements after using this product. These could be signs of a serious condition.
- you need to use a laxative for more than 1 week

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. (1-800-222-1222)

Directions

- do not exceed the maximum recommended daily dose in a 24 hour period
- shake well before use
- dose may be taken once a day preferably at bedtime, in divided doses, or as directed by a doctor
- drink a full glass (8 oz) of liquid with each dose

Age (yr)	Dose (mL)
adults and children 12 years and over	10 mL, not more than 20 mL in 24 hours
children under 12 years	ask a doctor

Other information

- **each 10 mL contains:** calcium 40 mg, sodium 35 mg, and magnesium 1000 mg
- store at 20-25°C (68-77°F)
- protect from excessive moisture
- do not use if lid seal is open or damaged
- sugar free, dye free, alcohol free
- see bottom of cup for lot number and expiration date

Inactive ingredients citric acid, glycerin, microcrystalline cellulose, methyl cellulose, purified water, saccharin sodium, sodium citrate, spearmint oil, xantham gum

Questions or comments?

Call 1-800-616-2471

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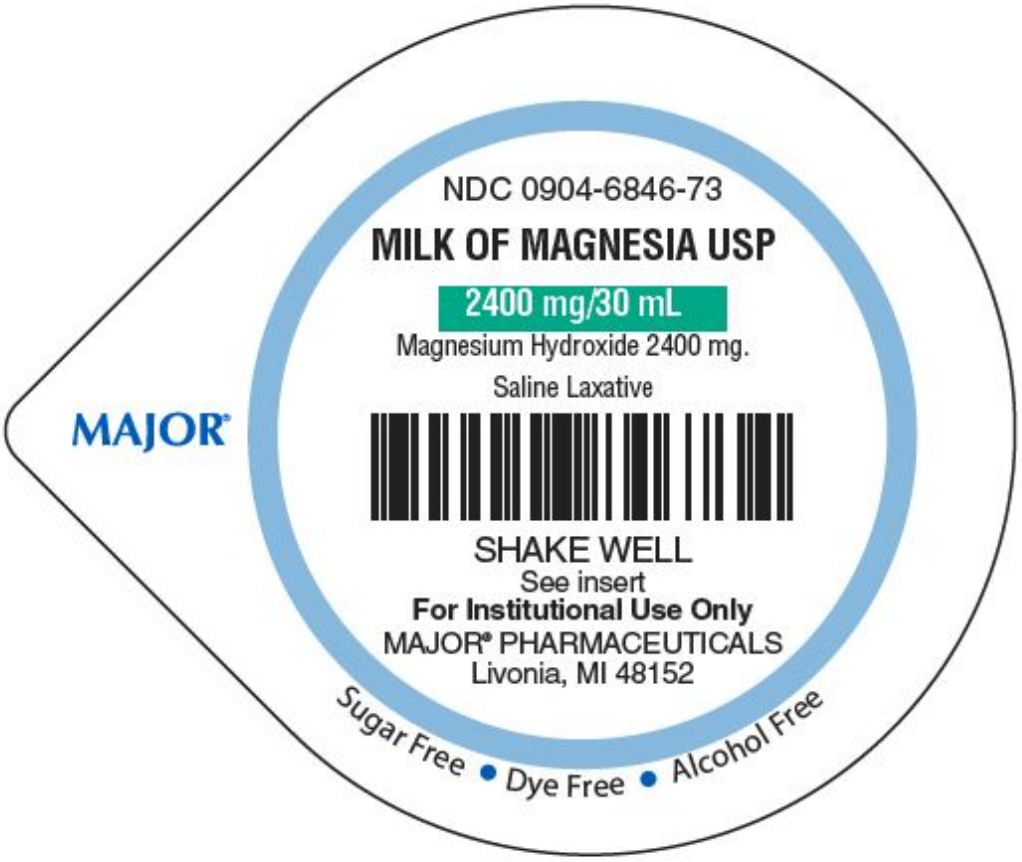
Re-order
No. 701033

M-154
C05019 R0
Rev. 03/19

Milk of Magnesia 2400 mg/30 mL

Major Pharmaceutical OTC Monograph



NDC 0904-6846-73

Milk of Magnesia USP

2400 mg/30 mL

Magnesium Hydroxide 2400 mg.

Saline Laxative

Shake Well

See Insert

For Instituional Use Only

MAJOR PHARMACEUTICALS

Livonia, MI 64152

Sugar Free - Dye Free - Alcohol Free

Milk of Magnesia 2400 mg/30 mL

Directions

- do not exceed the maximum recommended daily dose in a 24 hour period

- shake well before use

- dose may be taken once a day preferably at bedtime, or as directed by a doctor

- drink a full glass (8 oz) of liquid with each dose

Age (yr)	Dose (mL)
adults and children 12 years and over	30 mL, not more than 60 mL in 24 hrs.
children under 12 years	ask a doctor

Milk of Magnesia 2400 mg/ 30 mL

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away. (1-800-222-1222)

Milk of Magnesia 2400 mg/ 30 mL

Warnings

Ask a doctor before use if you have

- kidney disease

- a magnesium-restricted diet

- stomach pain, nausea, or vomiting

- a sudden change in bowel habits that lasts more than 2 weeks

Ask a doctor or pharmacist before use if you are taking any other drug. Take this product two or more hours before or after other drugs. Laxatives may affect how other drugs work.

Stop use and ask a doctor if

- you have rectal bleeding or no bowel movements after using this product. These could be signs of a serious condition.

- you need to use a laxative for more than 1 week

If pregnant or breast-feeding, ask a health professional before use.

Milk of Magnesia 2400 mg / 30 mL

Inactive ingredients citric acid, glycerin, microcrystalline cellulose, methyl cellulose, purified water, saccharin sodium, sodium citrate, spearmint oil, xanthan gum

Milk of Magnesia 2400 mg / 30 mL

Uses

- relieves occasional constipation (irregularity)

- generally produces bowel movement in ½ to 6 hours

Milk of Magnesia 2400 mg / 30 mL

Active ingredient (in each 30 mL cup)

Magnesium hydroxide USP 2400 mg

Milk of Magnesia 2400 mg / 30 mL

Saline laxative

Milk of Magnesia 2400 mg / 30 mL

Other information

- each 30 mL contains: calcium 40 mg, sodium 100 mg, and magnesium 1000 mg
- store at 20-25°C (68-77°F) -
- protect from excessive moisture
- do not use if lid seal is open or damaged -

sugar free, dye free, alcohol free

- see bottom of cup for lot number and expiration date

Milk of Magnesia 2400 mg / 30 mL

Product Insert

Milk of Magnesia, USP

NDC 0904-6846-73

10 x 30 mL Unit Dose Cups

Drug Facts

Active ingredient (in each 30 mL cup)	***Purpose***
Magnesium hydroxide USP 2400 mg	Saline laxative

Uses ■ relieves occasional constipation (irregularity)
■ generally produces bowel movement in ½ to 6 hours

Warnings

Ask a doctor before use if you have

■ kidney disease ■ a magnesium-restricted diet
■ stomach pain, nausea, or vomiting
■ a sudden change in bowel habits that lasts more than 2 weeks

Ask a doctor or pharmacist before use if you are taking any other drug. Take this product two or more hours before or after other drugs. Laxatives may affect how other drugs work.

Stop use and ask a doctor if ■ you have rectal bleeding or no bowel movements after using this product. These could be signs of a serious condition.
■ you need to use a laxative for more than 1 week

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. (1-800-222-1222)

Directions

■ do not exceed the maximum recommended daily dose in a 24 hour period
■ shake well before use
■ dose may be taken once a day preferably at bedtime, or as directed by a doctor
■ drink a full glass (8 oz) of liquid with each dose

Age (yr)	Dose (mL)
adults and children 12 years and over	30 mL, not more than 60 mL in 24 hrs.
children under 12 years	ask a doctor

Other information

■ **each 30 mL contains:** calcium 40 mg, sodium 100 mg, and magnesium 1000 mg
■ store at 20-25°C (68-77°F) ■ protect from excessive moisture
■ do not use if lid seal is open or damaged ■ sugar free, dye free, alcohol free
■ see bottom of cup for lot number and expiration date

Inactive ingredients citric acid, glycerin, microcrystalline cellulose, methyl cellulose, purified water, saccharin sodium, sodium citrate, spearmint oil, xanthan gum

Questions or comments?

Call 1-800-616-2471

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Re-order
No. 701034

M-154
C05020 R0
Rev. 03/19

ACETAMINOPHEN ORAL SOLUTION

acetaminophen oral solution solution

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0904-6739
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg in 10.15 mL

Inactive Ingredients	
Ingredient Name	**Strength**
GLYCERIN (UNII: PDC6A3C0OX)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
SORBITOL (UNII: 506T60A25R)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
METHYLCELLULOSE (15 CPS) (UNII: NPU9M2E6L8)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
XANTHAN GUM (UNII: TTV12P4NEE)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	

Product Characteristics			
Color	white (white to light pink)	**Score**	
Shape		**Size**	
Flavor	CHERRY	**Imprint Code**	
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:0904-6739-71	10 in 1 CASE	04/08/2019	
1		10 in 1 TRAY		
1		10.15 mL in 1 CUP, UNIT-DOSE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	04/08/2019	

DIPHENHYDRAMINE HYDROCHLORIDE

diphenhydramine hydrochloride liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0904-6740
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	12.5 mg in 5 mL

Inactive Ingredients	
Ingredient Name	**Strength**
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
AMMONIUM GLYCYRRHIZATE (UNII: 3VRD35U26C)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
TRISODIUM CITRATE DIHYDRATE (UNII: B22547B95K)	
POLOXAMER 407 (UNII: TUF2IVW3M2)	
GLYCERIN (UNII: PDC6A3C0OX)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics			
Color		**Score**	
Shape		**Size**	
Flavor	CHERRY	**Imprint Code**	
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:0904-6740-70	10 in 1 CASE	12/04/2018	
1		10 in 1 TRAY		
1		5 mL in 1 CUP, UNIT-DOSE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	12/04/2018	

DIPHENHYDRAMINE HYDROCHLORIDE

diphenhydramine hydrochloride liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0904-6741
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	25 mg in 10 mL

Inactive Ingredients	
Ingredient Name	**Strength**
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
AMMONIUM GLYCYRRHIZATE (UNII: 3VRD35U26C)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
TRISODIUM CITRATE DIHYDRATE (UNII: B22547B95K)	
POLOXAMER 407 (UNII: TUF2IVW3M2)	
GLYCERIN (UNII: PDC6A3C0OX)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics			
Color		**Score**	
Shape		**Size**	
Flavor	CHERRY	**Imprint Code**	
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:0904-6741-72	10 in 1 CASE	12/04/2018	
1		10 in 1 TRAY		
1		10 mL in 1 CUP, UNIT-DOSE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date

OTC monograph final	part341	12/04/2018	

ACETAMINOPHEN ORAL SOLUTION

acetaminophen oral solution solution

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0904-6738
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	160 mg in 5 mL

Inactive Ingredients	
Ingredient Name	**Strength**
GLYCERIN (UNII: PDC6A3C0OX)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
SORBITOL (UNII: 506T60A25R)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
METHYLCELLULOSE (15 CPS) (UNII: NPU9M2E6L8)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
XANTHAN GUM (UNII: TTV12P4NEE)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	

Product Characteristics			
Color	white (White to light pink)	**Score**	
Shape		**Size**	
Flavor	CHERRY	**Imprint Code**	
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:0904-6738-70	10 in 1 CASE	04/08/2019	
1		10 in 1 TRAY		
1		5 mL in 1 CUP, UNIT-DOSE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	04/08/2019	

ACETAMINOPHEN ORAL SOLUTION

acetaminophen oral solution solution

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0904-6820
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	650 mg in 20.3 mL

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
SORBITOL (UNII: 506T60A25R)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
METHYLCELLULOSE (15 CPS) (UNII: NPU9M2E6L8)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
XANTHAN GUM (UNII: TTV12P4NEE)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	

Product Characteristics

Color	white (white to light pink)	**Score**	
Shape		**Size**	
Flavor	CHERRY	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0904-6820-76	10 in 1 CASE	04/08/2019	
1		10 in 1 TRAY		
1		20.3 mL in 1 CUP, UNIT-DOSE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	04/08/2019	

MILK OF MAGNESIA

magnesium hydroxide suspension

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0904-6840
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MAGNESIUM HYDROXIDE (UNII: NBZ3QY004S) (HYDROXIDE ION - UNII:9159UV381P, MAGNESIUM CATION - UNII:T6V3LHY838)	MAGNESIUM HYDROXIDE	2400 mg in 10 mL

Inactive Ingredients

Ingredient Name	Strength
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
XANTHAN GUM (UNII: TTV12P4NEE)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
METHYLCELLULOSE (15 CPS) (UNII: NPU9M2E6L8)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
TRISODIUM CITRATE DIHYDRATE (UNII: B22547B95K)	
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics

Color	white (Suspension)	**Score**	
Shape		**Size**	
Flavor	SPEARMINT	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0904-6840-72	10 in 1 CASE	06/10/2019	
1		10 in 1 TRAY		
1		10 mL in 1 CUP, UNIT-DOSE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part331	06/10/2019	

MILK OF MAGNESIA

magnesium hydroxide suspension

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0904-6846
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MAGNESIUM HYDROXIDE (UNII: NBZ3QY004S) (HYDROXIDE ION - UNII:9159UV381P, MAGNESIUM CATION - UNII:T6V3LHY838)	MAGNESIUM HYDROXIDE	2400 mg in 30 mL

Inactive Ingredients

Ingredient Name	Strength
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
XANTHAN GUM (UNII: TTV12P4NEE)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
METHYLCELLULOSE (15 CPS) (UNII: NPU9M2E6L8)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
TRISODIUM CITRATE DIHYDRATE (UNII: B22547B95K)	
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics

Color	white (Suspension)	**Score**	
Shape		**Size**	
Flavor	SPEARMINT	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0904-6846-73	10 in 1 CASE	06/10/2019	
1		10 in 1 TRAY		
1		30 mL in 1 CUP, UNIT-DOSE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part331	06/10/2019	

Labeler - Major Pharmaceuticals (191427277)

Registrant - Plastikon Healthcare, LLC (041717941)

Establishment

Name	Address	ID/FEI	Business Operations
Plastikon Healthcare, LLC		041717941	manufacture(0904-6740, 0904-6741, 0904-6738, 0904-6739, 0904-6820, 0904-6840, 0904-6846)

Revised: 1/2020 Major Pharmaceuticals