

**RAPIDOL ASPIRIN DISPLAY 2X25- aspirin tablet, coated**  
**Pharmadel LLC**

*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.*

-----

**Rapidol Aspirin Display**

***Drug Facts***

***Active ingredient and Purpose***

---

| <b>Active ingredient</b><br>(in each tablet) | <b>Purpose</b> |
|--|----------------|
| Aspirin 325 mg (NSAID)*.....                 | Pain reliever  |
| *nonsteroidal anti-inflammatory drug         |                |

---

***Uses***

For the temporary relief of minor aches and pains due to:

- a cold
- a headache
- a toothache
- muscular aches
- a backache
- minor pains of arthritis

***Warnings***

**Reye's syndrome:** Children and teenagers who have or are recovering from chicken pox or flu-like symptoms should not use this product. When using this product, if changes in behavior with nausea and vomiting occur, consult a doctor because these symptoms could be an early sign of Reye's syndrome, a rare but serious illness.

**Allergy alert:** Aspirin may cause a severe allergic reaction, which may include:

- hives
- shock
- facial swelling
- asthma (wheezing)

If an allergic reaction occurs, stop use and seek medical help right away.

**Stomach bleeding warning:** This product contains an NSAID, which may cause severe stomach bleeding. The chance is higher if you:

- have had stomach ulcers or bleeding problems
- take a blood thinning (anticoagulant) or steroid drug
- take other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others)
- take more or for a longer time than directed

- are age 60 or older
- have 3 or more alcoholic drinks everyday while using this product

### **Do not use**

if you are allergic to aspirin or any other pain reliever/fever reducer.

### **Ask a doctor before use if**

- stomach bleeding warning applies to you
- you have a history of stomach problems, such as heartburn
- you have high blood pressure, heart disease, liver cirrhosis, or kidney disease
- you are taking a diuretic
- you have not been drinking fluids
- you have lost a lot of fluid due to vomiting or diarrhea
- you are taking a prescription drug for anticoagulation (thinning the blood), diabetes, gout or arthritis

### **Stop use and ask a doctor if**

you experience any of the following signs of stomach bleeding:

- feel faint
- vomit blood
- have bloody or black stools
- have stomach pain that does not get better
  
- pain persist, gets worse or last for more than 10 days
- ringing in the ears or a loss of hearing occurs, consult a doctor before taking any more of this product
- new symptoms occur
- redness or swelling is present

These could be signs of a serious condition.

### **If pregnant or breast-feeding,**

ask a health professional before use.

It is very important not to use aspirin during the last 3 months of pregnancy unless directed to do so by a doctor, because it may cause problems in the unborn child or complications during delivery.

### **Keep out of reach of children.**

In case of overdose, get medical help or contact a Poison Control Center right away.

### ***Directions***

- **do not take more than directed**
- drink a full glass of water with each dose
- **adults and children 12 years of age and over:**
- take two (2) tablet every 4 hours
- do not take more than 6 doses in 24 hours
- **children under 12 years of age:** consult a doctor

### **Other information**

- store between 68-77°F (20-25°C) in a dry place
- use by expiration date on package

**TAMPER EVIDENT:** Do not use if box or individual packets are broken or torn.

**Inactive ingredients**

corn starch, croscarmellose sodium, hypromellose, microcrystalline cellulose, mineral oil, titanium dioxide

**Questions or comments?**

1-866-359-3478 (M-F) 9AM to 5 PM EST or [www.pharmadel.com](http://www.pharmadel.com)

**Principal Display Panel**

NDC 55758-312-50

Rapidol

Aspirin/Aspirina

325 mg

Alivia Dolor (AINE) Pain Reliever (NSAID)

Relieves / Alivia

- ☐ Headaches/ Dolor de Cabeza
- ☐ Muscular Pain/ Dolores Musculares
- ☐ Minor Arthritis Pain/ Dolores de Artritis Leves

SIN CAFEINA / CAFFEINE FREE

25 Sobres x 2 Tabletas 25 packets of 2 tablets each



2 Coated Tablets

# Rapido<sup>®</sup> ASPIRIN

Pain Reliever (NSAID)\* 325 mg

## Drug Facts

**Active ingredient (in each tablet)** Aspirin 325 mg (NSAID)\* **Purpose** Pain reliever

\*nonsteroidal anti-inflammatory drug  
**Uses**

For the temporary relief of minor aches and pains due to: ■ a cold ■ a headache ■ a toothache ■ muscular aches ■ a backache ■ minor pains of arthritis

### Warnings

**Reye's syndrome:** Children and teenagers who have or are recovering from chicken pox or flu-like symptoms should not use this product. When using this product, if changes in behavior with nausea and vomiting occur, consult a doctor because these symptoms could be an early sign of Reye's syndrome, a rare but serious illness.

**Allergy alert:** Aspirin may cause a severe allergic reactions. Symptoms may include: ■ hives ■ facial swelling ■ asthma (wheezing) ■ shock  
If an allergic reaction occurs, stop use and seek medical help right away.

**Stomach bleeding warning:** This product contains an NSAID, which may cause severe stomach bleeding. The chance is higher if you: ■ have had stomach ulcers or bleeding problems ■ take a blood thinning (anticoagulant) or steroid drug ■ take other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others) ■ take more or for a longer time than directed ■ are age 60 or older ■ have 3 or more alcoholic drinks everyday while using this product. Do not use if you are allergic to aspirin or any other pain reliever/fever reducer. Ask a doctor before use if ■ stomach bleeding warning applies to you ■ you have a history of stomach problems, such as heartburn ■ you have high blood pressure, heart disease, liver cirrhosis, or kidney disease ■ you are taking a diuretic

### Drug Facts (continued)

■ you have not been drinking fluids ■ you have lost a lot of fluid due to vomiting or diarrhea ■ you are taking a prescription drug for anticoagulation (thinning the blood), diabetes, gout or arthritis  
**Stop use and ask a doctor if** ■ you experience any of the following signs of stomach bleeding:

- feel faint ■ vomit blood ■ have bloody or black stools
- have stomach pain that does not get better

■ pain persist, gets worse or last for more than 10 days  
■ ringing in the ears or a loss of hearing occurs, consult a doctor before taking any more of this product ■ new symptoms occur ■ redness or swelling is present. These could be signs of a serious condition.

**If pregnant or breast-feeding,** ask a health professional before use. It is very important not to use aspirin during the last 3 months of pregnancy unless directed to do so by a doctor, because it may cause problems in the unborn child or complications during delivery. **Keep out of reach of children.** In case of overdose, get medical help or contact a Poison Control Center right away

### Directions

- do not take more than directed ■ drink a full glass of water with each dose
- adults and children 12 years of age and over:
  - take two (2) tablet every 4 hours
  - do not take more than 6 doses in 24 hours
- children under 12 years of age: consult a doctor

### Other information

■ store between 68-77°F (20-25°C) in a dry place

### Inactive ingredients

corn starch, croscarmellose sodium, hypromellose, microcrystalline cellulose, mineral oil, titanium dioxide

**Questions or comments?** 1-866-359-3478 (M-F) 9AM to 5 PM EST or www.pharmadel.com

Distributed by:  
PHARMADEL LLC  
Georgetown, DE 19947

**DO NOT USE IF  
POUCH IS BROKEN  
OR TORN**



**ASPIRINA**  
325 mg  
Rapido<sup>®</sup>  
Alivia Dolor (AINE)

| Drug Facts   | Purpose       |
|--|---------------|
| <b>Active ingredient (in each tablet)</b> Aspirin 325 mg (NSAID)*<br><small>*nonsteroidal anti-inflammatory drug</small> | Pain reliever |

**Uses**  
For the temporary relief of minor aches and pains due to:  
■ a cold  
■ a headache  
■ a toothache  
■ muscular aches  
■ minor pains of arthritis

**Warnings**  
Reye's syndrome: Children and teenagers who have or are recovering from chicken pox or flu-like symptoms should not use this product. When using this product, if changes in behavior with nausea and vomiting occur, consult a doctor because these symptoms could be an early sign of Reye's syndrome, a rare but serious illness.  
**Stomach bleeding warning:** This product contains an NSAID, which may cause severe stomach bleeding. The chance is higher if you:  
■ have had stomach ulcers or bleeding problems  
■ take a blood thinning (anticoagulant) or steroid drug  
■ take other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others)  
■ take more or for a longer time than directed  
■ are age 60 or older  
■ have 3 or more alcoholic drinks everyday while using this product.  
Do not use if you are allergic to aspirin or any other pain reliever/fever reducer. Ask a doctor before use if:  
■ stomach bleeding warning applies to you  
■ you have a history of stomach problems, such as heartburn  
■ you have high blood pressure, heart disease, liver cirrhosis, or kidney disease  
■ you are taking a diuretic  
■ you have not been drinking fluids  
■ you have lost a lot of fluid due to vomiting or diarrhea

**Directions**  
■ do not take more than directed  
■ drink a full glass of water with each dose  
■ adults and children 12 years of age and over:  
■ take two (2) tablet every 4 hours  
■ do not take more than 6 doses in 24 hours  
■ children under 12 years of age: consult a doctor

**Other information**  
Store between 68°F (20°C) to 77°F (25°C) in a dry place. Use by expiration date on package.  
Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

**Inactive ingredients**  
corn starch, croscarmellose sodium, hypromellose, microcrystalline cellulose, mineral oil, titanium dioxide

**Questions or comments?** 1-866-359-3478 (M-F) 9AM to 5 PM EST or www.pharmadel.com

Distributed by / Distribuido por:  
PHARMADEL LLC  
Georgetown, DE 19947

8 52924 00623 1

**Datos Farmacológicos**

| Agente activo (por cada tableta)  | Propósito        |
|---|------------------|
| Aspirina 325 mg (AINE)*<br><small>*antiinflamatorio no esteroideo</small> | Alivio del dolor |

**Indicaciones**  
Alivio temporal de dolores menores y molestias debidos a:  
■ resfriado  
■ dolor de cabeza  
■ dolor de muelas  
■ dolores musculares  
■ dolores menores de artritis

**Advertencias**  
Síndrome de Reye: Niños y adolescentes que tienen o han estado teniendo síntomas de varicela o síntomas de gripe no deben usar este producto. Cuando se use este producto, si se observan cambios en el comportamiento con náuseas y vómitos, consulte a un médico porque estos síntomas podrían ser una señal temprana del síndrome de Reye, una enfermedad rara pero grave.  
**Alerta de sangrado estomacal:** Este producto contiene un AINE, el cual puede causar un sangrado estomacal severo. La posibilidad es mayor si:  
■ usted ha tenido úlceras estomacales o sangrado estomacal  
■ toma otros medicamentos que contengan AINE (aspirina, ibuprofeno, naproxeno, u otros)  
■ toma más o por un tiempo más largo del indicado  
■ tiene 60 años o más  
■ consume tres o más bebidas alcohólicas cada día mientras usa este medicamento.  
No use si:  
■ usted o alguien que se le ha cercado tiene una reacción alérgica a la aspirina o a cualquier otro analgésico/ reductor de fiebre.  
Pregunte a su médico o farmacéutico si:  
■ usted o alguien que se le ha cercado tiene problemas de sangrado estomacal o de úlceras estomacales, presión arterial alta, enfermedad del hígado, enfermedad de la vesícula biliar, enfermedad de la sangre o enfermedad de la sangre.

NDC 55758-212-50

**Rapido<sup>®</sup> ASPIRINA**  
325 mg

Alivia Dolor (AINE)  
Pain Reliever (NSAID)

**Relieves / Alivia**

- ✓ Headaches/ Dolor de Cabeza
- ✓ Muscular Pain/ Dolores Musculares
- ✓ Minor Arthritis Pain/ Dolores de Artritis Leves

**ASPIRIN**  
325 mg  
Pain Reliever (NSAID)

25 Sobres x 2 Tabletas  
25 packets of 2 tablets each

SIN CAFFEINA / CAFFEINE FREE

# RAPIDOL ASPIRIN DISPLAY 2X25

aspirin tablet, coated

## Product Information

|                                |                |                           |               |
|--------------------------------|----------------|---------------------------|---------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:55758-312 |
| <b>Route of Administration</b> | ORAL           |                           |               |

## Active Ingredient/Active Moiety

| <b>Ingredient Name</b>                                 | <b>Basis of Strength</b> | <b>Strength</b> |
|--|--------------------------|-----------------|
| ASPIRIN (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E) | ASPIRIN                  | 325 mg          |

## Inactive Ingredients

| <b>Ingredient Name</b>                        | <b>Strength</b> |
|---|-----------------|
| STARCH, CORN (UNII: O8232NY3SJ)               |                 |
| CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)      |                 |
| HYPROMELLOSES (UNII: 3NXW29V3WO)              |                 |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP)           |                 |
| MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U) |                 |
| MINERAL OIL (UNII: T5L8T28FGP)                |                 |

## Product Characteristics

|                 |       |                     |                          |
|-----------------|-------|---------------------|--------------------------|
| <b>Color</b>    | white | <b>Score</b>        | score with uneven pieces |
| <b>Shape</b>    | ROUND | <b>Size</b>         | 10 mm                    |
| <b>Flavor</b>   |       | <b>Imprint Code</b> | TCL011                   |
| <b>Contains</b> |       |                     |                          |

## Packaging

| # | <b>Item Code</b> | <b>Package Description</b>                      | <b>Marketing Start Date</b> | <b>Marketing End Date</b> |
|---|------------------|---|-----------------------------|---------------------------|
| 1 | NDC:55758-312-50 | 25 in 1 CARTON                                  | 10/09/2017                  |                           |
| 1 |                  | 2 in 1 POUCH; Type 0: Not a Combination Product |                             |                           |

## Marketing Information

| <b>Marketing Category</b> | <b>Application Number or Monograph Citation</b> | <b>Marketing Start Date</b> | <b>Marketing End Date</b> |
|---------------------------|---|-----------------------------|---------------------------|
| OTC monograph final       | part343   | 10/09/2017                  |                           |

**Labeler** - Pharmadel LLC (030129680)

**Registrant** - JMM Services (003488666)

