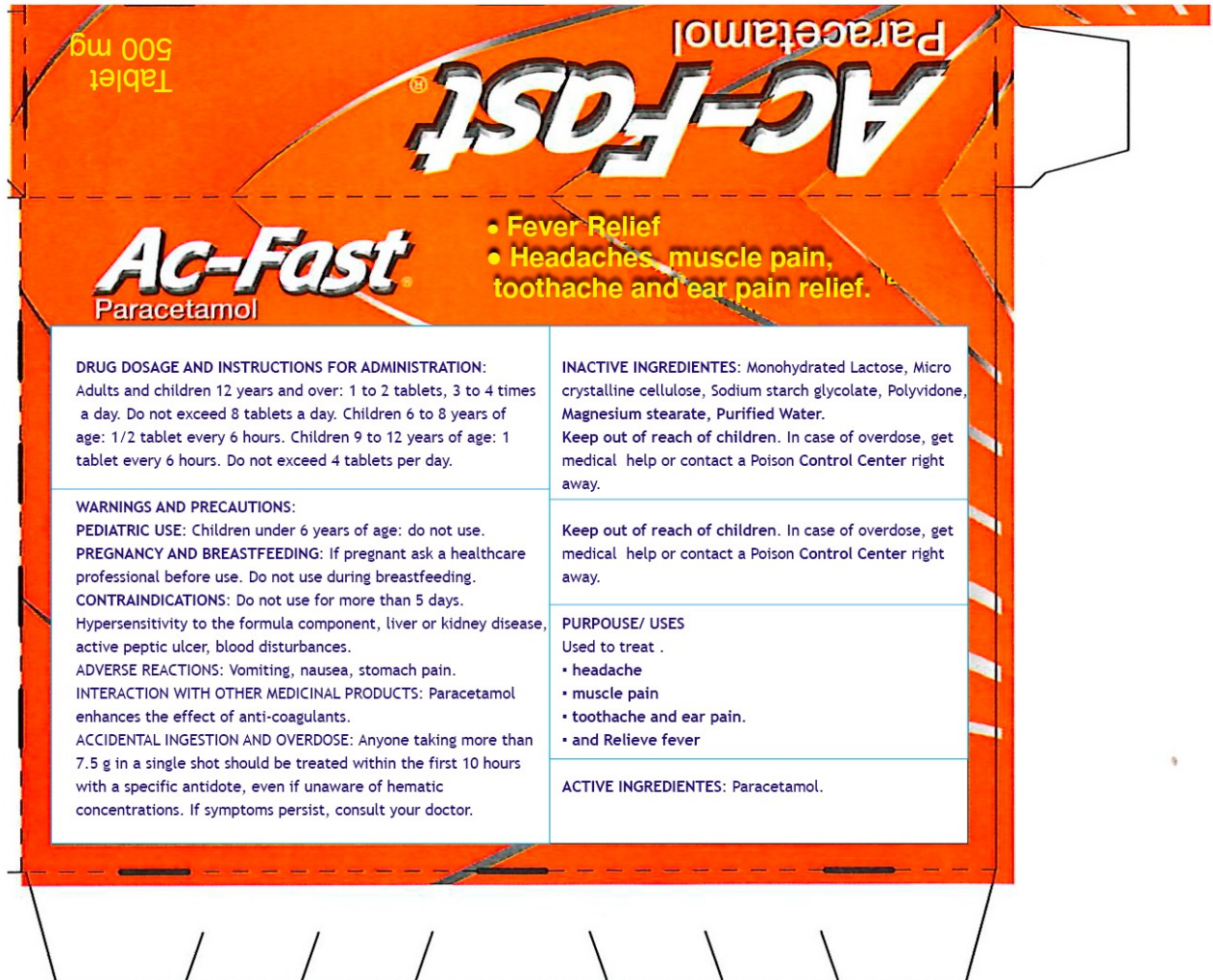


AC FAST- paracetamol capsule, coated
GRIMANN SA DE CV

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.



Tablet
500 mg

Paracetamol

Ac-Fast[®]

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Paracetamol

- Fever Relief
- Headaches, muscle pain, toothache and ear pain relief.

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Hypersensitivity to the formula component, liver or kidney disease, active peptic ulcer, blood disturbances.

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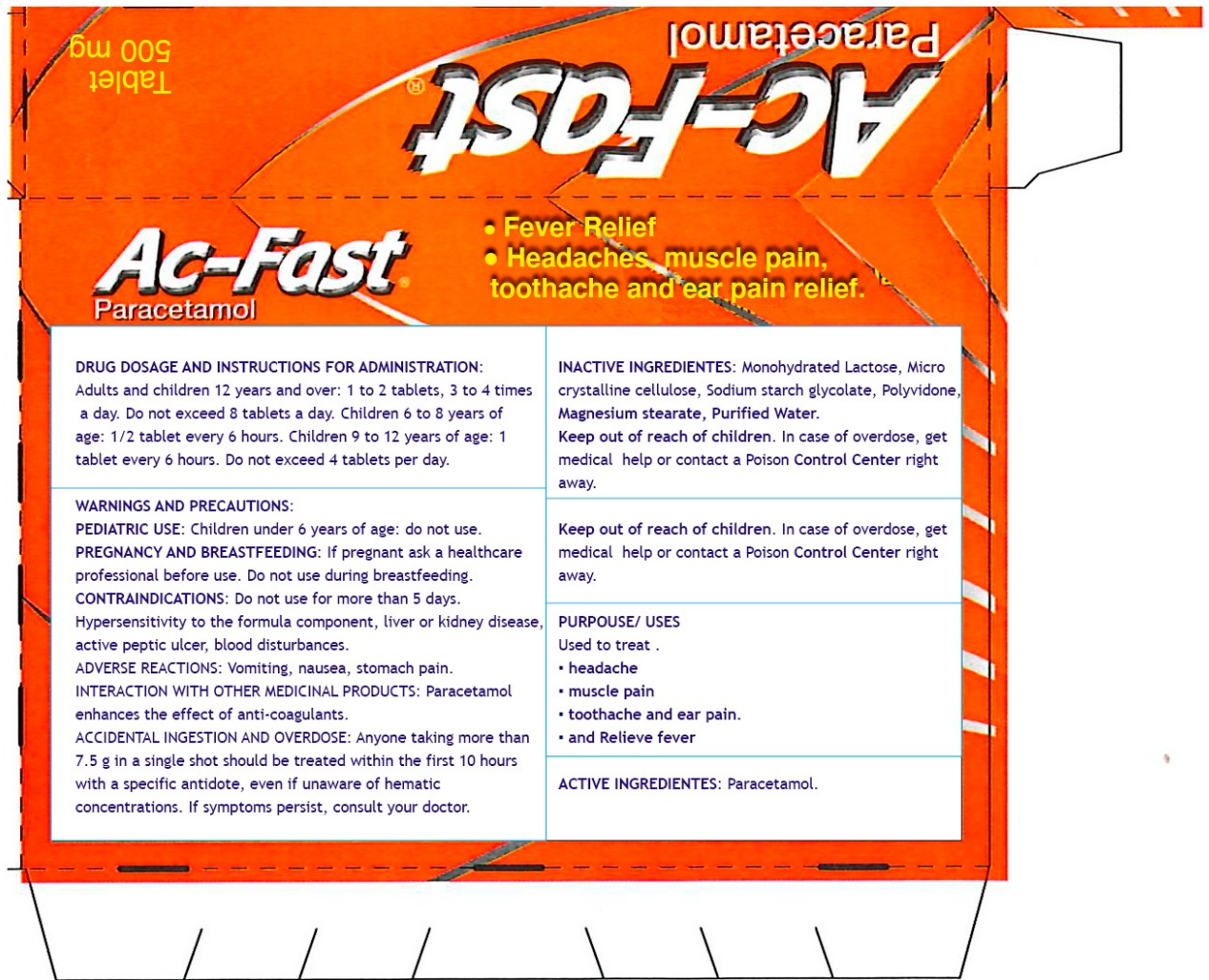
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paracetamol capsule, coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:81660-222
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	500 mg in 1 U

Inactive Ingredients

Ingredient Name	Strength
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	54 mg in 1 U
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	19 mg in 1 U
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)	15 mg in 1 U
MAGNESIUM STEARATE (UNII: 70097M6I30)	2 mg in 1 U
POLYVINYL ALCOHOL/POLYVINYL ACETATE COPOLYMER (4:1; 9500 MW) (UNII: 2AVG41YG39)	12 mg in 1 U

Product Characteristics

Color	white	Score	score with uneven pieces
Shape	OVAL	Size	12mm
Flavor		Imprint Code	500
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:81660-222-01	10 U in 1 BLISTER PACK; Type 0: Not a Combination Product	04/01/2021	



Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	04/01/2021	

Labeler - GRIMANN SA DE CV (812806982)

Registrant - GRIMANN SA DE CV (812806982)

Establishment

Name	Address	ID/FEI	Business Operations
GRIMANN SA DE CV		812806982	manufacture(81660-222)

Revised: 4/2021

GRIMANN SA DE CV